No. 25-12095-TT

In The United States Court of Appeals For The Eleventh Circuit

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STATE OF FLORIDA, ET AL.,
Plaintiffs-Appellants,

v.

DEPARTMENT OF HEALTH AND HUMAN SERVICES, ET AL.,
Defendants-Appellees.

Appeal from the United States District Court
for the Middle District of Florida
Case No. 8:24-cv-01080-WFJ-TGW

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Docket No. 25-12095-TT

State of Florida, et al., v. Department of Health and Human Services, et al.,

CERTIFICATE OF INTERESTED PERSONS AND CORPORATE DISCLOSURE STATEMENT

Plaintiffs-Appellants State of Florida, Florida Department of Management Services, Florida Agency for Health Care Administration, and Catholic Medical Association ("Plaintiffs"), file this Certificate of Interested Persons and Corporate Disclosure Statement pursuant to Eleventh Circuit Rules 26.1-1 through 26.1-3.

The following individuals and entities may have an interest in the outcome of this case:

1. Alliance Defending Freedom
2. Akey, Angeli Maun, of Gainesville, Florida
3. Blake, Julie Marie, Alliance Defending Freedom
4. Bowman, Matthew S., Alliance Defending Freedom
5. Boyden Gray PLLC
6. Catholic Medical Association
7. Centers for Medicare and Medicaid Services
8. Conde, James R., Boyden Gray PLLC
9. Cordova, Nicholas, Boyden Gray PLLC
10. Cortman, David A., Alliance Defending Freedom

11. Department of Health and Human Services

12. DeSousa, Jeffrey, Florida Attorney General's Office

13. Florida

14. Florida Agency for Health Care Administration

15. Florida Department of Management Services

16. Florida Attorney General's Office

17. Fortenberry, Walker, Boyden Gray PLLC

18. Holland, Liam C., U.S. Department of Justice

19. Honold, Ashley Cheung, U.S. Department of Justice

20. Jung, William Frederic, U.S. District Judge

21. Kaiser, Rachel T., of Nashville, Tennessee

22. Kehoe, Gregory W., U.S. Attorney for the Middle District of Florida

23. Kennedy, Jr., Robert F., Secretary, Department of Health and Human Services

24. Larson, Kristen, Florida Department of Management Services

25. McCotter, R. Trent, Boyden Gray PLLC

26. Oz, Mehmet, Administrator, Centers for Medicare and Medicaid Services

27. Parker, Michael S. of Mansfield, Ohio

28. Pope, Allison Holly, Alliance Defending Freedom

29. Pratt, Christine K., Florida Office of the Attorney General

30. Scarborough, Charles, U.S. Department of Justice

31. Shumate, Brett, U.S. Department of Justice

32. Sheeran, Andrew T., Florida Agency for Healthcare Administration

33. Sherwood, Zachary, U.S. Department of Justice

34. Stannard, Paula M., Director, Office for Civil Rights, Department of Health and Human Services

35. Uthmeier, James, Florida Attorney General

36. Van Meter, Quentin L. of Atlanta, Georgia

Plaintiffs are unaware of any publicly traded company or corporation that has an interest in the outcome of this appeal.

Dated: November 24, 2025

/s/ James R. Conde
James R. Conde

STATEMENT REGARDING ORAL ARGUMENT

Plaintiffs respectfully request oral argument. This case presents recurring issues relating to principles of mootness in challenges to executive agency action. Oral argument would substantially aid the Court in its resolution of the case.

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STATEMENT OF JURISDICTION

The district court dismissed this case "without prejudice as moot and not capable of repetition within any reasonable time frame" on June 9, 2025. Dkt. 79.[1] Florida timely appealed on June 16, 2025. Dkt. 80. This Court has appellate jurisdiction under 28 U.S.C. § 1291.

[1] References to the district court CM/ECF docket are labeled "Dkt. #."

INTRODUCTION

This civil action arises from a final rule published by the U.S. Department of Health and Human Services ("HHS") entitled "Nondiscrimination in Health Programs and Activities," 89 Fed. Reg. 37,522 (May 6, 2024) ("Final Rule"), Dkt. 12-1. The Final Rule purports to implement Section 1557 of the Affordable Care Act ("ACA"), 42 U.S.C. § 18116(a), which incorporates Title IX's longstanding prohibition against providing federal financial assistance to entities that intentionally discriminate "on the basis of sex," 20 U.S.C. § 1681 ("Title IX").

The Final Rule re-writes that law to cover "gender identity," and creates an accompanying regime meant to strongarm funding recipients into allowing males into private female spaces and providing and funding so-called "gender-affirming care," such as cross-sex hormones and surgeries meant to align an individual's sex characteristics with the individual's professed gender identity. *See, e.g.*, 45 C.F.R. §§ 92.101(a)(2)(iv), 92.206, 92.207. For good measure, the Final Rule also reads Section 1557 and the Social Security Act to authorize broad disparate-impact regulations on the basis of gender identity and other bases as well. *See, e.g.*, 42 C.F.R. § 438.3(d)(4). As the district court concluded when granting

preliminary relief, the Final Rule exceeds HHS's authority and manifestly conflicts with this Court's precedent interpreting Title IX. *See Florida v. HHS*, 739 F. Supp. 3d 1091 (M.D. Fla. 2024), Dkt. 41. And neither Section 1557 nor the Social Security Act grant HHS "the power to declare new civil rights guarantees for groups of people," or prohibit "disparate impacts." Dkt. 41, at 28.

Following a change in presidential administration, however, the district court proceedings took a strange turn. Instead of proceeding to final judgment, or holding the case temporarily in abeyance to allow the new administration an opportunity to reconsider the Final Rule, as often happens, the district court charted an unusual course. The district court, on its own initiative, fully closed the case and declared in an unreasoned docket entry that "[t]here is no case or controversy presently pending." Dkt. 76. In a later, also unreasoned, docket entry, the district court then instructed the clerk to "dismiss this case without prejudice as moot and not capable of repetition within any reasonable time frame." Dkt. 79. The district court thus summarily dismissed this lawsuit as moot without allowing the parties an opportunity to brief mootness.

In charting this unusual course, the district court violated "elementary principles of procedural fairness" by acting on its own motion without allowing Plaintiffs notice of its intent to dismiss and "an opportunity to" brief mootness. *See Ala. Legis. Black Caucus v. Alabama*, 575 U.S. 254, 271 (2015). And unsurprisingly, given the district court's summary process, the district court got it wrong. At the time of the summary dismissal, the Final Rule remained fully on the books, Plaintiffs were still threatened with harm, including through potential exposure to civil penalties, and the district court could have remedied the harm by vacating the Final Rule, enjoining HHS, and entering declaratory relief that would be binding on HHS in subsequent cases. The district court was wrong to bury this case alive.

After Plaintiffs appealed the dismissal, another district court vacated several of the regulations that Plaintiffs challenged in their operative complaint "to the extent that they expand Title IX's definition of sex discrimination to include gender-identity discrimination," but did not vacate the Final Rule's prohibition against discriminating on the basis of "sex characteristics" and "sex stereotypes." *Tennessee v. Kennedy*, No. 1:24-cv-161, 2025 WL 2982069, at *13 (S.D. Miss. Oct. 22, 2025). The

district court never considered this intervening event, so the Court should reverse the premature dismissal of the district court and remand for the district court to assess the partial vacatur's effect on this case in the first instance.

Regardless, even if this Court decides to consider the intervening event in the first instance, this case remains live. First, another district court's partial vacatur cannot moot this case until it is no longer possible that the partial vacatur will be overturned on appeal or that the United States will move for relief from the final judgment. Fed. R. Civ. P. 60(b). Second, because "potential relief remains available" to Plaintiffs, including a broader vacatur, declaratory relief, and injunctive relief, the case is "not moot." *SunAmerica Corp. v. Sun Life Assur. Co. of Can.*, 77 F.3d 1325, 1333 (11th Cir. 1996). Third, Plaintiffs raise Spending Clause, Free Exercise, Free Speech, and Religious Freedom Restoration Act ("RFRA") claims that would justify entering broader relief than vacatur of the Final Rule. In short, because it is not "impossible for the court to grant any effectual relief whatever," the case is not moot. *Church of Scientology of Cal. v. United States*, 506 U.S. 9, 12 (1992) (quotation marks omitted).

District courts have discretion to manage crowded dockets by entering a stay in some circumstances. Here, the district court could have temporarily entered "a stay of the case, retained jurisdiction, and maintained the full effect of its preliminary injunction in the interim," as HHS suggested. *Franciscan All., Inc. v. Becerra*, 553 F. Supp. 3d 361, 366 (N.D. Tex. 2021). What a district court cannot do is summarily dismiss cases as moot without process and without reasoning. That's what happened here. This Court should reverse and reinstate the preliminary injunction and stay until the district court complies with due process.

STATEMENT OF THE ISSUES

(1) Whether the district court violated due process when it dismissed this civil action on its own motion as moot in an unreasoned docket entry without allowing Plaintiffs an opportunity to brief the question of mootness.

(2) Whether this civil action was moot when the district court summarily dismissed it.

(3) Whether, if the Court reaches the question, a different district court's partial vacatur of the Final Rule moots this civil action in its entirety.

(4) Whether this Court should reinstate the preliminary relief entered by the district court.

STATEMENT OF THE CASE

I. BACKGROUND

A. SECTION 1557

Section 1557 of the ACA provides that "an individual shall not, on the ground prohibited under … title IX of the Education Amendments of 1972 (20 U.S.C. 1681 et seq.) … be subjected to discrimination under, any health program or activity, any part of which is receiving Federal financial assistance …." 42 U.S.C. § 18116(a). Title IX, in turn, states: "No person in the United States shall, *on the basis of sex*,… be subjected to discrimination under any education program or activity receiving Federal financial assistance …." 20 U.S.C. § 1681(a) (emphasis added).

Section 1557 applies to what HHS calls "covered entities." That includes recipients of HHS federal financial assistance through programs such as Medicaid, the Children's Health Insurance Program ("CHIP"), and several other healthcare programs and activities. *See* 89 Fed. Reg. at 37,694. HHS estimates that over 266,000 entities are covered by Section 1557, including state agencies, hospitals, physician offices, clinics, pharmacies, residential facilities for the developmentally disabled, home healthcare services, state-run health-insurance exchanges, and insurance issuers. *Id.* at 37,678.

Section 1557 authorizes HHS to "promulgate regulations to implement this section." 42 U.S.C. § 18116(c). Section 1557 also incorporates "[t]he enforcement mechanisms provided for and available under" the referenced statutes, including, as relevant here, Title IX. *Id.* "Title IX allows the Department to suspend or terminate federal … funding if [a covered entity] doesn't achieve voluntary compliance." *Tennessee v. Dep't of Educ.*, 104 F.4th 577, 589 (6th Cir. 2024) (citing 34 C.F.R. § 100.8); *see also* 45 C.F.R. §§ 92.301, 92.303, 92.304. HHS can also use "investigations, informal coercion, and compliance agreements" to impose hardship on funding recipients. *Tennessee*, 104 F.4th at 606. And so long as Plaintiffs accept federal financial assistance, they are subject to an implied right of action under the ACA by individuals alleging discrimination. *See Cummings v. Premier Rehab Keller, PLLC*, 596 U.S. 212, 218 (2022).

To further enforce these funding restrictions and the underlying regulations, HHS requires filing an assurance of compliance with the agency's regulations. *See, e.g.*, 89 Fed. Reg. at 37,696 (codifying 45 C.F.R. § 92.5); *see also Grove City Coll. v. Bell*, 465 U.S. 555, 574–75 (1984) (upholding defunding of a college for failure to file an assurance). This increases the stakes of non-compliance. Private entities filing knowingly

false assurances risk criminal or civil liability under the False Claims Act, including a civil penalty of up to $28,619 for each false claim, "plus 3 times the amount of damages which the Government sustains because of" the false claim. 31 U.S.C. § 3729(a)(1); 28 C.F.R. § 85.5(a); *see, e.g.*, *United States ex. rel. Main v. Oakland City Univ.*, 426 F.3d 914, 916 (7th Cir. 2005) (university subject to False Claims Act for violating federal regulations in funding program); *see also* Dep't of Justice, Press Release, *Justice Department Establishes Civil Rights Fraud Initiative* (May 19, 2025), https://perma.cc/WG6Y-QTPD. Under the False Claims Act, "a private person (the relator) may bring a qui tam civil action 'for the person and for the United States Government' against the alleged false claimant, 'in the name of the Government.'" *Vt. Agency of Nat. Res. v. United States ex rel. Stevens*, 529 U.S. 765, 769 (2000) (quoting 31 U.S.C. § 3730(b)(1)). If covered entities refuse to file an assurance of compliance, then they risk immediate termination of federal financial assistance. *See, e.g.*, *Grove City Coll.*, 465 U.S. at 574–75.

B. SECTION 1557'S REGULATORY PENDULUM

"In recent years, each time a new president has entered the White House, his administration has either repealed or reinstated many of his

predecessors' regulations while implementing dozens more of his own." Jeff Rosen, *The Regulatory Pendulum*, Nat'l Affs. (Fall 2024), https://perma.cc/8T55-393U. Section 1557 is a perfect example of this regulatory pendulum. As the district court explained, HHS's regulations are "ever-changing and unstable." Dkt. 41, at 33. HHS's regulations implementing Section 1557 shifted in 2016, 2020, and most recently in 2024. Each time, a district court enjoined HHS's regulations at least in part; then other courts enjoined the later repeal rules, leaving regulated entities in a fog of uncertainty.

1. The 2016 Rule and related litigation

On May 18, 2016, HHS published rules purporting to implement Section 1557. 81 Fed. Reg. 31,376 (May 18, 2016) ("2016 Rule"). Among other things, the 2016 Rule defined discriminating "on the basis of sex" to include discriminating against an individual "on the basis of … sex stereotyping, and gender identity." *Id.* at 31,467. The 2016 Rule also included some specific prohibitions, including a rule requiring that males who identify as women be given "equal access" to private female spaces and a ban on any "categorical coverage exclusion or limitation for all

health services related to gender transition" in state or private coverage policies. *Id.* at 31,471–72.

This 2016 Rule's expansive understanding of "on the basis of sex" was challenged in court. *See Franciscan All., Inc. v. Azar*, 414 F. Supp. 3d 928 (N.D. Tex. 2019). The district court granted summary judgment to the plaintiffs, holding "that the Rule violates the [Administrative Procedure Act ("APA")] and" RFRA insofar as it defined "on the basis of sex" in Section 1557 (and hence Title IX) to include gender identity, and vacated those portions of the 2016 Rule. *Id.* at 946–47. This vacatur remains "in effect." *Franciscan All., Inc. v. Becerra*, 47 F.4th 368, 377 (5th Cir. 2022). Later, the district court entered "a permanent injunction" prohibiting HHS "from interpreting or enforcing Section 1557 … against Plaintiffs … in a manner that would require them to perform or provide insurance coverage for gender-transition procedures or abortions." *Franciscan All.*, 553 F. Supp. 3d at 378, *aff'd*, 47 F.4th at 379; *see also Religious Sisters of Mercy v. Becerra*, 55 F.4th 583, 609 (8th Cir. 2022) (affirming permanent injunctive relief for the plaintiffs against a requirement to provide "gender-transition procedures" under Section 1557 on the ground that it violates RFRA).

2. The 2020 Repeal, Bostock, and related litigation

On June 12, 2020, HHS issued a final rule repealing the 2016 Rule's regulations relating to gender identity and replacing them with a simple ban on sex discrimination. 85 Fed. Reg. 37,160 (June 19, 2020) ("2020 Repeal").

Three days later, the Supreme Court decided *Bostock v. Clayton County*, 590 U.S. 644 (2020). *Bostock* involved Title VII of the Civil Rights Act of 1964, a law prohibiting employers from discriminating against employees "because of" their sex. 42 U.S.C. § 2000e-2(a)(1). According to the Supreme Court's opinion in *Bostock*, "[w]hen an employer fires an employee for being homosexual or transgender, it necessarily and intentionally discriminates against that individual in part because of sex." *Bostock*, 590 U.S. at 665. The Court, however, did "not purport to address bathrooms, locker rooms, or anything else of the kind," nor did it address other non-discrimination laws. *Id.* at 681.

Following *Bostock*, "[t]wo courts entered nationwide injunctions preventing much of the 2020 [Repeal] from going into effect, effectively reinstating portions of the 2016 Rule." *Franciscan Alliance*, 47 F.4th at 372 (citing *Whitman-Walker Clinic, Inc. v. HHS*, 485 F. Supp. 3d 1, 60

(D.D.C. 2020); *Walker v. Azar*, 480 F. Supp. 3d 417, 420 (E.D.N.Y. 2020)). "Both courts acknowledged they had no power to undo the [*Franciscan Alliance*] district court's vacatur in this case. But in effect they did just that. While those courts did not directly resurrect the [prior] prohibition on 'gender identity' discrimination, they did reanimate the rule's 'sex-stereotyping" prohibition. Both courts further reasoned that, in light of *Bostock*, sex-stereotyping discrimination encompasses gender identity discrimination." *Franciscan All.*, 47 F.4th at 372–73. Litigation relating to the 2020 Rule is ongoing, with a district court recently holding that the case is not moot. *Walker v. Kennedy*, 790 F. Supp. 3d 138, 139 (E.D.N.Y. 2025).

C. THE FINAL RULE

The regulatory pendulum swung again in 2021. The day he was sworn into office, President Biden signed an executive order asserting that "laws that prohibit sex discrimination … prohibit discrimination on the basis of gender identity or sexual orientation." Exec. Order No. 13,988, 86 Fed. Reg. 7,023, 7,023 (Jan. 25, 2021). Some three years later, on May 6, 2024, HHS promulgated the Final Rule challenged here. 89 Fed. Reg. 37,522 (May 6, 2024).

The Final Rule includes two separate components relevant to this appeal: first, "regulations to implement" Section 1557, *see* 42 U.S.C. § 18116(c), which are codified in Part 92 of Title 45 of the Code of Federal Regulations; second, Centers for Medicare & Medicaid Service ("CMS") regulations to implement different programs under Section 1557 and the Social Security Act, which are codified in Title 42 of the Code of Federal Regulations. The Final Rule was meant to be effective by "July 5, 2024." 89 Fed. Reg. at 37,522, 37,693 (45 C.F.R. § 92.1(b)).

1. The Part 92 regulations

Several aspects of the Part 92 regulations are relevant to this civil action.

Section 101. First, Section 101 of Part 92 defines "[d]iscrimination on the basis of sex" under Title IX, and hence Section 1557, to include discriminating based on "(i) Sex characteristics, including intersex traits; (ii) Pregnancy or related conditions; (iii) Sexual orientation; (iv) Gender identity; and (v) Sex stereotypes." 89 Fed. Reg. at 37,699 (45 C.F.R. § 92.101(a)(2)). "Gender identity" is undefined, but HHS claimed that "gender identity" can encompass a "full range of identities," *id.* at 37,592, including "transgender," "nonbinary," "gender nonconforming,"

"genderqueer," or "genderfluid," 87 Fed. Reg. 47,824, 47,867 (Aug. 4, 2022) ("NPRM"). "[S]ex characteristics" would include discrimination "based on anatomical or physiological sex characteristics (such as genitals, gonads, chromosomes, hormone function, and brain development/anatomy)" on the theory that accounting for biological reality in the medical field "is inherently sex-based." *Id.* at 47,858. HHS also asserted that by barring sex stereotypes the Final Rule prohibits "requiring persons to conform to stereotypical norms about sex and gender," which HHS claimed overlaps with "the prohibition against discrimination based on gender identity." 89 Fed. Reg. at 37,578.

Section 206. Second, Section 206 of Part 92 includes specific rules relating to "equal program access" to health programs and activities, which specifically cover not just "sex" but also "gender identity." *Id.* at 37,700–01 (45 C.F.R. § 92.206).

Section 206 includes a provision providing that covered entities "must not" have "any policy or practice … that prevents an individual from participating in a health program or activity consistent with the individual's gender identity," if this causes the individual "more than *de minimis* harm." *Id.* (45 C.F.R. § 92.206(b)(3)). Preventing a male who

identifies as a woman from sharing a dual-occupancy hospital room with a female "would result in more than *de minimis* harm," as that term includes emotional or dignitary harm. *Id.* at 37,593 ("A covered entity will be in violation of this rule if they refuse to admit a transgender person for care or refuse to place them in facilities consistent with their gender identity, because doing so would result in more than de minimis harm."); NPRM, 87 Fed. Reg. at 47,866–67 (same). HHS, however, asserted without explanation that "this provision" wouldn't prevent a physician from treating a pregnant female who identifies as a man "as a pregnant person, even though pregnancy is generally associated with 'female' sex characteristics, such as having a functioning uterus and ovaries." NPRM, 87 Fed. Reg. at 47,866.[2] And although "sex-specific clinical trials may be permissible," HHS must review them on a case-by-case basis. *Id.*

Section 206 further includes a provision stating that a covered entity "must not … [d]eny or limit health services sought for purpose of gender transition or other gender-affirming care that the covered entity

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[2] HHS never addressed its separate provision independently prohibiting discriminating based on "sex characteristics," which include a uterus and ovaries.

would provide to an individual for other purposes if the denial or limitation is based on an individual's sex assigned at birth, gender identity, or gender otherwise recorded." 89 Fed. Reg. at 37,700–01 (45 C.F.R. § 92.206(b)(4)). This includes "counseling, hormone therapy, surgery, and other services designed to treat gender dysphoria or support gender affirmation or transition." NPRM, 87 Fed. Reg. at 47,834 n.139; *see also* 89 Fed. Reg. at 37,596 ("gender-affirming care" includes "hormone therapy, surgery, and other related services").

Section 206, however, allows entities to show "a legitimate, nondiscriminatory reason for denying or limiting" gender-affirming care, including "where the covered entity reasonably determines that such health service is not clinically appropriate *for a particular individual*." 89 Fed. Reg. at 37,701 (45 C.F.R. § 92.206(c)) (emphasis added). The denial or limitation, however, must not be based on "animus or bias" or "pretext." *Id.*

Section 207. Third, Section 207 of Part 92 applies to covered entities "providing or administering health insurance coverage or other health-related coverage." 89 Fed. Reg. at 37,701 (45 C.F.R. § 92.207(a)). Like Section 206, Section 207 includes specific prohibitions relating to

"gender identity" and health-related coverage for "gender transition or other gender-affirming care." *Id.* (45 C.F.R. § 92.207(b)(3)–(5)). That includes prohibiting any "categorical" exclusion for gender-affirming care that "results in discrimination on the basis of sex." *Id.* (45 C.F.R. § 92.207(b)(4)–(5)). And like Section 206, Section 207 allows entities to raise a defense "where the covered entity has a legitimate, nondiscriminatory reason for denying or limiting coverage of the health service," and similarly prohibits "animus or bias" or "pretext." *Id.* (45 C.F.R. § 92.207(c)).

HHS did not define the terms "legitimate," "animus or bias" or "pretext." According to HHS, however, "[c]haracterizing" gender-affirming care as "experimental or cosmetic" would "be considered evidence of pretext because this characterization is not based on current standards of medical care." NPRM, 87 Fed. Reg. at 47,874.

Preemptive Effect. HHS claimed that the Final Rule preempts any state or local law that is an "obstacle" to the purpose of the Part 92 provisions. 89 Fed. Reg. at 37,535, 37,598. That includes state laws regulating gender transition. *Id.* at 37,598. In the Final Rule, HHS explained that a covered entity that "believes in good faith it is obligated to [deny

gender-affirming care] by State or local law" could keep its funding. *Id.* Evidence of "good faith," according to HHS, includes a "demonstrated … willingness to refer or provide accurate information about gender-affirming care." *Id.* HHS, however, assured the public that the Final Rule will "nevertheless generally preempt conflicting State law." *Id.* As explained in more detail below, numerous Florida laws and regulations arguably conflict with the Final Rule. *See* Fla. Stat. §§ 286.311, 456.001, 456.52, 553.865(5), (12); Fla. Admin. Code r. 59G-1.050(7), r. 64B8-9.019, and r. 64B15-14.014; *see also* Dkt. 1, ¶¶ 109–29 (describing Florida's laws).

General requirements. The Part 92 regulations contain other relevant requirements. Starting on July 5, 2024, each covered entity must (1) "submit an assurance" of compliance with the Part 92 regulations to continue receiving federal financial assistance, (2) "implement written policies and procedures in its health programs and activities that are designed to comply with the requirements of" Part 92, and (3) begin training employees to comply, among other things. 89 Fed. Reg. at 37,696–97 (45 C.F.R. §§ 92.5, 92.8, 92.9).

With respect to religious "covered entities," including individual physicians, Part 92 states that if certain religious freedom protections

are "applicable," then entities with objections may rely upon those protections. *Id.* at 37,701–02 (45 C.F.R. § 92.302). But Part 92 purports to give HHS discretion to decide *if* and *when* those protections apply. In doing so, the Final Rule seeks to force religious doctors and entities to *ask* HHS if it will recognize their religious liberty. *Id.* HHS estimates that the compliance cost for religious entities is $987.70 per request, and that over 6,000 such requests would be filed in the Final Rule's first year. *Id.* at 37,684.

2. The CMS rules

Two CMS rules are relevant to this appeal. The first applies to standard contract requirements for managed-care plans under Title XIX of the Social Security Act, known as Medicaid, and Title XXI, known as CHIP. The rule requires States to include in their contracts with managed-care organizations and similar contractors a promise that the entities

> will not use any policy or practice that has *the effect* of discriminating on the basis of … sex which includes discrimination on the basis of sex characteristics, including intersex traits; pregnancy or related conditions; sexual orientation; gender identity; and sex stereotypes.

89 Fed. Reg. at 37,691 (42 C.F.R. § 438.3(d)(4)) (emphasis added); *see also* 42 C.F.R. § 457.1201(d) (CHIP). Under the regulation, CMS "must review and approve all" contracts for compliance. 42 C.F.R. § 438.3(a). HHS relied upon Section 1557 to adopt this provision, but it also cited several provisions of the Social Security Act as authority. *See* 89 Fed. Reg. at 37,668 (citing 42 U.S.C. §§ 1396a(a)(4), (19), 1397aa(a)).

The second requires that State Medicaid and CHIP programs ensure the "delivery of services in a culturally competent manner to all beneficiaries … regardless of sex which includes … gender identity." *Id.* at 37,692 (42 C.F.R. §§ 440.262, 457.495(e)). HHS did not define "culturally competent."

II. PROCEDURAL HISTORY

A. THE DISTRICT COURT'S ORIGINAL PROCEEDINGS

On May 6, 2024, the day the Final Rule was published, Plaintiffs-Appellants, State of Florida, the Florida Department of Management Services ("DMS"), the Florida Agency for Health Care Administration ("AHCA") (collectively, "Florida Plaintiffs"), and the Catholic Medical Association ("CMA") sued HHS. Dkt. 1 (Complaint). The complaint raises eight counts, including challenges to the Final Rule under the APA, the

Spending Clause, the First Amendment, and RFRA. Dkt. 1, ¶¶ 216–312. The Complaint seeks not only vacatur, but also declaratory relief against HHS limiting how HHS may apply Section 1557 and Title XI in the future as well as injunctive relief. *Id.* at 81–82 (Prayer for Relief). The complaint targets the Final Rule's expansion of sex discrimination to "gender identity" as well to "sex characteristics" or "sex stereotypes." *Id.* ¶¶ 56, 132, 156.

Plaintiffs moved for preliminary relief on their APA claims, arguing that they will suffer irreparable harm, and asked this Court to stay the effective date of specific provisions of the Final Rule, and to enjoin enforcement of the Final Rule. Dkt. 12. Plaintiffs argued that specific provisions of the Final Rule are contrary to law because (1) Section 1557 does not prohibit discriminating on the basis of "gender identity;" (2) Section 1557 does not authorize certain "equal access" and "health-related coverage" provisions in Section 206 and 207 because they prohibit conduct that is not "discrimination" under Section 1557; and (3) the Social Security Act does not authorize the disparate-impact requirement for managed-care plans. *See id.* at 8–20. HHS opposed any preliminary relief, *see*

generally Dkt. 33, Plaintiffs filed a reply, Dkt. 35, and the district court held a hearing on June 21, 2024, Dkt. 41, at 1.

On July 3, 2024, the district court granted a stay and preliminary injunction within the State of Florida. *Id.* at 49–50.

The district court concluded that "Florida has shown that it faces an imminent injury in fact," *id.* at 13, that the suit was "fit for judicial decision," and that Florida would suffer "hardship" without judicial review, *id.* at 16–17. On the merits, the district court concluded that Plaintiffs were likely to succeed in their challenge to the Part 92 regulations:

> The Final Rule is stillborn and a nullity if Title IX does not prohibit discrimination on the basis of "gender identity." The Eleventh Circuit has spoken on this point, clearly: Title IX does not address discrimination on the basis of gender identity. *Adams v. Sch. Bd. of St. John's Cnty.*, 57 F. 4th 791, 812–15 (11th Cir. 2022) (*en banc*). Frankly, this ends the issue—the new Rule appears to be a dead letter in the Eleventh Circuit.

Id. at 20. Plaintiffs were also likely to succeed in their challenge to the CMS Rule: "The CMS contracts Rule, like the Title IX Rule, simply rewrites the statute." *Id.* at 28. Nothing in the laws invoked by CMS delegates to the agency "the power to declare new civil rights guarantees for groups of people" by forbidding "disparate impacts." *Id.*

The district court also concluded that "[i]f the Rule is implemented, on July 5, 2024, Florida will face irreparable harm." *Id.* at 29. As the Court noted, Florida's laws and regulations relating to gender-transition interventions and sex-separated facilities conflict with the Final Rule, placing Florida's agencies in an impossible situation: they "must either clearly violate Florida law, or clearly violate the new Rule." *Id.* Further, the Final Rule also caused irreparable harm on the State of Florida in its sovereign capacity, putting unlawful pressure on the State to change its policies. *Id.* at 30–32. Last, the balance of harms favored preliminary relief. *Id.* at 32–47. For CMA, however, the district court denied relief because "the Court simply believes that a nationwide injunction to cover all CMA members is improvident in this case for jurisprudential reasons." *Id.* at 47–48. The injunction covers some of CMA's members, however, including seven Florida state chapters ("guilds") and a specific declarant from Gainesville, Dkt. 1, ¶ 21; Dkt. 12, at 22 (citing Ex. C, Akey Decl., Dkt. 12-3). So CMA's Florida members obtained relief.

The Court stayed the effective date of the challenged requirements of the Final Rule and ordered that "[f]or the duration of this Order, an assurance of compliance with Part 92, see 45 C.F.R. § 92.5, shall not be

construed to assure compliance with any provisions stayed by this Order." Dkt. 41, at 49. The district court also enjoined HHS "from instituting or pursuing any enforcement proceedings under Section 1557, 42 U.S.C. § 18116(a), based on the interpretation of discrimination 'on the basis of sex' to be codified" in the Final Rule. *Id.* And the district court made the order run "throughout the State of Florida," applying the relief to the Florida Plaintiffs as well as to all "covered entities with Florida." *Id.* at 49–50.

HHS filed an interlocutory appeal. Dkt. 46 (docketed as No. 24-12826 (11th Cir.)); 28 U.S.C. § 1292(a)(1). CMA cross-appealed, Dkt. 52.

While HHS's interlocutory appeal remained pending, and shortly after the presidential election, the district court called for a one-page status update by November 15, 2024, to resolve whether it should stay the district court litigation pending the interlocutory appeal, asking the parties to "[c]onsider in this short discussion the pending appeals as well as the likelihood of mootness given a pending change in administration." Dkt. 58. The parties submitted a one-page status report. Plaintiffs noted the following:

> [The new administration] may move to repeal the regulations challenged here. But that will take time. A final rule repealing the

> challenged regulations could take years. And even when the regulations are repealed, a district court may still vacate the repeal rule and reinstate the current regulations.

Dkt. 60, at 2. HHS said only that it could not "speculate about possible future actions." Dkt. 61, at 1.

On December 13, 2024, while HHS's interlocutory appeal was pending, the district court directed the clerk "to administratively close this case," while noting that "[a]ny party may reopen at any time by filing a motion." Dkt. 62.

B. THE DISTRICT COURT'S PROCEEDINGS ON REMAND

1. President Trump's actions

On January 20, 2025, President Donald J. Trump was sworn as President of the United States. The same day, President Trump signed an executive order titled *Defending Women from Gender Ideology Extremism and Restoring Biological Truth to the Federal Government*. Exec. Order No. 14,168, 90 Fed. Reg. 8,615 (Jan. 20, 2025) ("*Defending Women*"). The executive order directs changes in the terminology used by agencies and also directs the "Attorney General [to] immediately issue guidance to agencies to correct the misapplication of the Supreme Court's decision in *Bostock* v. *Clayton County* (2020) to sex-based distinctions in agency

activities." *Id.* at 8,616. Federal agencies have begun implementing this executive order. *See* Mem. from the Acting Assoc. Att'y Gen., to C.R. Div., U.S. Dep't of Just. (Feb. 12, 2025), https://perma.cc/J5WF-STVB ("[I]t is the position of the Department of Justice that *Bostock*'s holding does not mandate gender identity-based access to single-sex spaces or athletics, nor does it impair Congress's guarantee to women of equal opportunity under Title IX."); *Sex-Based Definitions*, Off. on Women's Health, HHS, https://perma.cc/3HRP-LJYZ (updated Aug. 21, 2025) (mandating certain terms relating to sex).

On January 28, 2025, President Trump also signed Executive Order 14,187, titled *Protecting Children from Chemical and Surgical Mutilation* ("*Protecting Children*"). In that order, President Trump directed HHS to, among other things, "take all appropriate actions to end the chemical and surgical mutilation of children, including regulatory and sub-regulatory actions, which *may* involve … [S]ection 1557" of the ACA. 90 Fed. Reg. 8,771, 8,772 (Feb. 3, 2025) (emphasis added). To date, however, HHS has not proposed a repeal of the challenged provisions of the Final Rule in whole or in part, nor has it publicly announced any plans to do so by any date certain.

2. The district court's dismissal

A few weeks after these executive orders, HHS moved to dismiss its interlocutory appeal, this Court construed CMA's response thereto as a dismissal of its cross-appeal, and this Court dismissed the appeals on April 3, 2025, and issued the mandate. Dkt. 70; *see* 11th Cir. R. 41-4.

On remand, the district court proceedings took a strange turn. On April 9, 2025, without notice, the district court entered the following order:

> ENDORSED ORDER: Upon consideration of the Eleventh Circuit's Order of Dismissal and Mandate, the Clerk is directed to lift the stay and convert the administrative closure into a full closure.

Dkt. 71.

Confused by the "full closure," Plaintiffs moved to reopen and to clarify the effect, if any, of the Court's "full closure" order on the pending suit and the preliminary relief. Dkt. 73. As Plaintiffs explained "[w]ith no final judgment on the merits, or even an answer to the Complaint, fully closing the case is premature." *Id.* at 4. Plaintiffs accordingly requested that the district court "clarify (1) that the July 3, 2024 [stay and injunction] remain[] in place notwithstanding the April 9, 2025 full closure order, and (2) that there is, to date, no final appealable judgment." *Id.* at 5.

HHS responded that "[t]he parties do not dispute that this Court has not entered final judgment and that this Court's preliminary injunction has therefore not been dissolved." Dkt. 75, at 3. But, "[i]nsofar as this Court's April 9 Order has caused confusion on the part of Plaintiffs," HHS suggested, "the Court could simply vacate it." *Id.* HHS, however, opposed lifting the stay, claiming that "after *Protecting Children*, Plaintiffs and their members face no credible threat of any such enforcement action by Defendants." *Id.* at 5. HHS also claimed to be "committed to implementing the President's Executive Orders." *Id.* At no point, however, did HHS urge the district court to dismiss the case as moot, nor did HHS tell the Court that it was planning to repeal the Final Rule.

Instead of reopening the case (as Plaintiffs requested), or vacating the full closure order (as HHS suggested), or even awaiting a reply by Plaintiffs, the district court entered the following unreasoned order the day after HHS's response:

> ENDORSED ORDER denying 73 Motion to Reopen Case; denying 73 Motion for Reconsideration / Clarification. *There is no case or controversy presently pending.*

Dkt. 76 (emphasis added).

Four days later, the district court entered the following order:

> ENDORSED ORDER: The Clerk will dismiss this case without prejudice as moot and not capable of repetition within any reasonable time frame.

Dkt. 79.

On June 16, 2025, Plaintiffs filed this appeal. Dkt. 80.

C. INTERVENING EVENTS DURING THIS APPEAL

While this appeal was pending, another district court partially vacated portions of the Final Rule's specific "gender identity" textual provisions "to the extent they address gender-identity discrimination." *Tennessee*, 2025 WL 2982069, at *1. That court granted no injunctive relief, *id.* at *1 n.1, and left in place a provision that prohibits "discrimination on the basis of … sex stereotypes," 45 C.F.R. § 92.101(a)(2)(v). The deadline for the United States or an intervenor to appeal the judgment is December 22, 2025. *See* Fed. R. App. P. 4(a)(1)(B).

SUMMARY OF THE ARGUMENT

This Court should reverse the district court's aberrant *sua sponte* summary dismissal order because it violated Plaintiffs' due process rights and because the order wrongly asserted that this case was moot. The district court's summary dismissal without giving the parties notice or an opportunity to be heard violated due process under *Alabama*

Legislative Black Caucus v. Alabama, 575 U.S. at 270–71. The district court's summary mootness ruling was also wrong as a matter of law: Plaintiffs had standing at the outset, and it was not "impossible for a court to grant *any effectual relief whatever* to the prevailing party." *Knox v. Serv. Emps. Int'l Union, Loc. 1000*, 567 U.S. 298, 307 (2012) (emphasis added) (quotation marks omitted).

Another district court's recent partial vacatur in the *Tennessee* case doesn't moot the case. As an initial matter, the dismissal order under review predates that partial vacatur. Since this is "a court of review, not a court of first view," *Compulife Software Inc. v. Newman*, 959 F.3d 1288, 1309 (11th Cir. 2020), it should reverse and allow the district court to address the effect of the *Tennessee* court's partial vacatur in the first instance.

In any event, the partial vacatur doesn't moot this civil action. First, the partial vacatur cannot moot this case while it remains possible that the partial vacatur will be overturned on appeal or that the defendants or intervenors will seek relief from the final judgment. Second, the partial vacatur did not include the Final Rule's overlapping ban against discriminating based on "sex characteristics" or "sex stereotypes," so it

does not fully remedy the harm that Plaintiffs seek to eliminate here. The district court may award Plaintiffs additional relief under the APA by granting Plaintiffs' request to vacate the Final Rule more broadly and by entering a declaratory judgment or injunctive relief prohibiting HHS from (1) interpreting Section 1557 to cover gender identity as applied to Plaintiffs, (2) prohibiting an overlapping reading of sex characteristics or sex stereotyping that would have the practical effect of protecting an individual on the basis of asserted gender identity, or (3) banning disparate impacts, whether on the basis of sex, gender identity, sexual orientation, race and ethnicity, or national origin. Third, Plaintiffs assert Spending Clause, First Amendment, and RFRA claims independent of the Final Rule's validity that would justify further relief.

Finally, although the district court's summary *sua sponte* dismissal dissolved the preliminary relief, this Court should reinstate that relief. It would be inequitable to allow the district court's summary dismissal to collaterally eliminate the preliminary relief protecting Plaintiffs without giving them an opportunity to brief whether it should remain in place. This Court should not allow the district court's perplexing departure from

established legal procedures and substance to deny Plaintiffs recourse for their injuries.

ARGUMENT

I. THE DISTRICT COURT'S SUMMARY DISMISSAL VIOLATED DUE PROCESS

A district court has an "independent obligation to confirm its jurisdiction." *Ala. Legis. Black Caucus*, 575 U.S. at 270. But when a federal court determines it lacks jurisdiction *sua sponte*, it must comport with "elementary principles of procedural fairness," allowing the plaintiff "an opportunity to" be heard on the jurisdictional question. *Id.* at 271.

District courts considering their jurisdiction *sua sponte* routinely satisfy procedural fairness by entering a show cause order and allowing the parties to brief the jurisdictional question identified by the court. *See, e.g.*, *Cruz v. Bd. of Elections of City of New York*, 396 F. Supp. 2d 354, 355 (S.D.N.Y. 2005) (issuing show cause order asking the parties to brief mootness); *cf. Thomas v. Crosby*, 371 F.3d 782, 802 (11th Cir. 2004) (Tjoflat, J., specially concurring) ("Where a circuit panel decides to raise an issue *sua sponte*, the preferred method of doing so is by requesting supplemental briefing from the parties and permitting oral argument, as was done here.").

By contrast, the district court here summarily, without notice, and without allowing Plaintiffs an opportunity to be heard on the question of mootness, dismissed the case as moot in an unreasoned docket entry. That was improper "in these circumstances." *Ala. Legis. Black Caucus*, 575 U.S. at 271. Just as "a plaintiff must have ample opportunity to present evidence bearing on the existence of jurisdiction," a plaintiff must have ample opportunity to dispute mootness. *See Kennedy v. Floridian Hotel, Inc.*, 998 F.3d 1221, 1232 (11th Cir. 2021); *see also Frey v. EPA*, 270 F.3d 1129, 1132 (7th Cir. 2001) ("We have warned that *sua sponte* dismissals without prior notice or opportunity to be heard are hazardous and that unless the defect is clearly incurable a district court should grant the plaintiff leave to amend, allow the parties to argue the jurisdictional issue, or provide the plaintiff with the opportunity to discover the facts necessary to establish jurisdiction." (quotation marks omitted)); *see also* 5B *Wright & Miller's Federal Practice and Procedure* § 1350 (4th ed.) (same). Here, the district court gave Plaintiffs no opportunity to dispute mootness.

Alabama Legislative Black Caucus controls the analysis. In that case, the district court raised the plaintiff's standing to sue *sua sponte*

after a full trial. The district court held that the plaintiff, a membership association, failed to establish associational standing to challenge newly drawn district lines on racial gerrymandering grounds. *See* 575 U.S. at 268–69. Unrebutted testimony described the plaintiff-association as having members in nearly every Alabama county, but the district court deemed this evidence insufficient after trial because the association did not specify whether it had members that resided in the challenged districts. *Id.* at 269.

The Supreme Court held that the district court's summary dismissal violated due process. "[A]t the very least," the Court said, the evidence submitted by the plaintiff raised "[a] common sense inference … strong enough to lead the Conference reasonably to believe that, in the absence of a state challenge or a court request for more detailed information, it need not provide additional information such as a specific membership list." *Id.* at 270. Although a court has "an independent obligation to confirm its jurisdiction, even in the absence of a state challenge," the Court held that "elementary principles of procedural fairness required that the district court, rather than acting *sua sponte*, give the Conference an opportunity to provide evidence of member residence." *Id.* at 270–71.

This case follows *a fortiori* from *Alabama Legislative Black Caucus*. The *sua sponte* dismissal in *Alabama Legislative Black Caucus* was improper even though the plaintiff bears the burden of proof to show standing. *See Bischoff v. Osceola County*, 222 F.3d 874, 878 (11th Cir. 2000). The dismissal here was all the more improper because it involved mootness. A determination of mootness cannot be made on the face of the complaint, but requires assessing intervening facts outside the record, where "the Government, not [Plaintiffs], bears the burden to establish that a once-live case has become moot." *West Virginia v. EPA*, 597 U.S. 697, 719 (2022). A summary *sua sponte* dismissal on the ground of mootness is thus improper.

In this case, the district court's conclusion was still more surprising and unlawful because the district court had already preliminarily concluded that Plaintiffs had standing to challenge the Final Rule and had entered injunctive declaratory relief and a stay of the Final Rule. Dkt. 41, at 13–14, 49. Under these circumstances, and given that HHS bears the burden on mootness, "[a]t the very least, the common sense inference is strong enough to lead [Plaintiffs] reasonably to believe that, in the

absence of a … court request for more detailed information, it need not provide additional information." *Ala. Legis. Black Caucus*, 575 U.S. at 270.

Indeed, under this Court's precedent, Plaintiffs may even be entitled to an evidentiary hearing to the extent mootness raises questions of witness credibility. When there are disputed material facts relevant to standing implicating questions of credibility, a district court "*must* hold an evidentiary hearing." *Bischoff*, 222 F.3d at 879 (emphasis in original). Here, not only did the district court not hold an evidentiary hearing—it cited no facts, provided no reasoning, and allowed Plaintiffs no opportunity to submit evidence at all, or even briefing.

This should not be a hard question. Every court of appeals that has considered an analogous summary *sua sponte* dismissal reversed the district court. *Reynolds v. Army & Air Force Exch. Serv.*, 846 F.2d 746, 748 (Fed. Cir. 1988); *Ho v. Russi*, 45 F.4th 1083, 1086 (9th Cir. 2022); *Frey*, 270 F.3d at 1132; *Neiderhiser v. Borough of Berwick*, 840 F.2d 213, 216 n.6 (3d Cir. 1988).

None of the rare exceptions noted in out-of-circuit caselaw applies here. For example, the Ninth Circuit has identified "only two

circumstances in which a district court may dismiss for lack of subject matter jurisdiction without providing notice and an opportunity to respond." *Russi*, 45 F.4th at 1086.

First, "the district court may dismiss a litigant's claims without notice and an opportunity to respond when parties have previously argued the issue of jurisdiction." *Id.* Here, Plaintiffs argued standing and *won* at the preliminary stage. And the parties never litigated mootness. Plaintiffs' only opportunity to address mootness was in a one-page status report filed before the change in presidential administration addressing whether the Court should enter a temporary stay, where Plaintiffs explained that the case would not become moot even after the Final Rule is repealed, and HHS took no issue with Plaintiffs' argument. Dkt. 60, at 2; Dkt. 61, at 1. "At the very least, the common sense inference" from this was "strong enough to lead [Plaintiffs] reasonably to believe that, in the absence of a … court request for more detailed information, [they] need not provide additional information." *Ala. Legis. Black Caucus*, 575 U.S. at 270.

Second, "the district court may dismiss a litigant's claim without notice where lack of jurisdiction appears on the face of the complaint and

is obviously not curable." *Russi*, 45 F.4th at 1086. Because the district court dismissed based upon mootness, which requires pointing to intervening facts outside the record, this exception is inapplicable. Nor would Plaintiffs' argument against mootness in this case be "totally implausible, attenuated, unsubstantial, frivolous, devoid of merit, or no longer open to discussion." *Apple v. Glen*, 183 F.3d 477, 479 (6th Cir. 1999) (per curiam). Plaintiffs' argument that the case remained live at the time of dismissal is not only substantial—it is correct. *See infra* Part II.B (pp. 47–51).

II. THE CIVIL ACTION IS LIVE

The district court has already preliminarily agreed that the Florida Plaintiffs had standing at the time the complaint was filed. Dkt. 41, at 14. That was correct. CMA also has standing. And the case is not moot.

A. PLAINTIFFS HAD STANDING

Standing is assessed "at the time the action commences." *Friends of the Earth, Inc. v. Laidlaw Env't Servs. (TOC), Inc.*, 528 U.S. 167, 191 (2000). At the time Plaintiffs filed suit, there is no question they had Article III standing.

"Government regulations that require or forbid some action by the

plaintiff almost invariably satisfy both the injury in fact and causation requirements. So in those cases, standing is usually easy to establish." *FDA v. All. for Hippocratic Med.*, 602 U.S. 367, 382 (2024). This is one of those cases. Plaintiffs include covered entities that are directly regulated by the Final Rule.

The district court correctly concluded that "[t]he Florida Plaintiffs have standing." Dkt. 41, at 14. Florida AHCA and DMS filed declarations explaining they are covered entities subject to Part 92. *See* Dkt. 1, ¶¶ 167, 169; Ex. 1, Kniepmann Decl., Dkt. 1-1; Ex. 2, Sanders Decl., Dkt. 1-2. AHCA also administers Florida Medicaid and CHIP and so is regulated by the CMS Rule. Dkt. 1, ¶ 167. Plaintiffs also submitted a declaration from the Florida Agency for Persons with Disabilities ("APD"), a covered entity. Ex. B, Bailey Decl., Dkt. 12-2. Florida has broad authority to sue on behalf of its instrumentalities and has a proprietary interest in protecting its covered entities, including entities such as APD. Dkt. 1, ¶ 18; *Tennessee*, 104 F.4th at 588. The Final Rule would impose compliance costs on these covered entities. *See* 89 Fed. Reg. at 37,684–85, 37,689 (projecting costs). "[T]hose monetary costs are of course an injury." *Diamond Alt. Energy, LLC v. EPA*, 606 U.S. 100, 114 (2025)

(quotation marks omitted).

The Final Rule also at least "arguably proscribes [Plaintiffs'] conduct." *West Virginia v. U.S. Dep't of the Treasury*, 59 F.4th 1124, 1137–38 (11th Cir. 2023). AHCA, for example, has a regulatory policy against reimbursing "any other procedures that alter primary or secondary sexual characteristics," Fla. Admin. Code r. 59G-1.050(7), which is arguably proscribed by Sections 101 and 207 of Part 92. DMS similarly has a longstanding coverage exclusion for gender transition drugs and surgeries from the state employee health-insurance plan, which is arguably proscribed by the Final Rule. Dkt. 1, ¶¶ 169–70; Sanders Decl., Dkt. 1-2. APD has a policy of separating dual-occupancy rooms in its residential living facilities on the basis of biological sex, regardless of an individual's gender identity, which is arguably proscribed by Section 206 of Part 92. Baily Decl. ¶¶ 31–41, Dkt. 12-2; *see also* 89 Fed. Reg. at 37,593 ("A covered entity *will* be in violation of this rule if they refuse to admit a transgender person for care or refuse to place them in facilities consistent with their gender identity, because doing so would result in more than *de minimis* harm." (emphasis added)).

Florida is also injured in its capacity as a sovereign. Florida has enacted laws that require separating private spaces in public buildings based on biological sex or providing single-occupant facilities. *See* Fla. Stat. § 553.865(5), (12). Florida has also enacted health-related spending laws and regulations limiting the use of public funds for puberty blockers, hormone and hormone antagonists, sex-reassignment surgeries, and "[a]ny other procedures that alter primary or secondary sexual characteristics," used to treat "gender dysphoria." Fla. Admin. Code r. 59G-1.050(7); *see* Fla. Stat. § 286.311. Florida has also enacted standards of medical care, and legislation limiting gender-transition care. *See* Fla. Stat. §§ 456.001, 456.52; Fla. Admin. Code r. 64B8-9.019, r. 64B15-14.014; *see also* Dkt. 1, ¶¶ 109–29.

Florida's laws and regulations on their face appear to conflict with the Part 92 Rules, including the Final Rule's prohibition on discriminating based on "sex characteristics," "sex stereotypes," "gender identity," as well as the CMS Rules, and Plaintiffs faced a "credible threat of enforcement" when they sued, *West Virginia*, 59 F.4th at 1137. At the time Plaintiffs filed suit, HHS intended to enforce the Final Rule against Florida. HHS said that "Florida must comply with the Rule." Dkt. 33, at 27.

Indeed, the United States specifically claimed that Florida's health-related spending restrictions conflict with the Part 92 Rules. Brief for the United States as *Amicus Curiae* at 26 n.10, *Dekker v. AHCA*, No. 23-12155 (11th Cir. filed Dec. 4, 2023, withdrawn Feb. 28, 2025), https://perma.cc/9UYG-SVPL. Florida's fear that it would be coerced to abandon its laws, and that its citizens would be encouraged to violate Florida law, was "not unfounded. It comes directly from the text of the" Final Rule—and from the representations of the United States before this Court. *Tennessee*, 104 F.4th at 588–89. The Part 92 Rules therefore injured Florida's sovereign "interest in enforcing [its] duly enacted laws without contradiction from the federal government." *Id.* at 595. Florida and its agencies therefore established a substantial likelihood of Article III standing to challenge the Part 92 Rules and the CMS Rule. *Id.*

Only one party must show standing for the suit to move forward, and Florida certainly had standing. *Rumsfeld v. F. for Acad. & Institutional Rts., Inc.*, 547 U.S. 47, 52 n.2 (2006).

But regardless, CMA also had standing. Membership organizations may "assert standing solely as the representative of its members." *Students for Fair Admissions, Inc.* ("*SFFA*") *v. President & Fellows of*

Harvard Coll., 600 U.S. 181, 199 (2023) (quotation marks omitted). "To invoke it, an organization must demonstrate that (a) its members would otherwise have standing to sue in their own right; (b) the interests it seeks to protect are germane to the organization's purpose; and (c) neither the claim asserted nor the relief requested requires the participation of individual members in the lawsuit." *Id.* (quotation marks omitted).

CMA satisfies this test. "[A]lmost all practicing physicians [a]re likely covered by the rule." 89 Fed. Reg. at 37,685. So are "[o]ffices of physicians," which are covered entities. *Id.* at 37,688. CMA submitted detailed declarations of members, including physician members who are covered entities and injured by the Final Rule and members who own and operate covered doctors' offices. CMA's members explain that they have policies and practices that arguably conflict with the Final Rule, and do not wish to comply with the Final Rule's requirements for sincerely held ethical and religious reasons. Dkt. 12, at 22 (citing declarations). As directly regulated entities, their standing is "easy to establish." *All. for Hippocratic Med.*, 602 U.S. at 382.

CMA's members also had standing through the compliance costs imposed by the Final Rule. Although the Final Rule says HHS might

respect religious objections, it does not promise that it will conclude that religious protections apply. 89 Fed. Reg. at 37,701–02 (45 C.F.R. § 92.302). Instead, it tells CMA's members that HHS cannot know whether they are protected under RFRA unless they submit to HHS a request for "assurance" of their religious liberty. *Id.* at 37,702. HHS estimates that the cost of each request will be $987.70, and HHS expects over 6,000 requests in the Final Rule's first year alone. *Id.* at 37,684. HHS thus concedes that its Final Rule will result in pocketbook injuries on thousands of religious doctors and clinics. Because even downstream pocketbook harms from a regulation "are of course an injury," *Diamond Alt. Energy*, 606 U.S. at 114, these costs independently demonstrate standing for CMA's members.

CMA has also submitted a detailed declaration establishing that the interests it seeks to protect are germane to its mission. Ex. 3, Dickerson Decl., Dkt. 1-3. Last, this suit does not require individual participation by CMA's members, as CMA seeks only "prospective relief," not monetary damages. *Hunt v. Wash. State Apple Advert. Comm'n*, 432 U.S. 333, 343 (1977). CMA therefore had standing to challenge the Part 92 Rules.

Indeed, the Plaintiffs' standing to challenge the Final Rule is so clear that HHS didn't dispute Plaintiffs' standing in its opening brief on appeal from the preliminary injunction. *See* Brief for Appellants/Cross-Appellees, *Florida v. HHS*, No. 24-12826 (11th Cir. Jan. 2, 2025), ECF No. 26. Plaintiffs had standing.

B. THE CASE WAS LIVE WHEN THE DISTRICT COURT IMPROVIDENTLY DISMISSED IT

The case remains live unless intervening events have made it "impossible for a court to grant *any effectual relief whatever* to the prevailing party." *Knox*, 567 U.S. at 307 (emphasis added) (quotation marks omitted). "As long as the parties have a concrete interest, however small, in the outcome of the litigation, the case is not moot." *Id.* at 307–08 (alteration accepted). "[T]he Government, not petitioners, bears the burden to establish that a once-live case has become moot." *West Virginia*, 597 U.S. at 719. The government must show that it is "absolutely clear that the allegedly wrongful behavior could not reasonably be expected to recur." *Id.* at 720. That is a "formidable burden." *FBI v. Fikre*, 601 U.S. 234, 241 (2024).

The only intervening events that might have affected the case when the district court entered a dismissal order—President Trump's

Defending Women and *Protecting Children* executive orders—came nowhere close to making further effective relief impossible. Those orders did not (and could not) eliminate the Final Rule, nor did they commit HHS to not enforcing the Final Rule. Nor did the executive orders eliminate Plaintiffs' need for a final judgment. The executive orders did not relieve covered entities from compliance obligations, including their obligation to file an assurance of compliance with the Final Rule to receive federal funds. 45 C.F.R. § 92.5; *see Grove City Coll.*, 465 U.S. at 574–75. That obligation effectively coerces compliance regardless of HHS's current enforcement priorities. It means that, if covered entities say they will comply with the Final Rule, but do not mean it, they risked civil liability under the False Claims Act, 31 U.S.C. § 3729(a)(1), and a civil suit could be brought by the United States *or by a private relator*, *id.* § 3730.[3] The threat of liability against covered entities shows that this case was live. *Cf. Susan B. Anthony List v. Driehaus*, 573 U.S. 149, 164 (2014)

[3] To be clear, Florida and its agencies aren't subject to the False Claims Act. *Vt. Agency of Nat. Res.*, 529 U.S. at 787–88. But CMA members are subject to suit, and covered entities located within Florida are subject to suit, implicating Florida's sovereign interest in ensuring that Florida residents follow its laws, not HHS's extralegal dictates.

("The credibility of that [enforcement] threat is bolstered by the fact that authority to file a complaint with the Commission is not limited to a prosecutor or an agency. Instead, the false statement statute allows 'any person' with knowledge of the purported violation to file a complaint.").

As a sovereign, Florida also faces uncertainty about the validity of its laws and regulations when the district court dismissed this case. The Final Rule claimed that laws such as Florida's are preempted as obstacles to the regulation. 89 Fed. Reg. at 37,535, 37,598. So did the United States. Brief for the United States as *Amicus Curiae*, *supra*, at 26 n.10 (*Dekker*, No. 23-12155). Florida's sovereign interest alone means that this civil action was live.

Nor did the President's executive orders require HHS to repeal the Final Rule. *Defending Women* does not direct HHS to repeal the Final Rule. *See* 90 Fed. Reg. at 8,615–18. And *Protecting Children* instructs HHS only to take "all *appropriate* actions to end the chemical and surgical mutilation of children … which *may* involve" Section 1557, allowing HHS considerable regulatory discretion. *See* 90 Fed. Reg. at 8,772 (emphases added). Regardless, executive orders are not "enforceable." *See id.* at 8,773. And HHS must follow its rules. *United States v. Nixon*, 418 U.S.

683, 694–96 (1974) ("So long as this regulation remains in force the Executive Branch is bound by it."). "What matters is not whether a defendant repudiates its past actions, but what repudiation can prove about its future conduct." *Fikre*, 601 U.S. at 244. Here, the executive orders do not repudiate the Final Rule.

Binding precedent controls here. In *Socialist Workers Party v. Leahy*, this Court held that the Florida Secretary of State's disavowal of enforcement authority under a particular election law did not prevent a legal challenge to the law in part because of "the very real probability that a subsequent Secretary of State will … again attempt to apply the [challenged] requirement to plaintiff-appellants." 145 F.3d 1240, 1246 (11th Cir. 1998). That same "very real probability," *id.*, was (and is) present here, where HHS had never disavowed its authority to enforce the Final Rule. Further, HHS's quadrennial about-faces on Section 1557 in 2016, 2020, and 2024 should alone demonstrate the "very real probability" of future enforcement at the time of the district court's dismissal order.

FBI v. Fikre similarly shows that this case was not moot. In *Fikre*, the Supreme Court agreed that a plaintiff's challenge to the government

placing him on a no-fly list was live, even though the government had already removed the plaintiff off the no-fly list and filed a "declaration" promising not to place the plaintiff back on the list based on the then-available information. 601 U.S. at 239–43. Here, by contrast, HHS has not repealed the Final Rule or even filed a declaration abjuring enforcement now or in the future.

Because the district court erred as a matter of law in holding this case was moot, this Court should reverse.

C. THIS CASE REMAINS LIVE

This is "a court of review, not a court of first view." *Compulife Software Inc.*, 959 F.3d at 1309. This Court therefore need not consider the *Tennessee* district court's subsequent partial vacatur of the Final Rule. On the facts that existed when the district court dismissed this case as moot, this case was very much alive.

If this Court nevertheless decides to address the *Tennessee* district court's subsequent partial vacatur of the Final Rule in the first instance, this Court should hold that the partial vacatur doesn't moot the case on numerous grounds.

As an initial matter, this case remains live because the partial vacatur may be overturned on appeal or reopened. The United States or any third-party that intervenes can appeal the *Tennessee* district court's judgment through December 22, 2025. *See* Fed. R. App. P. 4(a)(1)(B). Further, the United States could possibly move for relief from the final judgment on various grounds. Fed. R. Civ. P. 60(b). This means that it is far from "absolutely clear that the allegedly wrongful behavior could not reasonably be expected to recur," so the case is not moot. *West Virginia*, 597 U.S. at 720.

The United States has recently argued that a case in a similar posture is not moot. In *Alabama v. U.S. Secretary of Education*, a coalition led by Alabama challenged a similar 2024 Department of Education final rule "expanding the definition of discrimination on the 'basis of sex' to include discrimination based on gender identity." No. 24-12444, 2024 WL 3981994, at *1 (11th Cir. Aug. 22, 2024). The district court denied preliminary relief, Alabama appealed, and this Court entered an injunction pending appeal. *Id.* at *1–2. While the interlocutory appeal remained pending, a district court in Kentucky vacated the rule nationwide. *Tennessee v. Cardona*, 762 F. Supp. 3d 615 (E.D. Ky. 2025). This Court called

for supplemental briefing, and the United States agreed that Alabama's challenge was not moot because a third party sought to intervene to appeal the district court's final judgment, showing it was "not 'impossible' that this Court could grant plaintiffs 'effectual relief.'" Supplemental Brief for Appellees at 3, *Alabama*, No. 24-12444 (Aug. 22, 2025), ECF No. 113 (quoting *Chafin v. Chafin*, 568 U.S. 165, 172 (2013)). If that case was not moot at that time according to the United States, then neither is this one now.[4]

Regardless, this case will remain live regardless of the partial vacatur's fate for several reasons.

First, Plaintiffs seek a broader vacatur of the Final Rule. Plaintiffs seek to vacate the redefinition of "sex" to include any form of discrimination on the basis of gender identity, whether express or disguised through labels such as "sex characteristics" or "sex stereotypes." Dkt. 1, ¶ 5 (quoting 45 C.F.R. § 92.101(a)(2)(i), (v)); *id.* ¶¶ 164, 221, 227; *id.* at 81 (Prayer for Relief (a)). The *Tennessee* Court did not vacate these portions of the

[4] Given the position of the United States in the *Alabama* case, the United States cannot possibly take the view that this case was moot when the district court dismissed it.

Final Rule, instead limiting vacatur "to the extent that" the Final Rule includes "gender identity" within the definition of "sex." *Tennessee*, 2025 WL 2982069, at *1, *11, *13. In particular, the *Tennessee* Court specified that it was vacating subparagraph (iv) of the Final Rule's definition, expanding sex discrimination to "gender identity," but conspicuously did *not* include subparagraphs (i) or (v) of that definition, which expands sex discrimination to "sex characteristics, including intersex traits" and "sex stereotypes." *Id.*

As history shows, HHS may accomplish the same goals though these alternative labels. District courts have concluded that "sex-stereotyping discrimination encompasses gender identity discrimination." *Franciscan All.*, 47 F.4th at 372–73. Indeed, a district court in New York has concluded that because HHS's 2016 Rule still prohibits stereotyping, it still *functionally* prohibits discriminating based on gender identity. *Walker v. Azar*, 480 F. Supp. 3d at 420; *Walker v. Kennedy*, 790 F. Supp. 3d at 141–42. HHS itself acknowledged that overlap in the Final Rule. 89 Fed. Reg. at 37,574. Plaintiffs seek broader relief against the Final Rule to prevent these types of claims, regardless of label. Dkt. 1, ¶¶ 56, 132, 156. Thus, vacatur of the "sex characteristics" and "sex stereotypes"

provisions are additional relief that the district court may still award Plaintiffs. Indeed, that further relief might prove necessary for the *Tennessee* Court's partial vacatur to collaterally deliver any meaningful relief at all to Plaintiffs.

Additionally, Plaintiffs challenge the Final Rule on the basis that it unlawfully purports to prohibit disparate impacts, Dkt. 1, ¶ 235, a claim that, if successful, would result in a broader vacatur of the Final Rule. This relief would include gender identity but would also extend to categories including sex, sexual orientation, race and ethnicity, and national origin. *See, e.g.*, 42 C.F.R. § 438.3(d)(4). This "potential relief remains available" to Plaintiffs, so the civil action is "not moot." *SunAmerica Corp.*, 77 F.3d at 1333.

Second, Plaintiffs seek not just vacatur but declaratory and injunctive relief. "[E]ven when the primary relief sought is no longer available, being able to imagine an alternative form of relief is all that's required to keep a case alive." *Dierlam v. Trump*, 977 F.3d 471, 476–77 (5th Cir. 2020). Alternative relief is easy to imagine here. Plaintiffs' Complaint seeks declaratory relief providing "that under any theory of Section 1557 and Title IX, [HHS] may not require covered entities to" have policies of

"allowing males into female restrooms" or "say[ing] that men can get pregnant and give birth." Dkt. 1, at 82 (Prayer for Relief (e)). If granted, this relief would go beyond vacatur of the Final Rule to prevent HHS from ever using Section 1557 in this manner against Plaintiffs, affording Plaintiffs durable relief against the whiplash of HHS's regulatory pendulum. *Cf. Franciscan All.*, 47 F.4th at 377 (recognizing that, whereas vacatur would only provide "relief from the 2016 Rule," an injunction would provide relief "from Section 1557 more broadly").[5] Further, because for purposes of standing and mootness this Court must assume that Plaintiffs prevail, "it does not matter how likely it is that [Plaintiffs] are entitled to" a declaration or injunction. *SFFA v. Univ. of Tex. at Austin*, 142 F.4th 819, 828 (5th Cir. 2025).

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[5] The Fifth Circuit's decision in *Franciscan Alliance* erroneously held that APA claims challenging a repealed regulation were moot because "[v]acatur is the only statutorily prescribed remedy for a successful APA challenge to a regulation." 47 F.4th at 374–75 (citing 5 U.S.C. § 706(2)(A)). On the contrary, the APA expressly authorizes "actions for declaratory judgments or writs of prohibitory or mandatory injunction," 5 U.S.C. § 703, and the archetypal APA pre-enforcement review case, *Abbott Laboratories v. Gardner*, 387 U.S. 136 (1967), held that declaratory and injunctive remedies are available on APA claims, *id.* at 148, 155.

Third, and relatedly, Plaintiffs assert non-APA claims under the Spending Clause, the First Amendment, and RFRA, Dkt. 1, ¶¶ 287–312, which remain live. As the Fifth Circuit explained in *Franciscan Alliance*, a RFRA claim "challenges burdens placed on religious conduct" rather than "a particular regulation," so the vacatur or repeal of a regulation that gives rise to a RFRA claim does not render the claim moot unless the defendant demonstrates "that it is absolutely clear the allegedly wrongful behavior could not reasonably be expected to recur." 47 F.4th at 374, 376 (quotation marks omitted).

In *Franciscan Alliance*, HHS could not make this showing. The plaintiff brought a RFRA claim arising from threatened enforcement of the 2016 Rule, and the Fifth Circuit held that neither vacatur of the 2016 Rule nor its repeal in 2020 mooted the claim. *Id.* at 376–77. That analysis applies here. Just as HHS's cagey "repeated[] refus[al] to disavow enforcement against Franciscan Alliance" kept that RFRA claim live, *id.* at 376, so too HHS's cagey refusal to abjure enforcement against CMA's members keeps this RFRA claim live, whatever becomes of Plaintiffs' other claims.

The same analysis applies for First Amendment claims, as well as Spending Clause claims, which would authorize broader forward-looking injunctive and declaratory relief against HHS. A successful Spending Clause, First Amendment, or RFRA claim could result in declaratory relief or an injunction preventing HHS from pursuing Florida or CMA for alleged discrimination on the basis of "gender identity" whether expressly or repackaged through the use of labels such as "sex characteristics" or "sex stereotypes" under the Final Rule or Section 1557 generally. *See, e.g.*, *Kennedy v. Braidwood Mgmt., Inc.*, 606 U.S. 748, 758 n.1 (2025) (noting that a RFRA claim resulted in an injunction against HHS enforcement of an ACA requirement). CMA's members could also rely on RFRA or First Amendment exemptions to defend private suits under Section 1557 or related claims.

This case is live.

III. THE COURT SHOULD REINSTATE THE PRELIMINARY RELIEF

This Court should also reinstate the preliminary injunction and stay. The district court never purported to dissolve this preliminary relief, either in its dismissal order, Dkt. 79, or its earlier orders closing the case, Dkt. 62, 71, 76. Even HHS did "not dispute that," because of the

district court's silence, the "preliminary injunction has therefore not been dissolved," at least through the date of the dismissal order. Dkt. 75, at 3.

Under this Court's precedents, however, "a preliminary injunction … cannot survive a final order of dismissal." *Cypress Barn, Inc. v. W. Elec. Co.*, 812 F.2d 1363, 1364 (11th Cir. 1987). Therefore, the district court's summary dismissal had the collateral effect of dissolving the preliminary relief. This Court, however, has power "to reinstate the preliminary injunction." *Georgia-Pac. Corp. v. Lieberam*, 959 F.2d 901, 908 (11th Cir. 1992); *Bryan v. Hall Chem. Co.*, 993 F.2d 831, 832 (11th Cir. 1993) (exercising this Court's power to "reinstate the preliminary injunction"). The same factors that apply to initial requests for preliminary relief also apply to requests to reinstate preliminary relief. *See, e.g.*, *Georgia-Pac. Corp.*, 959 F.2d at 908–09; *Does 1-10 v. Univ. of Wash.*, 849 F. App'x 706, 707 (9th Cir. 2021); *Morning Star, LLC v. Canter, Tr. of Ctr. Schoen Fam. Tr.*, No. 22-56119, 2023 WL 5092764, at *1 (9th Cir. Aug. 9, 2023). Unless the district court's initial grant of preliminary relief was an abuse of discretion, this Court should reinstate it, since the district court never revisited its conclusion that the applicable factors warrant preliminary relief. *Cf. Bryan*, 993 F.2d at 834–35, 836–37 (reinstating preliminary

injunction that Eleventh Circuit had suspended pending appeal because district court's initial grant was not abuse of discretion).

Under any standard, Plaintiffs remain entitled to preliminary relief for the reasons the district court found. *See supra* Part II.A; Dkt. 41, at 19–47. It remains true that the challenged Final "Rule appears to be a dead letter in the Eleventh Circuit" under this Court's precedents, Dkt. 41, at 20; that implementing the Final Rule would irreparably harm Florida and its agencies because the Final Rule's requirements conflict with Florida law, *id.* at 29–31; and that the balance of harms favors preliminary relief for several reasons, including that the public interest requires a lawful rule, *id.* at 32–47. It also remains true that CMA's Florida members, previously protected by the relief, are irreparably harmed by irrecoverable monetary costs and the threatened loss of First Amendment freedoms. Dkt. 1, ¶¶ 185–215. Yet another reason to reinstate the preliminary relief is that the district court's summary dismissal without notice or hearing was based on a mistaken legal premise and violated Plaintiffs' right to be heard. At a minimum, the Court should reinstate the preliminary relief until the district court

allows the parties to brief whether the preliminary relief should be dissolved.

CONCLUSION

For these reasons, this Court should reinstate the preliminary relief and reverse.

Dated: November 24, 2025

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

I hereby certify that this brief complies with the type-volume limitations of Federal Rule of Appellate Procedure 32(a)(7) because it contains 11,679 words, excluding the portions exempted by Rule 32(f). This brief complies with the typeface and type style requirements of Federal Rule of Appellate Procedure Rule 32(a)(5)–(6) because it has been prepared in a proportionally spaced typeface using Microsoft Word in Century Schoolbook and 14-point font.

Dated: November 24, 2025

/s/ *James R. Conde*
James R. Conde

CERTIFICATE OF SERVICE

I hereby certify that on November 24, 2025, I electronically filed the foregoing document with the Clerk of this Court by using the CM/ECF system, which will serve all parties automatically.

Dated: November 24, 2025

/s/ *James R. Conde*
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No. 25-12095-TT

In The United States Court of Appeals For The Eleventh Circuit

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STATE OF FLORIDA, ET AL.,
Plaintiffs-Appellants,

v.

DEPARTMENT OF HEALTH AND HUMAN SERVICES, ET AL.,
Defendants-Appellees.

Appeal from the United States District Court
for the Middle District of Florida
Case No. 8:24-cv-01080-WFJ-TGW

APPENDIX

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Docket Sheet

APPEAL,CLOSED

U.S. District Court
Middle District of Florida (Tampa)
CIVIL DOCKET FOR CASE #: 8:24-cv-01080-WFJ-TGW

State of Florida et al v. Department of Health and Human Services et al
Assigned to: Judge William F. Jung
Referred to: Magistrate Judge Thomas G. Wilson
Case in other court: Eleventh Circuit, 24-12826-J
Eleventh Circuit, 25-11927-B
Eleventh Circuit, 25-12095-B
Cause: 05:0702 Administrative Procedure Act

Date Filed: 05/06/2024
Date Terminated: 12/13/2024
Jury Demand: None
Nature of Suit: 899 Other Statutes: Administrative Procedures Act/Review or Appeal of Agency Decision
Jurisdiction: Federal Question

Date Filed	#	Docket Text
05/06/2024	1	COMPLAINT against All Defendants (Filing fee $405 receipt number AFLMDC-22063290) filed by All Plaintiffs. (Attachments: # 1 Exhibit 1, # 2 Exhibit 2, # 3 Exhibit 3, # 4 Exhibit 4, # 5 Exhibit 5, # 6 Civil Cover Sheet, # 7 Proposed Summons)(McCotter, R.) (Entered: 05/06/2024)
05/06/2024	2	CORPORATE Disclosure Statement by Catholic Medical Association, Florida Agency for Health Care Administration, Florida Department of Management Services, State of Florida. (McCotter, R.) (Entered: 05/06/2024)
05/07/2024	3	NEW CASE ASSIGNED to Judge William F. Jung and Magistrate Judge Thomas G. Wilson. New case number: 8:24-cv-1080-WFJ-TGW. (AJS) (Entered: 05/07/2024)
05/07/2024	4	NOTICE TO COUNSEL James R. Conde, Julie Marie Blake and Matthew S. Bowman Local Rule 2.01(c), Special Admission - File a Motion to Appear Pro Hac Vice. Co-counsel with filing rights may electronically file the motion on behalf of the lawyer seeking Special Admission or the motion may be filed in paper format; Pay the Special Admission Fee; Submit a Pro Hac Vice E-File Registration through PACER. Visit www.flmd.uscourts.gov/for-lawyers for details (Signed by Deputy Clerk). (AJS) (Entered: 05/07/2024)
05/07/2024	5	NOTICE TO COUNSEL R. Trent McCotter Local Rule 2.01(c), Special Admission - File a Motion to Appear Pro Hac Vice. Co-counsel with filing rights may electronically file the motion on behalf of the lawyer seeking Special Admission or the motion may be filed in paper format; Pay the Special Admission Fee; Submit a Pro Hac Vice E-File Registration through PACER. Visit www.flmd.uscourts.gov/for-lawyers for details (Signed by Deputy Clerk). (AJS) (Entered: 05/07/2024)
05/07/2024	6	SUMMONS issued as to Administrator, Centers for Medicare and Medicaid Services, Centers for Medicare and Medicaid Services, Department of Health and Human Services, Director, Office for Civil Rights, Secretary, Department of Health and Human Services, U.S. Attorney and U.S. Attorney General. (AJS) (Entered: 05/07/2024)
05/07/2024	7	PROOF of service by Catholic Medical Association, Florida Agency for Health Care Administration, Florida Department of Management Services, State of Florida (McCotter,

		R.) (Entered: 05/07/2024)
05/07/2024	16	**STANDING ORDER regarding Discovery Motions. Signed by Magistrate Judge Thomas G. Wilson on 5/7/2024. (KMN)** (Entered: 05/20/2024)
05/08/2024	8	NOTICE of Local Rule 1.07(c), Local Rule 3.02(a)(2), and Local Rule 3.03. **-Local Rule 1.07(c)** requires lead counsel to file *promptly* a **Notice of a Related Action** identifying and describing any related action either pending or closed in the Middle District or elsewhere. **-Local Rule 3.02(a)(2)** requires the parties in every civil proceeding, except those described in subsection (d), to file a case management report (CMR) using the uniform form at www.flmd.uscourts.gov. The CMR must be filed (1) within forty days after any defendant appears in an action originating in this court, (2) within forty days after the docketing of an action removed or transferred to this court, or (3) within seventy days after service on the United States attorney in an action against the United States, its agencies or employees. Judges may have a special CMR form for certain types of cases. These forms can be found at www.flmd.uscourts.gov under the Forms tab for each judge. **-Local Rule 3.03** requires each party to file a disclosure statement. Counsel must make their disclosures using the standard court form. The Disclosure Statement form can be found at www.flmd.uscourts.gov. (Signed by Deputy Clerk). (JCG) (Entered: 05/08/2024)
05/08/2024	9	NOTICE informing the parties that they may consent to the jurisdiction of a United States magistrate judge by filing Form AO 85 Notice, Consent, and Reference of a Civil Action to a Magistrate Judge using the event **Consent to Jurisdiction of US Magistrate Judge**. (Signed by Deputy Clerk). (JCG) (Entered: 05/08/2024)
05/14/2024	10	Unopposed MOTION for R. Trent McCotter to appear pro hac vice, Special Admission fee paid, Receipt No. AFLMDC-22090184 for $150 by Florida Agency for Health Care Administration, Florida Department of Management Services. (McCotter, R.) Motions referred to Magistrate Judge Thomas G. Wilson. (Entered: 05/14/2024)
05/14/2024	11	Unopposed MOTION for James R. Conde to appear pro hac vice, Special Admission fee paid, Receipt No. AFLMDC-22090231 for $150 by Florida Agency for Health Care Administration, Florida Department of Management Services. (McCotter, R.) Motions referred to Magistrate Judge Thomas G. Wilson. (Entered: 05/14/2024)
05/15/2024	12	MOTION for Preliminary Injunction *or Stay of Rule Under the APA* by all Plaintiffs. (Attachments: # 1 Exhibit A, # 2 Exhibit B, # 3 Exhibit C, # 4 Exhibit D, # 5 Text of Proposed Order)(McCotter, R.) Modified on 5/16/2024 to edit docket text; Chambers notified. (LD). (Entered: 05/15/2024)
05/15/2024	13	**ORDER granting 10 Motion to Appear Pro Hac Vice; granting 11 Motion to Appear Pro Hac Vice. R. Trent McCotter and James R. Conde are authorized to appear in this matter pro hac vice. Signed by Magistrate Judge Thomas G. Wilson on 5/15/2024. (KMN)** (Entered: 05/16/2024)
05/17/2024	14	NOTICE of Lead Counsel Designation by James R. Conde on behalf of Florida Agency for Health Care Administration, Florida Department of Management Services. Lead Counsel: James R. Conde. (Conde, James) (Entered: 05/17/2024)
05/20/2024	15	NOTICE of Lead Counsel Designation by Natalie Christmas on behalf of State of Florida. Lead Counsel: Natalie Christmas. (Christmas, Natalie) (Entered: 05/20/2024)
05/20/2024	17	Unopposed MOTION for Julie Marie Blake to appear pro hac vice, Special Admission fee paid, Receipt No. AFLMDC-22112080 for $150 by Catholic Medical Association.

		(McCotter, R.) Motions referred to Magistrate Judge Thomas G. Wilson. (Entered: 05/20/2024)
05/20/2024	18	Unopposed MOTION for Matthew S. Bowman to appear pro hac vice, Special Admission fee paid, Receipt No. AFLMDC-22112094 for $150 by Catholic Medical Association. (McCotter, R.) Motions referred to Magistrate Judge Thomas G. Wilson. (Entered: 05/20/2024)
05/21/2024	19	**ORDER granting 17 Motion to Appear Pro Hac Vice; granting 18 Motion to Appear Pro Hac Vice. Accordingly, Attorney Julie Marie Blake and Matthew S. Bowman are authorized to appear pro hac vice. Signed by Magistrate Judge Thomas G. Wilson on 5/21/2024. (KMN)** (Entered: 05/23/2024)
05/24/2024	20	MOTION for Extension of Time to File Response/Reply as to 12 MOTION for Preliminary Injunction OR Stay of Rule Under the APA by All Defendants. (Holland, Liam). (Entered: 05/24/2024)
05/24/2024	21	RESPONSE in Opposition re 20 MOTION for Extension of Time to File Response/Reply as to 12 MOTION for Preliminary Injunction or Stay of Rule Under the APA filed by Catholic Medical Association, Florida Agency for Health Care Administration, Florida Department of Management Services, State of Florida. (McCotter, R.). (Entered: 05/24/2024)
05/28/2024	22	**ENDORSED ORDER granting 20 Motion for Extension of Time to File Response / Reply. Response due by 6/13/2024. If Plaintiffs desires to file a Reply, it is due on or before 6/18/2024 by close of business. Signed by Judge William F. Jung on 5/28/2024. (CCB)** (Entered: 05/28/2024)
05/28/2024	23	NOTICE of Telephonic Hearing on 12 MOTION for Preliminary Injunction or Stay. Motion Hearing set for 6/21/2024 at 01:30 PM before Judge William F. Jung. Counsel are directed to call the reserved conference toll free number at 1-888-557-8511. Enter the access code: 4744914 followed by the # (pound) key. You will be prompted to enter the security code: 1080 followed by the # (pound) key. Please call in at least 10 minutes before the scheduled hearing. (CCB) (Entered: 05/28/2024)
05/28/2024	24	NOTICE of Lead Counsel Designation by Julie Marie Blake on behalf of Catholic Medical Association. Lead Counsel: Julie Marie Blake. (Blake, Julie) (Entered: 05/28/2024)
06/03/2024	25	**ENDORSED ORDER: Additionally, on June 21 by 5 pm each party should copy chambers email and each other with MSWord draft Orders that they would wish the Court to enter. Signed by Judge William F. Jung on 6/3/2024. (Jung, William)** (Entered: 06/03/2024)
06/10/2024	26	NOTICE of Hearing (change as to in person and time only) on 12 MOTION for Preliminary Injunction or Stay. Motion Hearing set for 6/21/2024 in person at 02:30 PM in Tampa Courtroom 15 B before Judge William F. Jung. (CCB) (Entered: 06/10/2024)
06/11/2024	27	Unopposed MOTION to File Excess Pages by All Defendants. (Holland, Liam) (Entered: 06/11/2024)
06/11/2024	28	**ENDORSED ORDER granting unopposed 27 Motion to File Excess Pages. Signed by Judge William F. Jung on 6/11/2024. (CCB)** (Entered: 06/11/2024)
06/12/2024	29	Unopposed MOTION for Allison H. Pope to appear pro hac vice, Special Admission fee paid, Receipt No. AFLMDC-22191849 for $150 by Catholic Medical Association. (Blake, Julie) Motions referred to Magistrate Judge Thomas G. Wilson. (Entered: 06/12/2024)
06/13/2024	30	**ENDORSED ORDER granting 29 Motion to Appear Pro Hac Vice. Attorney Pope may appear pro hac vice as counsel for Plaintiff Christian Medical Association,**

		subject to payment of the $150.00 special admission fee and submission of the Pro Hac Vice E-File Registration (see https://www.flmd.uscourts.gov/for-lawyers) within seven days of this order. Signed by Judge William F. Jung on 6/13/2024. (CCB) (Entered: 06/13/2024)
06/13/2024	31	CORPORATE Disclosure Statement by Administrator, Centers for Medicare and Medicaid Services, Centers for Medicare and Medicaid Services, Department of Health and Human Services, Director, Office for Civil Rights, Secretary, Department of Health and Human Services. (Holland, Liam) (Entered: 06/13/2024)
06/13/2024	32	NOTICE of a related action per Local Rule 1.07(c) by Administrator, Centers for Medicare and Medicaid Services, Centers for Medicare and Medicaid Services, Department of Health and Human Services, Director, Office for Civil Rights, Secretary, Department of Health and Human Services. Related case(s): Yes (Attachments: # 1 Exhibit 1 Neese Class Certification Order, # 2 Exhibit 2 Neese Final Judgment, # 3 Exhibit 3 ACP Amended Complaint, # 4 Exhibit 4 ACP Memorandum Opinion and Order, # 5 Exhibit 5 ACP Supplemental Briefing, # 6 Exhibit 6 Dekker Judgment, # 7 Exhibit 7 Dekker Opposition to Motion to Enforce the Court's Judgment or, Alternatively, to Clarify the Court's Judgment, # 8 Exhibit 8 McComb Complaint, # 9 Exhibit 9 Catholic Benefits Ass'n Amended Complaint, # 10 Exhibit 10 Tennessee Complaint, # 11 Exhibit 11 Texas Complaint)(Holland, Liam) (Entered: 06/13/2024)
06/13/2024	33	RESPONSE in Opposition re 12 MOTION for Preliminary Injunction or Stay of Rule Under the APA filed by Administrator, Centers for Medicare and Medicaid Services, Centers for Medicare and Medicaid Services, Department of Health and Human Services, Director, Office for Civil Rights, Secretary, Department of Health and Human Services. (Holland, Liam). (Entered: 06/13/2024)
06/18/2024	34	RESPONSE re 32 Notice of a Related Action filed by Florida Agency for Health Care Administration, Florida Department of Management Services. (Conde, James) (Entered: 06/18/2024)
06/18/2024	35	REPLY to Response to Motion re 12 MOTION for Preliminary Injunction *OR STAY OF RULE UNDER THE APA* filed by Florida Agency for Health Care Administration, Florida Department of Management Services. (Conde, James) (Entered: 06/18/2024)
06/21/2024	36	**ORDER permitting electronics for hearing of 6/21/2024 as to Counsel Allison Pope. Signed by Judge William F. Jung on 6/21/2024. (CCB)** (Entered: 06/21/2024)
06/21/2024	37	Minute Entry. In Person Proceedings held before Judge William F. Jung: MOTION HEARING held on 6/21/2024 re 12 MOTION for Preliminary Injunction *OR STAY OF RULE UNDER THE APA* filed by Florida Department of Management Services, Florida Agency for Health Care Administration, Catholic Medical Association, State of Florida. Court Reporter: Susan Cayler (JCG) (Entered: 06/21/2024)
06/21/2024	38	The court's Exhibit referenced at the Motion Hearing held on 6/21/2024.(JCG) (Entered: 06/21/2024)
06/26/2024	39	RESPONSE re 38 Exhibit list - court *Defendants' Response to the Court's Exhibit* filed by Administrator, Centers for Medicare and Medicaid Services, Centers for Medicare and Medicaid Services, Department of Health and Human Services, Director, Office for Civil Rights, Secretary, Department of Health and Human Services. (Attachments: # 1 Exhibit 1 -- Transcript of Preliminary Injunction Proceedings, Doe v. Noggle, No. 1:23-cv-02904-SEG (N.D. Ga. Aug. 10, 2023))(Holland, Liam) (Entered: 06/26/2024)
06/28/2024	40	NOTICE of supplemental authority re 34 Response by Catholic Medical Association. (Pope, Allison) (Entered: 06/28/2024)

07/03/2024	41	**ORDER granting in part and denying in part 12 Motion for Preliminary Injunction. Signed by Judge William F. Jung on 7/3/2024. (Jung, William)** (Entered: 07/03/2024)
07/08/2024	42	Consent MOTION for Extension of Time to File Answer re 1 Complaint by All Defendants. (Holland, Liam) (Entered: 07/08/2024)
07/08/2024	43	**ENDORSED ORDER granting 42 Consent Motion for Extension of Time to Answer. All Defendants' answer or response to the complaint is due 9/9/2024. Signed by Judge William F. Jung on 7/8/2024. (CCB)** (Entered: 07/08/2024)
07/24/2024	44	TRANSCRIPT of Motion Hearing held on 6.21.24 before Judge William F. Jung. Court Reporter/Transcriber: Susie Cayler. Email address: reportercayler@gmail.com. Telephone number: 15157785008. NOTICE TO THE PARTIES - The parties have seven (7) calendar days to file with the court a Notice of Intent to Request Redaction of this transcript. If no such notice is filed, the transcript may be made remotely available to the public without redaction after ninety (90) calendar days. Transcript may be viewed at the court public terminal or purchased through the Court Reporter/Transcriber before the deadline for Release of Transcript Restriction. After that date it may be obtained through PACER or purchased through the Court Reporter. Redaction Request due 8/14/2024. Redacted Transcript Deadline set for 8/26/2024. Release of Transcript Restriction set for 10/22/2024. (Cayler, Susan) (Entered: 07/24/2024)
08/29/2024	45	NOTICE of Appearance by Zachary Sherwood on behalf of Administrator, Centers for Medicare and Medicaid Services, Centers for Medicare and Medicaid Services, Department of Health and Human Services, Director, Office for Civil Rights, Secretary, Department of Health and Human Services (Sherwood, Zachary) (Entered: 08/29/2024)
08/30/2024	46	NOTICE OF APPEAL as to 41 Order on Motion for Preliminary Injunction by Administrator, Centers for Medicare and Medicaid Services, Centers for Medicare and Medicaid Services, Department of Health and Human Services, Director, Office for Civil Rights, Secretary, Department of Health and Human Services. Filing fee not paid. (Sherwood, Zachary) (Entered: 08/30/2024)
09/03/2024	47	MOTION to Stay *Proceedings* by Administrator, Centers for Medicare and Medicaid Services, Centers for Medicare and Medicaid Services, Department of Health and Human Services, Director, Office for Civil Rights, Secretary, Department of Health and Human Services. (Sherwood, Zachary) (Entered: 09/03/2024)
09/03/2024	48	RESPONSE in Opposition re 47 MOTION to Stay *Proceedings* filed by Florida Agency for Health Care Administration, Florida Department of Management Services. (Conde, James) (Entered: 09/03/2024)
09/04/2024	49	TRANSMITTAL of initial appeal package to USCA consisting of copies of notice of appeal, docket sheet, order/judgment being appealed, and motion, if applicable to USCA re 46 Notice of Appeal. Eleventh Circuit Transcript information form forwarded to pro se litigants and available to counsel at www.flmd.uscourts.gov under Forms and Publications/General. (LNR) (Entered: 09/04/2024)
09/05/2024	50	**ENDORSED ORDER granting in part and denying in part 47 Motion to Stay. This case is stayed pending a telephonic status conference that will be set by the Court. Signed by Judge William F. Jung on 9/5/2024. (CCB)** (Entered: 09/05/2024)
09/05/2024		Case Stayed. (Case inadvertently lifted on 12/13/2024) (BD) (Entered: 12/13/2024)
09/10/2024	51	NOTICE of Telephonic Hearing: Status Conference set for 11/13/2024 at 9:00 AM before Judge William F. Jung. Counsel are directed to call the reserved conference toll free

		number at 1-888-557-8511. Enter the access code: 4744914 followed by the # (pound) key. You will be prompted to enter the security code: 1080 followed by the # (pound) key. Please call in at least 10 minutes before the scheduled hearing. (CCB) (Entered: 09/10/2024)
09/11/2024	52	NOTICE OF CROSS APPEAL as to 41 Order on Motion for Preliminary Injunction by Catholic Medical Association. (Blake, Julie) (Entered: 09/11/2024)
09/12/2024	53	TRANSMITTAL of initial appeal package to USCA consisting of copies of notice of appeal, docket sheet, order/judgment being appealed, and motion, if applicable to USCA re 52 Notice of Cross Appeal. Eleventh Circuit Transcript information form forwarded to pro se litigants and available to counsel at www.flmd.uscourts.gov under Forms and Publications/General. (KME) (Entered: 09/12/2024)
09/12/2024		FEE PAID. Appeal fee, Receipt No. AFLMDC-22513165 for $605 paid Notice for appeal to the Eleventh Circuit Court of Appeals. (Blake, Julie) (Entered: 09/12/2024)
09/18/2024	54	TRANSCRIPT information form filed by Administrator, Centers for Medicare and Medicaid Services, Centers for Medicare and Medicaid Services, Department of Health and Human Services, Director, Office for Civil Rights, Secretary, Department of Health and Human Services for proceedings held on 06/21/2024 before Judge Jung re 46 Notice of Appeal USCA number: 24-12826. Electronic notification sent to Court Reporter Susan Caylor (Holland, Liam) (Entered: 09/18/2024)
09/19/2024	55	COURT REPORTER ACKNOWLEDGMENT by Susie Cayler re 46 Notice of Appeal,. Estimated transcript filing date: 9.20.24. USCA number: 24-12826. (Cayler, Susan) (Entered: 09/19/2024)
09/19/2024	56	NOTIFICATION that transcript has been filed by Susie Cayler re: 46 Notice of Appeal,. USCA number: 24-12826. (Cayler, Susan) (Entered: 09/19/2024)
10/10/2024	57	TRANSCRIPT information form filed by Catholic Medical Association re 52 Notice of Cross Appeal. USCA number: 24-12826. No transcript(s) requested. (Bowman, Matthew) (Entered: 10/10/2024)
11/12/2024	58	**ENDORSED ORDER: Counsel, there is no need for a status conference tomorrow and it is canceled. Please file a one-page update no later than November 15, informing the Court your view of the present status before this District Court. Consider in this short discussion the pending appeals as well as the likelihood of mootness given a pending change in administration. Signed by Judge William F. Jung on 11/12/2024. (Jung, William)** (Entered: 11/12/2024)
11/12/2024	59	NOTICE canceling status conference hearing scheduled for 11/13/2024. (CCB) (Entered: 11/12/2024)
11/15/2024	60	RESPONSE re 58 Order filed by Catholic Medical Association, Florida Agency for Health Care Administration, Florida Department of Management Services, State of Florida. (Conde, James) (Entered: 11/15/2024)
11/15/2024	61	STATUS report by Secretary, Department of Health and Human Services, Director, Office for Civil Rights, Administrator, Centers for Medicare and Medicaid Services, Centers for Medicare and Medicaid Services, Department of Health and Human Services. (Holland, Liam) (Entered: 11/15/2024)
12/13/2024	62	**ENDORSED ORDER directing the Clerk to administratively close this case. Any party may reopen at any time by filing a motion. Signed by Judge William F. Jung on 12/13/2024. (CCB)** (Entered: 12/13/2024)

01/14/2025	63	Unopposed MOTION for James H. Percival to Withdraw as Attorney by State of Florida. (Percival, James) Motions referred to Magistrate Judge Thomas G. Wilson. (Entered: 01/14/2025)
01/15/2025	64	**ENDORSED ORDER granting 63 Motion to Withdraw as Attorney Attorney James Hamilton Percival, II terminated. Signed by Judge William F. Jung on 1/15/2025. (Jung, William)** (Entered: 01/15/2025)
02/06/2025	65	NOTICE of Appearance by Allen Huang on behalf of State of Florida (Huang, Allen) (Entered: 02/06/2025)
02/18/2025	66	MOTION for Natalie Christmas to Withdraw as Attorney by State of Florida. (Christmas, Natalie) Motions referred to Magistrate Judge Thomas G. Wilson. Modified on 2/19/2025 to edit text (ELA). (Entered: 02/18/2025)
02/18/2025	67	**ORDER granting 66 Motion to Withdraw as Attorney. Attorney Natalie Christmas terminated. Signed by Magistrate Judge Thomas G. Wilson on 2/18/2025. (Wilson, Thomas)** (Entered: 02/18/2025)
02/19/2025	68	MOTION for Henry Charles Whitaker to Withdraw as Attorney by State of Florida. (Huang, Allen) Motions referred to Magistrate Judge Thomas G. Wilson. (Entered: 02/19/2025)
02/19/2025	69	**ORDER granting 68 Motion to Withdraw as Attorney. Attorney Henry Charles Whitaker terminated. Signed by Magistrate Judge Thomas G. Wilson on 2/19/2025. (Wilson, Thomas)** (Entered: 02/19/2025)
04/03/2025	70	ORDER of USCA: Appellants' "Unopposed Motion to Dismiss Appeal" is GRANTED. Cross-Appellant Catholic Medical Association's "Response to Unopposed Motion to Dismiss Appeal," which the Court construes as a motion to voluntarily dismiss the cross-appeal, is GRANTED as to 52 Notice of Cross Appeal filed by Catholic Medical Association. EOD: 4/3/2025. Issued as the mandate USCA number: 24-12826-JJ. (MCB) (Entered: 04/07/2025)
04/09/2025	71	**ENDORSED ORDER: Upon consideration of the Eleventh Circuit's Order of Dismissal and Mandate, the Clerk is directed to lift the stay and convert the administrative closure into a full closure. Signed by Judge William F. Jung on 4/9/2025. (CCB)** (Entered: 04/09/2025)
04/09/2025		Case Stay Lifted. (ELA) (Entered: 04/09/2025)
04/09/2025	72	NOTICE of Local Rule 1.11(e), which provides that, unless an order states another time, a seal under Rule 1.11 expires ninety days after a case is closed and all appeals are exhausted. To prevent the content of a sealed item from appearing on the docket after the seal expires, a party or interested non-party must move for relief before the seal expires. (Signed by Deputy Clerk). (ELA) (Entered: 04/09/2025)
05/02/2025	73	MOTION to Reopen Case , MOTION for Clarification *of the Court's April 9, 2025 order* by All Plaintiffs. (Attachments: # 1 Text of Proposed Order)(Conde, James) (Entered: 05/02/2025)
05/05/2025	74	**ENDORSED ORDER taking under advisement 73 Motion to Reopen Case and to Clarify. The Department of Health and Human Services is directed to file an update on the status within thirty (30) days. All other parties are directed to file a reply to the HHS filing fourteen (14) days thereafter. Signed by Judge William F. Jung on 5/5/2025. (CCB)** (Entered: 05/05/2025)
06/04/2025	75	RESPONSE to Motion re 73 MOTION to Reopen Case, MOTION for Clarification *of the Court's April 9, 2025 order and Status Report* filed by Administrator, Centers for Medicare

		and Medicaid Services, Centers for Medicare and Medicaid Services, Department of Health and Human Services, Director, Office for Civil Rights, Secretary, Department of Health and Human Services. (Attachments: # 1 Defending Women Executive Order, # 2 Protecting Children Executive Order)(Holland, Liam) (Entered: 06/04/2025)
06/05/2025	76	**ENDORSED ORDER denying 73 Motion to Reopen Case; denying 73 Motion for Reconsideration / Clarification. There is no case or controversy presently pending. Signed by Judge William F. Jung on 6/5/2025. (Jung, William)** (Entered: 06/05/2025)
06/06/2025	77	NOTICE OF APPEAL as to 76 Order on Motion to Reopen Case, Order on Motion for Reconsideration / Clarification, 71 Order by Florida Agency for Health Care Administration. Filing fee $ 605, receipt number AFLMDC-23454867. (Conde, James) (Entered: 06/06/2025)
06/09/2025	78	TRANSMITTAL of initial appeal package to USCA consisting of copies of notice of appeal, docket sheet, order/judgment being appealed, and motion, if applicable to USCA re 77 Notice of Appeal. Eleventh Circuit Transcript information form forwarded to pro se litigants and available to counsel at www.flmd.uscourts.gov under Forms and Publications/General. (JKB) (Entered: 06/09/2025)
06/09/2025	79	**ENDORSED ORDER: The Clerk will dismiss this case without prejudice as moot and not capable of repetition within any reasonable time frame. Signed by Judge William F. Jung on 6/9/2025. (Jung, William)** (Entered: 06/09/2025)
06/16/2025	80	NOTICE OF APPEAL as to 79 Order by Catholic Medical Association, Florida Agency for Health Care Administration, Florida Department of Management Services, State of Florida. Filing fee $ 605, receipt number AFLMDC-23489152. (Conde, James) (Entered: 06/16/2025)
06/17/2025	81	TRANSMITTAL of initial appeal package to USCA consisting of copies of notice of appeal, docket sheet, order/judgment being appealed, and motion, if applicable to USCA re 80 Notice of Appeal,. Eleventh Circuit Transcript information form forwarded to pro se litigants and available to counsel at www.flmd.uscourts.gov under Forms and Publications/General. (JTM) (Entered: 06/17/2025)
06/20/2025	82	Unopposed MOTION for to Withdraw as Attorney by State of Florida. (Guard, John) Motions referred to Magistrate Judge Thomas G. Wilson. (Entered: 06/20/2025)
06/23/2025	83	**ORDER granting 82 Motion to Withdraw as Attorney. Attorney John Matthew Guard terminated. Signed by Magistrate Judge Thomas G. Wilson on 6/23/2025. (KMN)** (Entered: 06/23/2025)
10/02/2025	84	OPINION of USCA: DISMISSED as to 77 Notice of Appeal filed by Florida Agency for Health Care Administration. EOD: 10/2/2025. Mandate to issue at a later date. USCA number: 25-11927-FF. (MCB) (Entered: 10/02/2025)

PACER Service Center			
Transaction Receipt			
10/03/2025 09:09:57			
PACER Login:	jlucardi1	**Client Code:**	5154112
Description:	Docket Report	**Search Criteria:**	8:24-cv-01080-WFJ-TGW
Billable Pages:	8	**Cost:**	0.80

Dkt. 1

IN THE UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
TAMPA DIVISION

STATE OF FLORIDA; FLORIDA AGENCY FOR HEALTH CARE ADMINISTRATION; FLORIDA DEPARTMENT OF MANAGEMENT SERVICES; CATHOLIC MEDICAL ASSOCIATION, on behalf of its current and future members,

Plaintiffs,

No. 8:24-cv-1080

DEPARTMENT OF HEALTH AND HUMAN SERVICES; XAVIER BECERRA, in his official capacity as Secretary of the Department of Health and Human Services; MELANIE FONTES RAINER, in her official capacity as the Director of the Office for Civil Rights; CENTERS FOR MEDICARE AND MEDICAID SERVICES; CHIQUITA BROOKS-LASURE, in her official capacity as Administrator of the Centers for Medicare and Medicaid,

Defendants.

COMPLAINT FOR DECLARATORY RELIEF AND PRELIMINARY AND PERMANENT INJUNCTIVE RELIEF

INTRODUCTION

1. Under the guise of federal non-discrimination rules, the Department of Health and Human Services ("HHS") seeks to redefine the practice of medicine. HHS's rules threaten the livelihood of doctors who refuse to provide experimental, sterilizing, "gender-change" interventions to persons suffering from psychological distress—including minor children. To do so, HHS purports to override the State of

Florida's laws and regulations protecting the health and safety of its residents. HHS further threatens the loss of federal funds for States and insurance issuers that refuse to cover these interventions. Plaintiffs bring this action to stop HHS's interference with the ethical practice of medicine and state police powers.

2. Section 1557 of the Affordable Care Act ("ACA") forbids covered entities, including States, from discriminating in health programs or activities "on the ground prohibited under … title IX of the Education Amendments of 1972." 42 U.S.C. § 18116(a). Title IX, in turn, prohibits discriminating "on the basis of sex." 20 U.S.C. § 1681(a).

3. On May 6, 2024, HHS and the Centers for Medicare and Medicaid Services ("CMS") promulgated rules purporting to implement Section 1557 (collectively, the "2024 Rules"). 89 Fed. Reg. 37,522 (May 6, 2024).

4. But the 2024 Rules go far beyond the limits of Section 1557 and Title IX. The 2024 Rules require Florida to allow and even fund drugs and surgeries for "gender-transition." The 2024 Rules do this through a series of missteps that are foreclosed by logic and Eleventh Circuit precedent.

5. First, the 2024 Rules define "[d]iscrimination on the basis of sex" to include discriminating based on "(i) Sex characteristics, including intersex traits; (ii) Pregnancy or related conditions; (iii) Sexual orientation; (iv) Gender identity; and (v) Sex stereotypes." 89 Fed. Reg. at 37,699, *to be codified at* 45 C.F.R. § 92.101(a)(2). Despite this, HHS claims "it is not necessary to define 'sex' in this rule." 89 Fed. Reg. at 37,575.

6. Second, the 2024 Rules make it presumptively discriminatory for covered hospitals, clinics, residential treatment centers, medical practices, and pharmacies to "[d]eny or limit" puberty blockers, cross-sex hormones, or surgeries "sought for purpose of gender transition," if covered entities provide those services for "other purposes." 89 Fed. Reg. at 37,701, *to be codified at* 45 C.F.R. § 92.206(b)(4). For example, under the final rule, a gynecological surgeon who performs a hysterectomy to treat endometrial cancer is presumptively required to remove a healthy uterus for a "gender transition." *Id.*; *see also* Notice of Proposed Rulemaking ("NPRM"), 87 Fed. Reg. 47,824, 47,867 (Aug. 4, 2022).

7. A medical practice that refuses to assist a gender transition may avoid sanctions if HHS's Office for Civil Rights ("OCR") deems a refusal "clinically appropriate *for a particular individual*." 89 Fed. Reg. at 37,701, *to be codified at* 45 C.F.R. § 92.206(c) (emphasis added). OCR will review "medical necessity standards or guidelines" to ensure a clinical or ethical judgment is "bona fide" in a particular case, and not pretextual. 89 Fed. Reg. at 37,613.

8. Repeatedly, however, HHS emphasizes that covered entities must make an "*individualized* clinical judgment" for gender-change interventions. *Id.* at 37,575, 37,595–97 (emphasis added). OCR will review a "non-categorical denial[]" of a gender-change intervention "on a case-by-case basis." *Id.* at 37,607. The implied threat is clear: Any medical provider that categorically refuses to follow OCR's preferred "standards or guidelines" of care—*i.e.*, gender transition—risks crippling enforcement proceedings and punishment.

9. Third, on top of this, the 2024 Rules force States and insurance issuers to subsidize gender transitions. The 2024 Rules make it presumptively illegal for covered insurance providers and other entities—including States administering HHS programs such as ACA health-insurance exchanges, Medicaid, and a Childrens Health Insurance Program ("CHIP")—to set "limitations or restrictions" on claims "for specific health services related to gender transition" if doing so "results in discrimination on the basis of sex." 89 Fed. Reg. at 37,701, *to be codified at* 45 C.F.R. § 92.207(b)(5). Again, under the 2024 Rules, sex discrimination includes discriminating based on "gender identity," and does not distinguish between providing a service for one purpose as opposed to another. *Id.* at 37,699, 37,701. An insurer that covers a hysterectomy to treat endometrial cancer is presumptively required to cover the removal of a healthy uterus for a "gender transition."

10. An insurance issuer or a State may avoid sanctions by showing no "medical necessity" for a gender-transition intervention in a particular case. But the 2024 Rules prohibit a "categorical coverage exclusion … for all health services related to gender transition." 89 Fed. Reg. at 37,701, *to be codified at* 45 C.F.R. § 92.207(b)(4), (c). In other words, HHS has already determined that "gender transition" is medically necessary and that disagreeing with HHS is a pretext for discriminating on the basis of sex. Indeed, according to HHS, merely referring to gender-change interventions as "experimental or cosmetic would be considered evidence of pretext because this characterization is not based on current standards of medical care." NPRM, 87 Fed. Reg. at 47,874.

11. HHS's attempt to mandate gender-transition interventions and force States to subsidize the cost is unlawful under binding Eleventh Circuit precedent. To begin, the meaning of "sex" under Section 1557 extends no further than "sex" in Title IX. *See* 89 Fed. Reg. at 37,638 (admitting that "Section 1557 is best read to incorporate existing interpretations of what constitutes sex discrimination under title IX, including regulatory interpretations and case law"). In *Adams v. School Board of St. Johns County*, the Eleventh Circuit held that "sex" in Title IX *unambiguously* means "biological sex," *not* "sexual orientation" or "gender identity," 57 F.4th 791, 812–15 (11th Cir. 2022) (en banc).

12. Moreover, under *Adams*, the prohibition against discriminating "on the basis of sex" in Title IX must be read to permit some sex-based differences—including separate living facilities and bathrooms. *Id.* at 814 (citing 28 U.S.C. § 1686; 34 C.F.R. § 106.33). But reading Title IX to protect "'gender identity,' as [HHS does], would result in situations where an entity would be prohibited from" separating living facilities such as dual-occupancy hospital rooms based on sex whenever that comes "into conflict with a transgender person's gender identity." *Id.* That is wrong, and it is foreclosed by *Adams*. *Id.* "Whether [Section 1557] should be amended to equate 'gender identity' and 'transgender status' with 'sex'"—therefore—"should be left to Congress"—not an unelected administrative agency. *Id.* at 817. By purporting to do what may be done *only* by Congress, the 2024 Rules exceed HHS's statutory authority under Section 1557.

13. Further, a refusal to provide or subsidize these treatments is not "discrimination" anyway. 42 U.S.C. § 18116. *See Discriminate*, Webster's Third New International Dictionary 648 (1976) ("to make a difference in treatment or favor on a class or categorical basis in disregard of individual merit"); *Discrimination*, Black's Law Dictionary 534 (9th ed. 2009) ("failure to treat all persons equally when no reasonable distinction can be found between those favored and those not favored"). Refusing to provide interventions to anyone because of doubts about medical efficacy or ethical misgivings is not treating transgender individuals differently at all, much less on the basis of sex.

14. In medicine, therapeutic purpose matters. Removing organs with cancer is not "to [a doctor's mind], materially identical in all respects" to removing a healthy organ for a gender transition. *Bostock v. Clayton Cnty.*, 590 U.S. 644, 660 (2020). It is therefore not discriminatory for a State to prohibit interventions based on a clinical or ethical judgment that those interventions are not safe and effective or ethical to treat gender dysphoria, while allowing those interventions to treat materially *different* health conditions such as cancer.

15. HHS's false equivalency across treatments with different therapeutic purposes is foreclosed by logic and at odds with binding precedent. The Eleventh Circuit has held that a State does not discriminate or stereotype "on the basis of sex" (the exact same words used in Title IX) when it categorically forbids hormonal treatments or the removal of healthy organs for a gender transition. *Eknes-Tucker v. Governor of Ala.*, 80 F.4th 1205, 1227–30 (11th Cir. 2023) (Equal Protection Clause);

see id. at 1233–34 (Brasher, J., concurring). By ignoring material differences in therapeutic purpose, the 2024 Rules would fundamentally redefine the practice of medicine and place OCR lawyers in the strange position of overseeing—and second-guessing—the clinical and ethical judgments of health care professionals and state medical boards across the country.

16. Section 1557 is an ordinary non-discrimination law, not a Trojan horse empowering OCR to play doctor and decree gender-transition interventions as the federal standard of care through threats of enforcement. Because the 2024 Rules are unauthorized by law, violate the clear-notice requirements of the Spending Clause, raise major questions and usurp traditional police powers without clear authority, fail to grapple with contrary evidence showing gender-transition interventions are not safe and effective, and depart from prior agency positions without explaining or considering reliance interests, this Court must set aside the 2024 Rules as contrary to law and arbitrary and capricious.

PARTIES

17. Plaintiff State of Florida is a sovereign State and has the authority and responsibility to protect its public fisc and the health, safety, and welfare of its citizens. Florida has the sovereign authority to regulate the practice of medicine within the State, promulgate standards of care for licensed physicians, determine what medical procedures are reasonable for purposes of Medicaid coverage, and decide what services and procedures should be covered by its employee health insurance policies. Florida has agencies and healthcare facilities that receive federal financial assistance

and participate in HHS health-related programs subject to Section 1557 and the 2024 Rules.

18. Ashley Moody, the Attorney General of Florida, has authority to sue in the name of the State. *See* Fla. Stat. § 16.01(4)–(5). That power is incredibly broad, and includes the power to vindicate injuries to the State at any governmental level. *See, e.g.*, *Florida v. Nelson*, 576 F. Supp. 3d 1017, 1030 (M.D. Fla. 2021) (finding standing based on an injury to a state university); *Florida v. Becerra*, 544 F. Supp. 3d 1241, 1253–54 (M.D. Fla. 2021) (finding standing based on injuries to political subdivisions of the State).

19. Plaintiff Florida Agency for Health Care Administration ("AHCA") administers Florida's Medicaid and CHIP programs and assists CMS in regulating facilities that participate in Medicare. Exhibit 1, Kniepmann Decl. ¶¶ 1–2 ("Ex. 1").

20. Plaintiff Florida Department of Management Services ("DMS") is the business arm of Florida's government. DMS's primary mission is to support sister agencies as well as current and former state employees with workforce and business-related functions, including the provision of State Group Insurance. Exhibit 2, Sanders Decl. ¶ 3 ("Ex. 2").

21. Plaintiff Catholic Medical Association ("CMA") is the largest association of Catholic individuals in healthcare. CMA has 2,500 members nationwide in all fields of practice. CMA has a Florida statewide guild called the Florida Catholic Medical Association. CMA also has seven local Florida guilds, which are located in Gainesville, Miami, Orlando, Jacksonville, Palm Beach, Pensacola, and

St. Petersburg/Tampa Bay. CMA's 2024 national conference will be held in Orlando, Florida, as was CMA's 2021 national conference. CMA is organized as a Virginia nonprofit corporation.

22. Most CMA members provide medical care in health programs and activities that receive federal financial assistance and are subject to Section 1557. CMA seeks relief on behalf of its current and future members for all aspects of their practices.

23. CMA and its members hold the position that gender-transition procedures are unethical and dangerous. Providing, facilitating, referring for, or endorsing gender-transition efforts violates their medical views, their core religious beliefs, and their oath to "do no harm." CMA's members have medical and ethical positions contrary to the 2024 Rules' requirements, and they also have overlapping religious objections. It is within CMA's advocacy mission to advocate and litigate for its members' right to the conscientious and faithful practice of medicine.

24. The Executive Director of CMA is Mario Dickerson. Additional facts about CMA's membership are set forth in Mr. Dickerson's attached declaration ("Ex. 3") and in attached declarations from representative CMA members Dr. Michael S. Parker of Mansfield, Ohio ("Ex. 4"), and Dr. Quentin L. Van Meter of Atlanta, Georgia ("Ex. 5"). CMA's members are similarly situated to Drs. Parker and Van Meter.

25. Defendant Department of Health and Human Services is the agency of the United States that promulgated and now enforces the 2024 Rules.

26. Defendant Xavier Becerra is the Secretary of the Department of Health and Human Services. Plaintiffs sue Defendant Becerra in his official capacity only.

27. Defendant Melanie Fontes Rainer is the Director of the Office for Civil Rights within HHS and now enforces the 2024 Rules. Plaintiffs sue Defendant Fontes Rainer in her official capacity only.

28. Defendant Centers for Medicare and Medicaid Services is an agency within HHS.

29. Defendant Chiquita Brooks-LaSure is the Administrator of CMS. Plaintiffs sue Defendant Brooks-LaSure in her official capacity only.

JURISDICTION AND VENUE

30. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331, 1346, and 1361.

31. Plaintiffs are "entitled to judicial review" under 5 U.S.C. § 702.

32. The Court is authorized to award the requested declaratory and injunctive relief against Defendants under 5 U.S.C. §§ 703, 706, 28 U.S.C. §§ 1361, 2201–02, the Constitution, and the Court's equitable powers.

33. This Court may award costs and attorneys' fees under the Equal Access to Justice Act, 28 U.S.C. § 2412, and the Religious Freedom Restoration Act ("RFRA"), 42 U.S.C. § 1988(b).

34. Venue is proper under 28 U.S.C. § 1391(e)(1) because an agency of the United States is a Defendant, and Plaintiff the State of Florida is a resident of every judicial district and division in its sovereign territory, including this judicial district

and division. *See Florida v. United States*, No. 3:21-cv-1066, 2022 WL 2431443, at *2 (N.D. Fla. Jan. 18, 2022) ("It is well established that a state 'resides at every point within its boundaries.'" (alteration omitted) (quoting *Atlanta & F.R. Co. v. W. Ry. Co. of Ala.*, 50 F. 790, 791 (5th Cir. 1892))); *see also California v. Azar*, 911 F.3d 558, 569–70 (9th Cir. 2018) ("[A] state with multiple judicial districts 'resides' in every district within its borders."); *Utah v. Walsh*, No. 2:23-cv-016-Z, 2023 WL 2663256, at *3 (N.D. Tex. Mar. 28, 2023) ("Texas resides everywhere in Texas."); *Alabama v. U.S. Army Corps of Eng'rs*, 382 F. Supp. 2d 1301, 1329 (N.D. Ala. 2005) ("[C]ommon sense dictates that a state resides throughout its sovereign borders.").

LEGAL BACKGROUND

I. The Affordable Care Act and Title IX

35. In March 2010, Congress passed, and President Obama signed, the ACA. Pub. L. No. 111-148, 124 Stat. 119.

36. Section 1557 of the ACA provides that "an individual shall not, on the ground prohibited under … title IX of the Education Amendments of 1972 (20 U.S.C. 1681 et seq.) … be excluded from participating in, be denied the benefits of, or be subjected to discrimination under, any health program or activity, any part of which is receiving federal financial assistance, or under any program or activity that is administered by an Executive agency or any entity established under [the ACA]." 42 U.S.C. § 18116(a).

37. Section 1557 does not reference sexual orientation or gender identity. Its sole basis for prohibiting sex discrimination is a cross-reference to "the ground prohibited under … title IX (20 U.S.C. 1681 et seq.)."

38. Title IX states: "No person in the United States shall, on the basis of sex, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any education program or activity receiving Federal financial assistance … ." 20 U.S.C. § 1681(a).

39. That general prohibition includes several sex-specific limitations and rules of construction. *Id.* Section 1686, for example, provides that nothing in Title IX "shall be construed to prohibit … maintaining separate living facilities for the different sexes." 20 U.S.C. § 1686.

40. Title IX furthermore does not apply to covered entities "controlled by a religious organization if the application of this subsection would not be consistent with the religious tenets of such organization." 20 U.S.C. § 1681(a)(3).

41. Section 1554 of the ACA provides that "notwithstanding any other provision of [the ACA, HHS] shall not promulgate any regulation that— … violates the principles of informed consent and the ethical standards of health care professionals." 42 U.S.C. § 18114(5).

42. Section 1557 applies to what HHS calls "covered entities," which includes recipients of federal financial assistance programs such as Medicaid and CHIP. Covered entities include hospitals, clinics, and doctors that accept patients

paying for services through these financial assistance programs, as well as pharmacies and insurance issuers.

43. An entity "any part of which" participates in HHS financial assistance programs is subject in all aspects of its health programs and activities to Section 1557. *Id.* § 18116(a). That means that any hospital or doctors' office that accepts a single Medicaid or CHIP patient must follow Section 1557 for *all* its patients, no matter how other patients pay for care.

44. The ACA incorporates Title IX's public and private enforcement mechanisms for Section 1557 and HHS's implementing regulations. 42 U.S.C. § 18116(a).

45. If OCR finds a covered entity in noncompliance, HHS may require providers to take remedial action or lose federal funding.

46. Section 1557 allows members of the public to sue covered entities to require compliance and seek damages. *See Cummings v. Premier Rehab Keller, P.L.L.C.*, 596 U.S. 212, 218 (2022).

II. Prior 1557 Rules, Guidance, and Related Litigation

A. The 2016 Rules

47. On May 18, 2016, HHS published rules purporting to implement Section 1557. Those rules defined discriminating "on the basis of sex" to include discriminating against an individual "on the basis of pregnancy, false pregnancy, termination of pregnancy, or recovery therefrom, childbirth or related medical

conditions, sex stereotyping, and gender identity." 81 Fed. Reg. 31,376, 31,467 (May 18, 2016). HHS defined the term "gender identity" in that rule as "an individual's internal sense of gender, which may be male, female, neither, or a combination of male and female, and which may be different from an individual's sex assigned at birth." *Id.* at 31,467.

48. On December 21, 2016, the U.S. District Court for the Northern District of Texas vacated the 2016 rules and enjoined HHS from "enforcing the [rules] prohibition against discrimination on the basis of gender identity or termination of pregnancy." *Franciscan All., Inc. v. Burwell*, 227 F. Supp. 3d 660, 696 (N.D. Tex. 2016). On gender identity, the Court reasoned that "the meaning of sex in Title IX unambiguously refers to 'the biological and anatomical difference between male and female students as determined at their birth.'" *Id.* at 687. It then held that "HHS's expanded definition of sex discrimination exceeds the grounds incorporated by Section 1557." *Id.* at 689.

49. The Court's vacatur of the 2016 rules remains "in effect." *Franciscan All., Inc. v. Becerra*, 47 F.4th 368, 377 (5th Cir. 2022) ("In short, Franciscan Alliance's APA claim is moot, its RFRA claim is not, and we leave the district court's vacatur of the 2016 Rule in effect."); *see also Religious Sisters of Mercy v. Becerra*, 55 F.4th 583, 609 (8th Cir. 2022) ("affirm[ing] the district court's grant of permanent injunctive relief against a requirement to provide 'gender-transition procedures' under Section 1557 on the ground that it violates the Religious Freedom Restoration Act").

B. The 2020 Rules

50. On June 12, 2020, HHS issued new rules rescinding the 2016 rules. 85 Fed. Reg. 37,160 (June 19, 2020) (the "2020 Rules").

51. The 2020 Rules repealed HHS's expansive definition of "on the basis of sex" and relied instead on the self-executing text of Section 1557, which speaks for itself. It also recognized the applicability of Title IX's religious exemption.

52. On June 15, 2020, three days after HHS issued its new rules, the U.S. Supreme Court decided *Bostock v. Clayton County*, 590 U.S. 644 (2020).

53. *Bostock* interpreted Title VII of the Civil Rights Act of 1964, which prohibits employers from discriminating "because of … sex." 42 U.S.C. § 2000e-2(a)(1). The Court in *Bostock* "proceed[ed] on the assumption that 'sex'" refers "only to biological distinctions between male and female." *Bostock*, 590 U.S. at 655. The Supreme Court then interpreted the text of Title VII to mean that "[a]n employer violates Title VII when it intentionally fires an individual employee based in part on sex." *Id.* at 659. "If the employer intentionally relies in part on an individual employee's sex when deciding to discharge the employee—put differently, if changing the employee's sex would have yielded a different choice by the employer—a statutory violation has occurred." *Id.* at 659–60.

54. Applying that rule to employers who fired their employees solely on the basis of the employee "being homosexual or transgender," the Supreme Court held the employers could be liable under Title VII. As the Court explained, when an employer fires a man who identifies as a woman solely for "traits or actions" it

tolerates in a female colleague, the employees "are, to the employer's mind, materially identical in all respects, except that one is a man and the other a woman." *Id.* at 660. The Court reasoned that biological sex is, therefore, a but-for cause of the employees' disparate treatment.

55. The Court, however, made clear its decision was limited to employment discrimination under Title VII. "The employers worry that our decision will sweep beyond Title VII to other federal or state laws that prohibit sex discrimination. … But 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.* at 681.

56. After *Bostock*, "[t]wo courts entered nationwide injunctions preventing much of the 2020 Rule[s] from going into effect, effectively reinstating portions of the 2016 Rule[s]," even though the 2016 rules had already been vacated. *Franciscan All.*, 47 F.4th at 372 (citing *Whitman-Walker Clinic, Inc. v. HHS*, 485 F. Supp. 3d 1, 60 (D.D.C. 2020); *Walker v. Azar*, 480 F. Supp. 3d 417, 420 (E.D.N.Y. 2020)). These courts concluded that, "in light of *Bostock*, sex-stereotyping discrimination encompasses gender identity discrimination." *Id.* at 372–73.

C. The 2021 and 2022 Notices

57. The day he was sworn into office, President Biden issued an executive order asserting that "laws that prohibit sex discrimination … prohibit discrimination

on the basis of gender identity or sexual orientation." Exec. Order No. 13,988, 86 Fed. Reg. 7023, 7023 (Jan. 20, 2021).

58. On May 25, 2021, pursuant to this executive order, HHS published a document titled "Notification of Interpretation and Enforcement of Section 1557 of the Affordable Care Act and Title IX of the Education Amendments of 1972." 86 Fed. Reg. 27,984 (May 25, 2021). The May 2021 notice announced that "consistent with the Supreme Court's decision in *Bostock* and Title IX," HHS would "interpret and enforce section 1557 of the Affordable Care Act prohibition on discrimination on the basis of sex to include: Discrimination on the basis of sexual orientation; and discrimination on the basis of gender identity." *Id.* at 27,984.

59. Shortly thereafter a group of physicians challenged the notification on the grounds that it would force them to treat youth suffering from gender dysphoria in a manner that violated their clinical judgment and conscience. *Neese v. Becerra*, No. 2:21-cv-163-Z, 2022 WL 16902425, at *1–2 (N.D. Tex. Nov. 11, 2022). The U.S. District Court for the Northern District of Texas found the Notification to be "not in accordance with the law." *Id.* at 3. The Court entered a declaratory judgment declaring that "Section 1557 of the ACA does not prohibit discrimination on account of sexual orientation and gender identity, and the interpretation of 'sex' discrimination that the Supreme Court of the United States adopted in [*Bostock*] is inapplicable to the prohibitions on 'sex' discrimination in Title IX of the Education Amendments of 1972 and in Section 1557 of the ACA." Final Judgment, *Neese*, 2:21-cv-163-Z (N.D. Tex. Nov. 22, 2022), ECF No. 71.

60. In March of 2022, HHS published another document titled "Notice and Guidance on Gender Affirming Care, Civil Rights, and Patient Privacy," https://perma.cc/LX26-59QR ("2022 Notice"). The 2022 Notice asserted that HHS "unequivocally" takes the position that restricting gender-change interventions even "for minors … is dangerous." HHS announced that its Office of Civil Rights would consider bringing enforcement actions against medical providers who comply with state laws that "restrict" the use of these interventions for minors. HHS also claimed that refusal to provide these interventions could be discriminating on the basis of disability. *Id.*

61. In *Texas v. Equal Employment Opportunity Commission*, the U.S. District Court for the Northern District of Texas vacated the 2022 Notice. 633 F. Supp. 3d 824, 847 (N.D. Tex. 2022). Among other things, the Court held that the 2022 Notice misread *Bostock*, and did not adequately explain how, despite the specific exclusion of gender identity disorders from the definition of disability in the Rehabilitation Act (and hence in Section 1557, *see* 42 U.S.C. § 18116(a) (including "section 794 of title 29"), failure to provide cross-sex hormones or surgeries to these individuals could be discriminating on the basis of a disability. *Id.* at 836–38.

FACTUAL BACKGROUND

I. Sex, Gender Dysphoria, and "Gender-Change" Interventions

A. Sex and Gender

62. As the Supreme Court and the Eleventh Circuit have observed, "sex … is an immutable characteristic." *Adams*, 57 F.4th at 807 (quoting *Frontiero v. Richardson*,

411 U.S. 677, 686 (1973) (plurality opinion)); *see also* Expert Report of Stephen B. Levine 8 (Feb. 23, 2022), *in* Attachments to Comments of Alliance Defending Freedom, *Factual Evidence*, HHS-OS-2022-0012-68192.

63. Sex, therefore, is not arbitrarily "assigned at birth," as HHS's terminology implies. Rather, an individual's sex is male or female "according to [the individual's] reproductive organs and functions assigned by the chromosomal complement." Inst. of Medicine, *Exploring the Biological Contributions to Human Health: Does Sex Matter* 13 n.2 (2001) (*Does Sex Matter*); Levine, *supra*, at 8–9 (same); *see also* Fla. Stat. § 456.001(8) ("'Sex' means the classification of a person as either male or female based on the organization of the human body of such person for a specific reproductive role, as indicated by the person's sex chromosomes, naturally occurring sex hormones, and internal and external genitalia present at birth."); *Sex*, American Heritage Dictionary 1605 (5th ed. 2011) ("Either of two divisions, designated female and male, by which most organisms are classified on the basis of their reproductive organs and functions.").

64. Sex should not be confused with "gender," which is increasingly understood by some to mean a person's "self-perception" as male, female, or perhaps something else. *Does Sex Matter*, *supra*, at 13 n.2. HHS, for example, claims that gender identity may be female, male, both, somewhere in between, or neither. 81 Fed. Reg. at 31,467. Unlike sex, gender cannot be reliably determined by inspecting reproductive organs or genetic testing. And unlike sex, gender is not an immutable characteristic. A person's gender identity may change over time.

65. Sex begins in the cells and the womb before anyone writes a birth certificate. "With some exceptions, individuals are either chromosomally XX and developmentally female or chromosomally XY and developmentally male." *Does Sex Matter*, *supra*, at 17. "It is the overriding presence of a gene on the Y chromosome (SRY) that results in development of the male gonadal pathway." *Id.* at 33. The testes start developing "by the 6th to 7th week of gestation." *Id.* at 55. By the 12th to 14th week, "male and female fetuses can be distinguished by inspection of the external genitalia." *Id.* at 61.

66. Physical differences between boys and girls become pronounced during puberty. This process of sexual maturation and growth is "primarily the consequence of testosterone secretion by the Leydig cells in boys and of estrogen secretion by the granulosa cells in girls." *Id.* at 66; *see also Adams*, 57 F.4th at 819–20 (Lagoa, J., specially concurring) (discussing some of the significant physical differences that develop during puberty).

67. Some individuals are born with disorders of sex development. These disorders may result in physiological traits that are inconsistent with chromosomal sex, and, in rare cases, a body that cannot be classified as male or female. These individuals are sometimes labeled "intersex." *See Adams*, 57 F.4th at 822–23 (Wilson, J., dissenting) (discussing "intersex people"). The prevalence of intersex individuals has been estimated at 1 in 5,000 per live birth. Leonard Sax, *How Common is Intersex? A Response to Anne Fausto-Sterling*, 39 J. Sex Res. 174 (2002). Intersex traits are caused

by congenital chromosomal, genetic, or hormonal abnormalities that prevent normal sexual development. *See* Levine, *supra*, at 9.

B. Gender Dysphoria

68. The American Psychological Association previously defined an incongruence between sex and gender as a "gender identity disorder." Am. Psych. Ass'n, *Diagnostic and Statistical Manual* 71 (3d ed. 1987).

69. In 2013, the American Psychological Association discontinued the term "gender identity disorder" and defined the psychological condition now known as "gender dysphoria" as a discomforting or distressing discordance between a person's biological sex and sense of "gender identity." Am. Psych. Ass'n, *Diagnostic and Statistical Manual* 451–53 (5th ed. 2013).

70. Not all transgender individuals experience "dysphoria." *Id.*

71. Gender dysphoria, like gender, is not necessarily permanent. In children, gender dysphoria usually resolves as the child undergoes puberty, as the child's gender identity may change. This is why "watchful waiting" became the standard approach for treating gender dysphoria in minors. Levine, *supra*, at 17–19.

C. The "Gender-Change" Protocol

72. "What the medical profession has come to call gender-affirming care was not available for minors until just before the millennium." *L.W. v. Skrmetti*, 83 F.4th 460, 467 (6th Cir. 2023). Over the past decade or so, influential interest groups in the United States have advocated for treating gender dysphoria by "affirming" a child or

adult's sense of incongruence with sex through a protocol of social, chemical, and surgical interventions aimed at changing a patient's physical characteristics and behavior to accord with his or her sense of "gender." *Id.* These groups claim these interventions, often labeled "gender-affirming care," are medically necessary for many, including minors undergoing puberty, even though the treatments may lead to infertility and other serious side effects.

73. One of these groups is the World Professional Association for Transgender Health ("WPATH"), which publishes what it styles as "standards of care" for treating gender dysphoria in both children and adults. *See* WPATH, *Standards of Care for the Health of Transgender and Gender Diverse People*, Version 8, 23 Int'l J. of Transgender Health S1 (2022) ("WPATH 8"); WPATH, *Standards of Care for the Health of Transsexual, Transgender, and Gender-Nonconforming People*, Version 7 (2012), HHS-OS-2022-0012-4074 ("WPATH 7").

74. HHS has previously described WPATH as an "advocacy group." 85 Fed. Reg. at 37,186–87. For good reason. WPATH members must show a commitment to "transgender rights" and need not be medical professionals. Levine, *supra*, at 26. "Contrary viewpoints have been known to be shouted down and effectively silenced by the large numbers of nonprofessional adults who attend the organization's biennial meetings." *Id.*

75. According to WPATH, psychological treatment or counseling "aimed at trying to change a person's gender identity and expression to become more congruent with [biological sex] … is no longer considered ethical." WPATH 7, *supra*, at 16;

WPATH 8, *supra*, at S53 (same). WPATH's guidelines instead steer health care professionals into a gender-change regimen.

76. Another organization is the Endocrine Society, an association of endocrinologists that stand to benefit from an increase in the prevalence of hormone therapy. The Endocrine Society has published a guideline with recommendations for treating gender dysphoria in minors and adults. Although its recommendations "do not establish a standard of care" for gender dysphoria, the Endocrine Society claims hormonal and surgical interventions are medically necessary to treat many children as well as adults suffering from dysphoria. *See* Wyle C. Hembree, *Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline*, 10 J. Clin. Endocrinol Metab. 3869, 3896 (2017), HHS-OS-2022-0012-4060 ("Endocrine Society Guideline").

77. The gender-change protocol embraced by these groups proceeds in four escalating steps: (1) social transition and mental health treatment, (2) puberty blockers, (3) cross-sex hormones, and (4) sex-reassignment surgery. Jason Rafferty et al., *Ensuring Comprehensive Care and Support for Transgender and Gender-Diverse Children and Adolescents*, 142 Pediatrics 1, 6–7 (2018) (Adults who have gone through puberty don't need puberty blockers.).

78. For pre-pubescent children, the protocol begins with "social transition"—that is, usually, encouraging a child to adopt the stereotypical behaviors, clothing, and hairstyle associated with members of the opposite sex, and allowing the child to adopt a name and pronouns used by the opposite sex. *Id.* at 6.

79. During the onset of puberty, the next step is administering a long-acting GnRH analogue, commonly known as a puberty blocker, to suppress the child's normal puberty, and hence the child's normal physical and sexual development. *Id.*

80. Most minors administered a puberty blocker for gender dysphoria are then prescribed supraphysiological levels of "cross-sex" hormones—hormones associated with the physiological development of the opposite sex: Estrogen for males, and testosterone for females. Levine, *supra*, at 48–49.

81. The last step is "gender-reassignment" surgery. That can include a double mastectomy to remove healthy breasts, "bottom surgery" to remove the healthy reproductive organs of either sex, and plastic surgery and cosmetic procedures to imitate the genitals and the physical appearance of the opposite sex. *See* WPATH 7, *supra*, at 57; WPATH 8, *supra*, at S258, App'x E (listing the procedures in a list that "is not intended to be exhaustive").

82. Gender-reassignment surgery cannot reassign sex. It does not change an individual's chromosomes or replace sexual organs with the functioning reproductive organs of the opposite sex. Rather, bottom-surgery renders an individual permanently infertile.

83. The medical guidelines of WPATH and the Endocrine Society have become more aggressive over time. "Today, these guidelines permit the use of puberty blockers or cross-sex hormones from the early stages of pubertal development. Therapy or time spent living as the desired gender is no longer required before or along with such treatments. Many surgical treatments initially restricted to adults have

become available to minors in the past six years, often without any prerequisites for therapy or cross-sex hormone treatments." *L.W.*, 83 F.4th at 467–68 (citations omitted).

84. Diagnoses for gender dysphoria have simultaneously increased. "In the last few years, the number of doctors prescribing sex-transition treatments and the number of children seeking them have grown." *Id.* at 468. At the same time, "[t]he percentage of youth identifying as transgender has doubled from 0.7% of the population to 1.4% in the past few years, while the percentage of adults (0.5% of the population) has remained constant." *Id.*

D. Health Risks of the Gender-Change Protocol

85. Although groups such as WPATH and the Endocrine Society claim these gender-change interventions have psychological benefits, "no one disputes that these treatments carry risks or that the evidence supporting their use is far from conclusive." *L.W.*, 83 F.4th at 489.

86. The FDA may approve the marketing of drugs as safe and effective to treat a condition based on "adequate and well-controlled investigations"—typically a double-blind, randomized, clinical trial. 21 U.S.C. § 355(d). The FDA has approved puberty blockers to rectify a hormonal imbalance in young children caused by precocious puberty, but it has not approved marketing these drugs as part of a regimen to treat gender dysphoria in minors or adults. The use of these drugs for that purpose is therefore "off-label."

87. As WPATH 7 acknowledged, "[t]o date, no controlled clinical trials of any feminizing/masculinizing hormone regimen have been conducted to evaluate safety or efficacy in producing physical transition." WPATH 7, *supra*, at 47. That remains true today.

88. Even supporters acknowledge that puberty blockers have health risks. The Endocrine Society, for example, acknowledges that the "primary risks of pubertal suppression" are "adverse effects on bone mineralization," "compromised fertility if the person subsequently is treated with sex hormones, and unknown effects on brain development." Endocrine Society Guideline, *supra*, at 3882.

89. Although little is known about the long-term effects of puberty blockers used for a gender transition on brain function and brain development, the FDA recently required drug manufacturers to warn that puberty blockers may cause "pseudotumor cerebri, including headache, papilledema, blurred or loss of vision, diplopia, pain behind the eye or pain with eye movement, tinnitus, dizziness and nausea." FDA, *Risk of Pseudotumor Cerebri Added to Labeling for Gonadotropin-Releasing Hormone Agonist* (July 1, 2022).

90. Cross-sex hormones such as testosterone and estrogen have not been approved by the FDA to treat gender dysphoria. (Testosterone is a Class III controlled substance because it "may lead to moderate or low physical dependence or high psychological dependence," so it is not available over the counter. 21 U.S.C. §§ 802(41), 812(b)(3)(C), (c), Schedule III(e)).

91. Cross-sex hormone interventions also have physical side effects and increase serious health risks. *See L.W.*, 83 F.4th at 489 (listing side effects and potential health risks in detail).

92. Giving adolescent girls the high doses of testosterone needed for a gender-change induces hyperandrogenism. According to WPATH 8, this causes "clitoral enlargement" (clitoromegaly), "vaginal atrophy" (atrophy of the vagina's lining), "deepening of the voice," "facial/body hair growth" (hirsutism), "acne," and "scalp hair loss." WPATH 8, *supra*, at S254, App'x C, Tbl. 1 (cleaned up); *see also* WPATH 7, *supra*, at 37 (similar).

93. According to WPATH 8, induced hyperandrogenism in adolescent girls also, at a minimum, increases the risk of "polycythemia" (bone marrow producing too many red blood cells, which increases the risk of blood clots and heart attacks), "infertility," "weight gain," "acne," "sleep apnea," "androgenic alopecia" (balding), "hypertension" (high blood pressure), "decreased HDL ['good'] cholesterol and increased LDL ['bad'] cholesterol," "cardiovascular disease," "hypertriglyceridemia" (high levels of triglycerides (fats) in the blood, leading to plaque buildup in arteries (atherosclerosis) which can result in heart attacks, strokes, blood clots, and similar complications), and possibly of "type 2 diabetes," among other health risks. WPATH 8, *supra*, at S254, App'x C, Tbl. 2 (cleaned up); *see also* WPATH 7, *supra*, at 40 (similar).

94. Giving adolescent boys high doses of estrogen induces hyperestrogenemia. According to WPATH 8, this causes "breast growth" "decrease

in muscle mass and strength," "softening of skin/decreased oiliness," and various forms of sexual dysfunction.

95. According to WPATH 8, induced hyperandrogenism in adolescent boys also, at a minimum, increases the risk of "venous thromboembolism" (life-threatening blood clots), "infertility," "cholelithiasis" (gallstones), "hyperkalemia" (high potassium levels that cause life-threatening heartbeat abnormalities, muscle weakness, or paralysis), "meningioma" (a primary central nervous system tumor), "polyuria/dehydration" (increased urine production), "weight gain," "hypertriglyceridemia" (high levels of triglycerides (fats) in the blood, leading to plaque buildup in arteries (atherosclerosis) which can result in heart attacks, strokes, blood clots, and similar complications), "cardiovascular disease," "cerebrovascular disease" (affecting the blood flow and blood vessels in the brain), and possibly "hypertension" (high blood pressure), "erectile dysfunction," "type 2 diabetes," "low bone mass/osteoporosis" (leading to weak and brittle bones), and "hyperprolactinemia" (high levels of the hormone prolactin, causing infertility and other issues). WPATH 8, *supra*, at S254, App'x C, Tbl. 2 (cleaned up); *see also* WPATH 7, *supra*, at 38, 40 (similar).

96. By suppressing sexual development during puberty, a cross-sex hormone regimen for minors will likely cause lifelong sterility. Levine, *supra*, at 67; WPATH 8, *supra*, at S254, App'x C, Tbl. 2 (warning of a "clinically significant" risk of infertility). That is why WPATH and the Endocrine Society recommend warning "adolescents" seeking gender-change interventions about the "potential loss of fertility and available

options to preserve fertility." WPATH 8, *supra*, at S57, S156–57 (discussing the risk of infertility from hormone interventions); Endocrine Society Guideline, *supra*, at 3871 (similar).

97. Bottom-surgery (the removal of healthy reproductive organs) also causes irreversible sterility. As WPATH acknowledges, the surgeries also lead to an increased risk of infection and other serious and potentially lifelong medical complications. WPATH 7, *supra*, at 62–64.

98. WPATH, the Endocrine Society, and other interest groups nevertheless claim the side effects and downsides of gender-change interventions, including infertility, are often outweighed by the purported benefits of reduced psychological distress resulting from gender dysphoria, improved mental well-being, and allegedly reduced suicide risk.

99. But the evidence available to date is not robust enough to conclude these hormones and surgeries increase long-term mental health outcomes, and persons with gender dysphoria continue to commit suicide at vastly disproportionate rates even after all these interventions. *See* Levine, *supra*, at 49–61.

100. Some experts believe this protocol may actually decrease mental wellbeing and increase suicide by, among other things, preventing desistance. Some believe it to be an unethical experiment on humans, particularly on minors. There is no universal consensus on these clinical or ethical questions, but one thing is clear: the evidence of benefit is weak at best, and the evidence of harm is clear. *See* Levine, *supra*, at 22–30; The Cass Review, *Independent Review of Gender Identity Services for Children and*

You People: Interim Report 47 (Feb. 2022), HHS-OS-2022-0012-4075 (finding no consensus); Comment of the Society for Evidence Based Gender Medicine (Oct. 3, 2022), HHS-OS-2022-0012-73218 (arguing that the empirical evidence of a benefit is weak and is outweighed by clear evidence of harm); Comment of Florida AHCA (Oct. 28, 2022), HHS-OS-2022-0012-69566 (same).

101. In other words, as the Fifth Circuit has observed, "the WPATH Standards of Care reflect not consensus, but merely one side in a sharply contested medical debate." *Gibson v. Collier*, 920 F.3d 212, 221 (5th Cir. 2019).

102. National public health authorities have taken a variety of views on the safety and efficacy of this protocol.

103. Start with HHS. In 2016, during the Obama Administration, HHS refused to require national coverage of gender-reassignment surgeries under Medicare, concluding in a thorough review that "[b]ased on an extensive assessment of the clinical evidence …, there is not enough high quality evidence to determine whether gender reassignment surgery improves health outcomes for Medicare beneficiaries with gender dysphoria and whether patients most likely to benefit from these types of surgical intervention can be identified prospectively." Tamara S. Jensen et al., Decision Memo, CAG #00446N (Aug. 30, 2016), https://perma.cc/R2ME-YQRA. "Overall, the quality and strength of evidence were low due to mostly observational study designs with no comparison groups, subjective endpoints, potential confounding (a situation where the association between the intervention and outcome is influenced

by another factor such as a co-intervention), small sample sizes, lack of validated assessment tools, and considerable lost to follow-up." *Id.*

104. In 2020, HHS again concluded that there is "a lack of scientific and medical consensus to support" this gender-change regimen. 85 Fed. Reg. at 37,187. HHS expressly noted the "lack of high-quality scientific evidence supporting such treatments." *Id.*

105. But during the Biden Administration, HHS changed its tune. In 2022, the Office of Population Affairs released a two-pager entitled "Gender-Affirming Care and Young People." https://perma.cc/H3CS-94KX. In this two-pager, the Office of Population Affairs asserted that "[r]esearch demonstrates that" so-called "gender-affirming care improves the mental health and overall well-being of gender diverse children and adolescents." *Id.* HHS further asserted that "[f]or transgender and nonbinary children and adolescents, early gender-affirming care is crucial to overall health and well-being." *Id.* The two-pager prominently highlighted the treatment guidelines from the Endocrine Society and WPATH. *Id.* At the same time, in the 2022 Notice, HHS threatened to sue anyone who disagreed with this purported "standard of care."

106. HHS's change in position is more striking because the international trend is in the opposite direction. The "public healthcare entities of Sweden, Finland, France, Australia, New Zealand, and the United Kingdom have raised concerns about the risks associated with puberty blockers and cross-sex hormone treatment and

supported greater caution and/or more restrictive criteria in connection with such interventions." *Eknes-Tucker*, 80 F.4th at 1218; Levine, *supra*, at 31.

107. For example, the Swedish National Board of Health has stated that "the risks of hormonal interventions for gender dysphoric youth outweigh potential benefits." *Summary of Key Recommendations from the Swedish National Board of Health and Welfare (Socialstyrelsen/NBHW)*, SEGM.org (Feb. 27, 2022), HHS-OS-2022-0012-10295, https://perma.cc/NWB6-3XEU. Finland's Council for Health Choices has concluded that gender-change interventions in minors are "an experimental practice" and that "no irreversible treatment should be initiated" before adulthood. *Medical Treatment Methods for Dysphoria Related to Gender Variance in Minors* (2020), https://perma.cc/PX74-4LBK. The United Kingdom has similarly restricted puberty blockers after finding the evidence inadequate to conclude they are safe and effective to treat gender dysphoria. *B.P.J. by Jackson v. W. Va. State Bd. of Educ.*, No. 23-1078, 2024 WL 1627008, at *18 n.7 (4th Cir. Apr. 16, 2024) (Agee, J., concurring in part and dissenting in part).

108. Plenty of governments are skeptical on this side of the Atlantic too. At least 21 states in the United States prohibit hormone treatment and surgery for minors suffering from gender dysphoria. *L.W.*, 83 F.4th at 471 (citing statutes).

II. Florida's Actions to Protect the Public from Experimental Treatments for Gender Dysphoria

109. Florida, for its part, has concluded that the alleged psychological benefits of gender-change interventions are far too speculative to justify the risks, particularly

in minors. Florida has accordingly acted to protect the health and safety of its citizens, protect the fertility and health of its youth, and promote the ethical practice of medicine.

A. Florida Guidance

110. "The purpose" of the Florida Department of Health ("DOH") "is to promote the health of all residents and visitors," by, among other things, "[r]egulat[ing] health practitioners for the preservation of the health, safety, and welfare of the public." Fla. Stat. § 20.43(1)(g).

111. On April 20, 2022, in response to the misleading two-pager published by the HHS Office of Population Affairs, DOH provided its own public guidance on the treatment of gender dysphoria in children. *Treatment of Gender Dysphoria for Children and Adolescents* (Apr. 20, 2022), https://perma.cc/BB4N-2QH4.

112. DOH noted that "[s]ystematic reviews on hormonal treatment for young people show a trend of low-quality evidence, small sample sizes, and medium to high risk of bias." *Id.* Citing a "lack of conclusive evidence, and the potential for long-term, irreversible effects," the DOH concluded that "social gender transition" should not be recommended to youth, "puberty blockers or hormone therapy" should not be prescribed to children under 18, and that "gender reassignment surgery should not be a treatment option for children or adolescents." *Id.*

B. Florida Medicaid

113. Medicaid is a public assistance program that provides medical services for low-income individuals. 42 U.S.C. §§ 1396-1, 1396a. It is "the primary federal

program for providing medical care to indigents at public expense." *Mem'l Hosp. v. Maricopa Cnty.*, 415 U.S. 250, 262 n.19 (1974). The program is administered jointly by the States and the federal government through a "contract[ual]" relationship. *NFIB v. Sebelius*, 567 U.S. 519, 577 (2012).

114. Florida Medicaid reimburses the "services and procedures" of a medical doctor when "medically necessary for the treatment of an injury, illness, or disease." Fla. Stat. § 409.905(9). But "clinically unproven" or "experimental treatments" are not reimbursed. *Id.* To qualify as medically necessary, AHCA rules require that the treatment be "consistent with generally accepted professional medical standards as determined by the Medicaid program, and not experimental or investigational." Fla. Admin. Code r. 59G-1.010(2.83).

115. Pursuant to its obligations, AHCA separately investigated the safety and efficacy of gender transition interventions to treat psychological distress. To make this determination, AHCA followed its regulatory process. *Id.* r. 59G-1.035.

116. As required by that process, on June 2, 2022, AHCA published a report, titled "Generally Accepted Professional Medical Standards Determination on the Treatment of Gender Dysphoria." https://perma.cc/7RZM-L3SN ("GAPMS Report").

117. The GAPMS Report included a lengthy review of the available evidence and literature, and the actions taken by public health authorities, and concluded that so-called "gender-affirming care" interventions are "experimental and investigational":

> Following a review of available literature, clinical guidelines, and coverage by other insurers and nations, Florida Medicaid has determined that the research supporting sex reassignment treatment is insufficient to demonstrate efficacy and safety. In addition, numerous studies, including the reports provided by the clinical and technical experts listed above, identify poor methods and the certainty of irreversible physical changes. Considering the weak evidence supporting the use of puberty suppression, cross-sex hormones, and surgical procedures when compared to the stronger research demonstrating the permanent effects they cause, these treatments do not conform to GAPMS and are experimental and investigational. *Id.* at 3.

118. The GAPMS Report concluded that the "treatments pose irreversible consequences, exacerbate or fail to alleviate existing mental health conditions, and cause infertility and sterility." *Id.* at 38. Consequently, the GAPMS Report "does not recommend sex reassignment treatment as a health service that is consistent with generally accepted professional medical standards." *Id.*

119. The GAPMS Report also attached five assessments by subject-matter experts in the field. *Id.* at 2. One of those five assessments "examined the quality of 61 articles published between 2020 and 2022" purporting to support treatment for gender dysphoria. *Id.* at 27. The expert review concluded these articles were of "low quality" and do not permit an inference that hormonal or surgical treatments reduce distress or suicide rates. *Id.*

120. Following the recommendations of the GAPMS Report, AHCA went through a public notice-and-comment rulemaking process and held a public hearing on the topic.

121. Thereafter, on August 21, 2022, AHCA promulgated Rule 59G-1.050(7). Under Rule 59G-1.050(7), Florida Medicaid will not cover services related to gender

transition including puberty blockers, hormone and hormone antagonists, sex-reassignment surgeries, and "any other procedures that alter primary or secondary sex characteristics." Fla. Admin. Code r. 59G-1.050(7).

C. Florida Medical Ethics

122. Under Florida law, DOH has a duty to regulate "health practitioners for the preservation of the health, safety, and welfare of the public." Fla. Stat. § 20.43(g).

123. The Florida Board of Medicine ("Board") is the state agency responsible for the regulation of licensed physicians. The Board has authority to establish "standards of practice and standards of care" for licensed physicians. Fla. Stat. § 458.331(1)(v).

124. On July 28, 2022, DOH petitioned the Board to initiate rulemaking on treatment of gender dysphoria in children and adults. DOH Petition, https://perma.cc/97HK-Y4XS.

125. The Petition observed that the "lack of quality evidence in support of gender transition treatments" had caused "confusion" in the medical community and posed a danger to public health. *Id.* at 5. It further observed that "the use of such treatments for gender dysphoria should be considered experimental and should require fully informed consent of the risks and limitations." *Id.* at 5–6. In particular, the Petition observed that "[c]hildren do not possess the cognitive or emotional maturity to comprehend the consequences of these invasive and irreversible procedures." *Id.* at 6. The Petition asked the Board to adopt a standard of care prohibiting surgery, puberty blockers, and hormones to treat gender dysphoria for patients under 18 years of age

and requiring the use of pre-approved informed consent forms for adults receiving these treatments. *Id.* at 6–7.

126. Effective March 16, 2023, the Florida Board of Medicine published Rule 64B8-9.019 which prohibits "(a) [s]ex reassignment surgeries, or any other surgical procedures, that alter primary or secondary sexual characteristics; [and] (b) [p]uberty blocking, hormone, and hormone antagonist therapies" for treatment of gender dysphoria in minors, except for minors already being treated with these drugs. Fla. Admin. Code r. 64B8-9.019.

127. Effective March 28, 2023, the Board of Osteopathic Medicine published Rule 64B15-14.014, which is identical to Rule 64B8-9.019. Fla. Admin. Code r. 64B15-14.014.

D. Florida Health and Safety Laws

128. On May 17, 2023, Florida Governor Ron DeSantis signed into law SB 254. SB 254 prohibits "sex-reassignment prescriptions or procedures" for minors, requires informed consent in adults, and requires that sex-reassignment services for adults be performed by a licensed physician. *See* Fla. Stat. §§ 456.001 (definitions), 456.52 (restrictions). SB 254 also prohibits the use of state funds for sex-reassignment interventions. *Id.* § 286.311.

129. On May 17, 2023, Governor DeSantis also signed into law HB 1521. HB 1521 requires educational institutions, detention facilities, correctional institutions, juvenile correctional facilities, and public buildings with a restroom or changing

facility to designate separate facilities based on sex or to provide one-person unisex facilities. *See* Fla. Stat. § 553.865(5), (12).

III. The 2024 Rules

130. The 2024 Rules are comprised of two different sets of rules. HHS is promulgating one set of rules purporting to implement Section 1557, to be codified in Part 92 of Title 45 of the Code of Federal Regulations and enforced by OCR (the "OCR Rules"). CMS is also promulgating separate non-discrimination rules for specific aid programs, relying on both Section 1557 and provisions of the Social Security Act and the Public Health Service Act.

131. With some exceptions, the 2024 Rules will be effective on Friday, July 5, 2024. 89 Fed. Reg. at 37,522.

A. The OCR Rules

132. The OCR Rules generally provide: "Discrimination on the basis of sex includes, but is not limited to, discrimination on the basis of: (i) Sex characteristics, including intersex traits; (ii) Pregnancy or related conditions; (iii) Sexual orientation; (iv) Gender identity; and (v) Sex stereotypes." 89 Fed. Reg. at 37,699, *to be codified at* 45 C.F.R. § 92.101(a)(2).

133. Section 206 would require covered entities such as hospitals, clinics, and pharmacies receiving federal funds to ensure "equal access" without discriminating based on sex. 89 Fed. Reg. at 37,700, *to be codified at* 45 C.F.R. § 92.206(a).

134. According to Section 206, equal access means health care providers may not "[d]eny or limit health services, including those that have been typically or exclusively provided to, or associated with, individuals of one sex, to an individual based upon the individual's sex assigned at birth, gender identity, or gender otherwise recorded." *Id.*, *to be codified at* 45 C.F.R. § 92.206(b)(1).

135. Section 206 further prohibits any policy or practice that separates or treats persons based on sex, including any policy or practice that prevents an individual from being treated "consistent with the individual's gender identity," if this causes the person harm—including emotional or dignitary harm—that is more than *de minimis*. *Id.* at 37,701, *to be codified at* 45 C.F.R. § 92.206(b)(3). For example, HHS explains, a hospital that assigns patients to dual-occupancy rooms based on sex would be *required* to allow a man who identifies as a woman to share a room with a woman. *Id.* at 37,593 ("A covered entity will be in violation of this rule if they refuse to admit a transgender person for care or refuse to place them in facilities consistent with their gender identity, because doing so would result in more than *de minimis* harm."); NPRM, 87 Fed. Reg. at 47,866–67.

136. Section 206 also specifically prohibits denying or limiting "health services sought for purpose of gender transition or other" so-called "gender-affirming care that the covered entity would provide to an individual *for other purposes* if the denial or limitation is based on an individual's sex assigned at birth, gender identity, or gender otherwise recorded." 89 Fed. Reg. at 37,701, *to be codified at* 45 C.F.R. § 92.206(b)(4) (emphasis added). That includes, according to HHS, "counseling, hormone therapy,

surgery, and other services designed to treat gender dysphoria or support gender affirmation or transition." NPRM, 87 Fed. Reg. at 47,834 n.139; *see* 89 Fed. Reg. at 37,596 ("gender-affirming care" includes "hormone therapy, surgery, and other related services").

137. For example, under Section 206, it would be presumptively discriminatory for a clinic to prescribe and administer puberty blockers to treat precocious puberty—an FDA-approved use—but not a "gender transition"—a non-FDA-approved use. It would similarly be presumptively discriminatory for a hospital to provide an orchidectomy to treat testicular cancer, but refuse to remove healthy testicles for a "gender transition."

138. Section 206(c) purports to provide a safe harbor. A covered entity need not provide such services when the covered entity typically declines to provide such services to any individual for any diagnosis or when they are "not clinically appropriate for a particular individual." 89 Fed. Reg. at 37,701, *to be codified at* 45 C.F.R. § 92.206(c). Accordingly, HHS at least acknowledges that a doctor can refuse to perform a prostate exam on a person "who does not anatomically have a prostate." *Id.* at 37,607. And OCR would review whether the services are "clinically appropriate" for a particular individual in the first instance. When it comes to gender-change interventions, OCR indicates it would review "medical necessity standards or guidelines" and "the clinical, evidence-based criteria or guidelines relied upon to make the medical necessity determination; and the medical substantiation for the medical necessity determination." *Id.* at 37,613. Decisions based on evidence or ethical and

moral reasoning that OCR deems insufficient "may be considered evidence of pretext for discrimination." *Id.*

139. Although OCR disclaims an attempt to mandate standards of care for gender-transition services in the final rule, the proposed rule mentioned the clinical "guidelines" it expects covered entities will follow: the guidelines of the WPATH and Endocrine Society, the entities discussed above at length. NPRM, 87 Fed. Reg. at 47,868 (asserting that covered entities "should follow clinical practice guidelines and professional standards of care," and citing WPATH 7 & Endocrine Society Guideline). OCR doesn't disavow that endorsement in the final rule or provide any examples of competing guidelines that would not require covered entities to support a "gender-transition."

140. The decision to refuse gender-change interventions "must not be based on unlawful animus or bias, or constitute a pretext for discrimination." 89 Fed. Reg. at 37,701, *to be codified at* 45 C.F.R. § 92.206(c). This circular reasoning grants HHS wide discretion to decide who has "discriminated." HHS has made clear that it views a general or categorical refusal to provide gender-change interventions as "unlawful animus," even if required by state law. HHS repeatedly emphasizes that it might be permissible to refuse a gender-change intervention "*for a particular individual*," *id.*, *to be codified at* 45 C.F.R. § 92.206(c) (emphasis added), after exercising "*individualized* clinical judgment," *Id.* at 37,575, 37,595–97 (emphasis added). The negative implication is obvious: Any doctor who reviews the evidence above and decides that

a specific gender-change intervention is categorically too risky or unethical is a "discriminator."

141. OCR further announces that it will target any provider who does not hew to HHS's changed (and quite suspect) view of the evidence. OCR states its enforcement decisions will be informed by "consideration of … whether that covered entity demonstrated a willingness to refer or provide accurate information about gender-affirming care." 89 Fed. Reg. at 37,598. But a doctor who reviews the evidence and concludes, like 21 states and several Western European countries, that a gender-change protocol for minors or adults is dangerous and experimental medicine is not showing sufficient "willingness to … provide" HHS-approved "accurate information." *See* NPRM, 87 Fed. Reg. at 47,874.

142. Even providers that don't categorically rule out gender-change interventions can face enforcement at the whim of OCR under a malleable standard. If OCR concludes that a provider "reflect[ed] unlawful animus or bias" by "assert[ing]" a "judgment" that gender-change interventions are unwarranted in a particular case, *id.* at 37,598, then OCR can initiate enforcement proceedings, leading to a Star Chamber hearing in which HHS acts as prosecutor, judge, and jury. 45 C.F.R. §§ 80.8(c), 80.10; *see generally* HHS, *Guidelines—Civil Rights Reviewing Authority Review of Civil Rights Enforcement Decisions for HHS Programs*, https://perma.cc/D8RB-C654.

143. As the proposal made clear, in the view of HHS, claiming that gender-change interventions are "experimental or cosmetic would be considered evidence of pretext because this characterization is not based on current standards of medical

care," that is, the WPATH standards and the Endocrine Society Guideline discussed above. NPRM, 87 Fed. Reg. at 47,874. In other words, according to HHS, simply agreeing with the Florida Board of Medicine Standards of Medical Care, Finland's Council for Health Choices, or the Sixth Circuit, is evidence of animus. OCR seeks not just to coerce every covered entity to provide gender-transition interventions; it wants to chill any speech by covered entities that would discourage such interventions.

144. In response to First Amendment concerns about "what would be required of providers in terms of expressing support of transgender people who wish to access gender-affirming care, using the name and pronouns requested by patients, and speaking about gender-affirming care," OCR simply noted that whether "discrimination is unlawful or considered harassment is necessarily fact-specific" and that "conduct, including verbal harassment, that is so severe or pervasive that it creates a hostile environment on the basis of sex is a form of sex discrimination." 89 Fed. Reg. at 37,596.

145. As a result, under the OCR Rules, covered entities arguably cannot tell their patients that in their best medical opinions, gender-transition efforts or procedures are categorically experimental and dangerous. The OCR Rules arguably force covered entities to give patients the impression that "gender-transition" efforts can in some cases be clinically indicated or beneficial. They suggest that OCR may determine that a healthcare entity creates a hostile environment when it speaks in ways that categorically deny the medical legitimacy of gender transitions.

146. The OCR Rules likewise may consider it discrimination for a covered entity to categorically speak or write using a patient's pronouns that align with his or her sex according to the patient's biology if the patient prefers different pronouns that correspond to his or her gender identity. Under the OCR Rules, covered entities might need to refer to those persons using pronouns that are inconsistent with their sex.

147. Under the OCR Rules, covered entities may need to tell patients that males can get pregnant, give birth, and breastfeed. As HHS explains in the proposal, doctors are responsible for "'discrimination, stigma, and erasure'" if they speak or act in way that treats "pregnancy and childbirth … as something exclusively experienced by … women." NPRM, 87 Fed. Reg. at 47,865.

148. Section 207 applies to entities involved in federally funded health insurance and health-related coverage administered by HHS, such as Medicaid or CHIP. Section 207 generally prohibits discrimination in a variety of healthcare coverage and claim practices, in insurance benefit design, and in marketing practices. 89 Fed. Reg. at 37,701, *to be codified at* 45 C.F.R. § 92.207(a), (b)(1), (b)(2).

149. In addition, separate provisions within Section 207 specifically make it presumptively discriminatory for a covered entity to impose limits or restrictions on coverage or claims, including cost sharing, "based upon the individual's sex assigned at birth, gender identity, or gender otherwise recorded." *Id.*, *to be codified at* 45 C.F.R. § 92.207(b)(3). In the proposal, HHS suggested that denying "hormone therapy coverage" to a transgender person of color for a gender transition is, alone, evidence of "pervasive" "transphobia and racism." NPRM, 87 Fed. Reg. at 47,870.

150. Section 207 also makes it per se discriminatory to have a "categorical coverage exclusion or limitation for all health services related to gender transition or other gender-affirming care." 89 Fed. Reg. at 37,701, *to be codified at* 45 C.F.R. § 92.207(b)(4).

151. Section 207 further makes it presumptively discriminatory to "deny or limit coverage, deny or limit coverage of a claim, or impose additional cost sharing or other limitations or restrictions on coverage, for specific health services related to gender transition or other gender-affirming care if such denial, limitation, or restriction *results in* discrimination on the basis of sex." 89 Fed. Reg. at 37,701, *to be codified at* 45 C.F.R. § 92.207(b)(5) (emphasis added). This results-oriented text doesn't appear to require a discriminatory motive, but would reach facially neutral insurance policies that tend to screen out services used by transgender individuals, even if those policies are not motivated by sex or gender identity. *See Brnovich v. Democratic Nat'l Comm.*, 141 S. Ct. 2321, 2332 (2021) (citing 52 U.S.C. § 10301(a)).

152. That is, apparently, the point: according to HHS, excluding coverage for gender-transition services is unlawful disparate treatment because "transgender individuals are the only individuals who seek transition-related care." NPRM, 87 Fed. Reg. at 47,871. But by that logic, an issuer's refusal to cover vasectomies is discriminatory because only a male can get a vasectomy. *But see Eknes-Tucker*, 80 F.4th at 1229–30 ("[T]he regulation of a course of treatment that, by the nature of things, only transgender individuals would want to undergo" is not discrimination "on the

basis of sex" unless it were "mere pretext designed to effect an invidious discrimination" (cleaned up)).

153. Section 207(c) also purports to provide a safe harbor. It says it is not discriminatory to deny coverage "where the covered entity has a legitimate, nondiscriminatory reason for denying or limiting coverage of the health service or determining that such health service fails to meet applicable coverage requirements, including reasonable medical management techniques such as medical necessity requirements." 89 Fed. Reg. at 37,701, *to be codified at* 45 C.F.R. § 92.207(c). "Such coverage denial or limitation must not be based on unlawful animus or bias, or constitute a pretext for discrimination," *id.*, *to be codified at* 45 C.F.R. § 92.207(c), which OCR will assess based on the "guidelines" discussed above. But there is no safe harbor for categorical judgments of medical necessity.

154. Failure to comply with the prohibitions of Section 1557 may cause Florida to lose all federal funding, including Medicaid funding. 45 C.F.R. §§ 80.8, 92.303.

B. The CMS Rules

155. The 2024 Rules also amend regulations relating to Medicaid, CHIP, and the Program of All-Inclusive Care for the Elderly ("PACE") (collectively, "CMS Rules").

156. The CMS Rules amend three pre-existing Medicaid and CHIP rules to include HHS's new, expansive interpretation of sex discrimination. The first relates to contracts with entities that deliver services. Those contracts must now include a

promise that the entities "will not discriminate against individuals eligible to enroll on the basis of … sex which includes sex characteristics, including intersex traits; pregnancy or related conditions; sexual orientation; gender identity; and sex stereotypes; and will not use any policy or practice that has the effect of discriminating on the basis of …sex which includes discrimination on the basis of sex characteristics, including intersex traits; pregnancy or related conditions; sexual orientation; gender identity; and sex stereotypes." 89 Fed. Reg. at 37,691, *to be codified at* 42 C.F.R. § 438.3(d)(4). Under this rule, it would seem, any facially neutral policy or practice that has a discriminatory *effect* on transgender individuals, not just a discriminatory purpose, may violate the relevant contract.

157. In addition, those same entities must "promote the delivery of services in a culturally competent manner to all enrollees, … and regardless of sex which includes … gender identity." *Id.*, *to be codified at* 42 C.F.R. § 438.206(c)(2).

158. The other two rules require that States "have methods to promote access and delivery of services in a culturally competent manner to all beneficiaries, … and regardless of *sex* which includes sex characteristics, including intersex traits; pregnancy or related conditions; sexual orientation; gender identity; and sex stereotypes." *Id.* at 37,692, *to be codified at* 42 C.F.R. §§ 440.262 (Medicaid), 457.495(e) (CHIP).

159. For these amendments, CMS relies not only upon its authority under Section 1557, but also upon Section 1902(a)(4) of the Social Security Act ("SSA") for Medicaid, 42 U.S.C. § 1396a(a)(4), and Section 2101(a) of the SSA for CHIP, *id.* § 1397aa(a).

160. "CMS interprets sections 1902(a)(4) and 2101(a) of the SSA as authorizing CMS to adopt regulations prohibiting discrimination on the basis of gender identity or sexual orientation because such prohibitions on discrimination are necessary for the proper and efficient operation of a state plan, are in the best interest of beneficiaries, and enable states to provide child health assistance in an effective and efficient manner." NPRM, 87 Fed. Reg. at 47,892.

161. Under this regime, HHS also serves as lawmaker, prosecutor, and jury. HHS can withhold payments from States for noncompliance with state-plan requirements after notice and a hearing. 42 U.S.C. § 1396c; 42 C.F.R. § 430.35. When a State challenges that decision in court, "[t]he findings of fact by the Secretary, if supported by substantial evidence, shall be conclusive." 42 U.S.C. § 1316(a)(4); 42 C.F.R. § 430.38(c)(1).

162. PACE is a Medicare and Medicaid program that helps people meet their health care needs in the community instead of going to a nursing home or other care facility.

163. In Florida, PACE is administered by AHCA in consultation with the Department for Elder Affairs.

164. The 2024 Rules amend two PACE regulations: 42 C.F.R. §§ 460.98(b)(3) and § 460.112(a). Section 460.98 regulates services provided by State PACE programs, while § 460.112 establishes the rights of PACE participants. The 2024 Rules change the word "sex" to "sex (including sex characteristics, including intersex traits; pregnancy or related conditions; sexual orientation; gender identity; and sex

stereotypes)" in the PACE regulations. *See* 89 Fed. Reg. at 37,692, *to be codified at* 42 C.F.R. §§ 460.98(b)(3), 460.112(a).

165. In addition to Section 1557, CMS relies upon the Public Health Service Act ("PSA") to promulgate the PACE-related statutory provisions, specifically Sections 1894(f)(A) and 1934(f)(A) of the SSA. 42 U.S.C. § 1395eee(f); *id.* § 1396u-4(f).

IV. Injury to Florida

166. AHCA and DMS administer health-related programs or activities that receive federal financial assistance or programs or activities administered by HHS as defined in the 2024 Rules, so they are subject to the 2024 Rules. They must comply with the rules or risk losing federal funds and being subject to private lawsuits for discrimination.

167. AHCA administers the state Medicaid, CHIP, and PACE programs, which are regulated by the 2024 Rules. Ex. 1 ¶ 2. Under state law, Florida Medicaid and CHIP currently do not cover or reimburse gender-transition hormonal or surgical interventions. *See* Ex. 1 ¶ 10–11.

168. In total, Florida Medicaid, CHIP, and PACE received $24,671,603,227 in federal funds from HHS in Fiscal Year 2022-2023. Ex. 1 ¶ 9.

169. DMS purchases and administers healthcare coverage plans for Florida's 310,750 active and retired state employees and their families. Specifically, the Division of State Group Insurance within DMS purchases and administers state employee and

retiree health insurance under the Florida State Group Health Insurance Program. DMS receives federal financial assistance from CMS through, for example, the Retiree Drug Subsidy. Ex. 2 ¶ 6. DMS is therefore a covered entity for this purpose under the OCR Rules.

170. For approximately 40 years, insurance coverage procured for the State Group Health Insurance Program has excluded gender-change interventions. Ex. 2 ¶ 7.

171. Florida law also requires generally excluding coverage for "sex-reassignment prescriptions or procedures" in "the state group health insurance program." Fla. Stat. § 286.311.

172. The 2024 Rules would purport to make that exclusion of coverage discriminatory. 45 C.F.R. § 92.207(b)(4). This would injure DMS and require the plan to incur additional claim costs. Ex. 2 ¶ 10.

173. Florida's Agency for Persons with Disabilities receives HHS funding and has a policy and practice of separating multiple-occupancy rooms in state hospitals on the basis of sex, regardless of gender identity.

174. Florida has also promulgated laws, rules, and standards of care restricting gender-change interventions and separating facilities based on sex to protect the health, safety, and fertility of Florida residents, particularly minors. *See supra* Part II. Florida has a sovereign interest in protecting these laws from conflicting federal agency rules that do not comply with federal law. *Florida v. Nelson*, 576 F. Supp. 3d 1017, 1032 (M.D. Fla. 2021) ("the state suffers sovereign injury when unlawful agency action

preempts state law"); *see also Texas v. United States*, 787 F.3d 733, 749 (5th Cir. 2015) ("States have a sovereign interest in the power to create and enforce a legal code" (cleaned up)).

A. Florida's Medicaid and CHIP Program

175. Under the 2024 Rules, Florida may not refuse reimbursement or coverage for gender-change interventions on the ground that they are "experimental" and not medically necessary healthcare treatments. The 2024 Rules would therefore require covering puberty blockers, cross-sex hormones, surgeries, and related services to treat gender dysphoria under Florida Medicaid, CHIP, and other state programs subject to the 2024 Rules, contrary to Florida law. Fla. Admin. Code r. 59-1.050(7); Fla. Stat. § 286.311.

176. According to WPATH 8, the purportedly medically necessary drug interventions for a gender transition include:

a. Prescribing and administering puberty blockers off-label, and;

b. Prescribing supraphysiological levels of cross-sex hormones off-label and related visits and tests.

177. According to WPATH 8, the purportedly "medically necessary" so-called "gender-affirming surgical procedures," WPATH 8, *supra*, at S18, S128, include the following:

a. "Hysterectomy" (removal of healthy uterus);

b. "Mastectomy" (removal of healthy breasts);

c. "Salpingo-oophorectomy" (removal of healthy ovaries and fallopian tubes);

d. "Orchiectomy" (removal of healthy testicles);

e. "Phalloplasty" (constructing penis-like structure using tissue from skin), including "urethral lengthening," "prosthesis," "colpectomy" (closure of healthy vagina), "colpoclesis" (shortening of healthy vagina), and "scrotoplasty" (creating new scrotums);

f. "Metoidioplasty" (constructing penis-like structure using tissue from a hormone-enlarged clitoris), including "urethral lengthening," "prosthesis," "colpectomy" (closure of healthy vagina), "colpoclesis" (shortening of healthy vagina), and "scrotoplasty" (creating new scrotums);

g. "Vaginoplasty" (constructing vagina-like structure), including methods of "[penile] inversion" (using combination of skin surrounding penis and scrotal skin), "peritoneal [flaps pull-through]" (pulling down peritoneum (inner lining of abdominal wall) into space between rectum and urethra/prostate), and "intestinal" technique (using section of terminal large intestine);

h. "Vulvoplasty" (constructing vulva-like structures)

i. "Hair line advancement and/or hair transplant;"

j. "Facelift/mid-face lift (following alteration of the underlying skeletal structures);"

k. "Platysmaplasty" (neck lift);

l. "Blepharoplasty" (eye and lid modification);

m. "Rhinoplasty" (nose reshaping);

n. "Cheek" surgery, including "implant[s]" and "lipofilling;"

o. "Lip" surgery, including "augmentation" and "upper lip shortening;"

p. "Lower jaw" surgery, including "augmentation" and "reduction of the mandibular angle" (cutting or shaving the corner of the lower jaw);

q. "Chin reshaping" surgery;

r. "Chondrolaryngoplasty" (shaving down Adam's apple);

s. "Vocal cord surgery;"

t. "Breast reconstruction" and "augmentation" (mammoplasty);

u. "Body contouring" surgeries, including "liposuction," "lipofilling," and "implants" (such as "pectoral, hip, gluteal, [and] calf");

v. "Monsplasty" (reduction of mons pubis tissue around the public bone, which is more pronounced in biological females);

w. "Nipple-areola tattoo;"

x. "Uterine transplantation" (uterus from donor);

y. "Penile transplantation" (penis from donor);

z. "Hair removal," including "laser epilation" (laser removal) or "electrolysis" (permanent removal by destroying hair follicles).

WPATH 8, *supra*, at S258, App'x E (cleaned up).

178. WPATH claims that "it is imperative to understand this list is not intended to be exclusive." WPATH 8, *supra*, at S258, App'x E.

179. The 2024 Rules will have a "substantial" fiscal effect on Florida. NPRM, 87 Fed. Reg. at 47,903. Although the total potential fiscal exposure is difficult to measure, covering gender-transition treatments under Florida Medicaid and CHIP could cost some $200,000,000 a year. Ex. 1 ¶ 21.

180. This cost, to be sure, pales in comparison with the human cost of aiding and abetting experimental interventions that could render thousands of Floridian minors infertile for life.

B. Florida's Standard of Care

181. "[T]he State has a significant role to play in regulating the medical profession," *Gonzales v. Carhart*, 550 U.S. 124, 157 (2007), as well as "an interest in protecting the integrity and ethics of the medical profession," *Washington v. Glucksberg*, 521 U.S. 702, 731 (1997). This includes "maintaining high standards of professional conduct" in the practice of medicine. *Barsky v. Bd. of Regents of Univ. of N.Y.*, 347 U.S. 442, 451 (1954).

182. The State also "has an interest in protecting vulnerable groups … from mistakes," *Glucksberg*, 521 U.S. at 731, and in "the elimination of particularly gruesome or barbaric medical procedures," *Dobbs v. Jackson Women's Health Org.*, 597 U.S. 215, 301 (2022). Furthermore, "[i]t is evident beyond the need for elaboration that a State's interest in 'safeguarding the physical and psychological well-being of a

minor' is 'compelling.'" *New York v. Ferber*, 458 U.S. 747, 756 (1982) (quoting *Globe Newspaper Co. v. Superior Court*, 457 U.S. 596, 607 (1982)).

183. As described in Part II, Florida has enacted laws and promulgated rules delineating the proper standard of medical care as it relates to children suffering from gender dysphoria. Florida's Board of Medicine and Board of Osteopathic Medicine developed their standard of care after careful review of the available literature and studies. The Florida legislature and Surgeon General have also reached similar conclusions about health and safety and restricted cross-sex hormones and surgeries for minors more broadly.

184. Most medical providers in Florida, however, accept federal funds and are "covered entit[ies]" under the 2024 Rules. The 2024 Rules will therefore force healthcare providers in Florida to choose between accepting federal funds and complying with Florida law regarding treatments for persons suffering from gender dysphoria. Indeed, under the 2024 Rules, compliance with Florida's ethical requirements, laws, and regulations may be deemed a pretextual reason for discriminating, triggering an Office of Civil Rights investigation, and potentially, an enforcement proceeding.

V. Injury to Catholic Medical Association Members

A. The OCR Rules' New Policy and Training Requirements

185. The OCR Rules prohibit covered entities from having or applying policies not "consistent with" the OCR Rules' definition of sex discrimination or the

Rules' prohibitions. The OCR Rules require covered entities to adopt and publish policies that comply with the OCR Rules. 89 Fed. Reg. at 37,696–99, *to be codified at* 45 C.F.R. §§ 92.8(a), (b), & (h), 92.101.

186. The OCR Rules require covered entities to provide an updated notice of nondiscrimination to patients stating that they will not discriminate on the basis of gender identity. 89 Fed. Reg. at 37,697, *to be codified at* 45 C.F.R. § 92.10(a)(1)(i). The notice to patients must be provided annually and on request. *Id.* at 37,698, *to be codified at* 45 C.F.R. § 92.10(a)(2)(i)–(ii).

187. The notice must be posted "at a conspicuous location on the covered entity's health program or activity website" and "[i]n clear and prominent physical locations … where it is reasonable to expect individuals seeking service from the health program or activity to be able to read or hear the notice." *Id.*, *to be codified at* 45 C.F.R. § 92.10(a)(2)(iii)–(iv).

188. The OCR Rules require covered entities to train each relevant employee on the OCR Rules' required policies and procedures and document that training. *Id.* at 37,697, *to be codified at* 45 C.F.R. § 92.9(a)–(c).

189. Under the OCR Rules, covered entities must submit an assurance of compliance to HHS that they have adopted the OCR Rules' new policies as a contractual condition of receipt of federal funding, or else they will be unable to apply or maintain eligibility for federal funding. *Id.* at 37,696, *to be codified at* 45 C.F.R. § 92.5.

190. Every time a covered entity requests a federal health funding payment from HHS, it impliedly certifies to HHS that it follows governing regulations, and the

OCR Rules import the prohibition on gender identity discrimination into those implied certifications. Covered entities unwilling to agree to make such an assurance or certification of compliance cannot apply for or maintain eligibility for federal health funding from HHS unless an exception applies.

B. The OCR Rules' New Liability Risks

191. Failure to follow the OCR Rules and their interpretation of Section 1557, Title IX, and HHS regulations risks the burdens and costs of federal investigations and enforcement proceedings. It also risks disallowance, exclusion, suspension, and debarment from receipt of federal funding.

192. Failure to follow the OCR Rules and their interpretation of Section 1557, Title IX, and HHS regulations arguably risks liability under a cause of action in civil litigation, including in suits brought by the public.

193. CMA members care for all people without discrimination on the basis of sex or any other characteristic prohibited by law. They believe that a patient with medical needs should be given the best care possible, regardless of the patient's identity. But CMA members cannot harm or lie to patients.

194. Based on the Hippocratic Oath, on science, on medical ethics, on conscience, and on religious faith, CMA members like Dr. Parker and Dr. Van Meter hold the categorical position that providing, facilitating, referring for, or endorsing gender-transition efforts violates their core religious beliefs and their medical oath to "do no harm." CMA members hold the categorical view that gender-transition procedures harm patients—particularly children—and can result in infertility, heart

attacks, strokes, and other chronic illnesses, and that medical science does not support the provision of such procedures. CMA members hold the categorical view that sex is a biological, immutable characteristic—a scientific reality, not a social construct. CMA members hold the categorical view that to eliminate sex-specific private spaces violates fundamental rights to privacy, dignity, safety, and security.

195. CMA members' categorical exclusion of providing, facilitating, or affirming gender transitions, and their commitment to state law, precludes CMA members from:

a. Prescribing puberty blockers, cross-sex hormone therapies, or other similar ongoing interventions to treat gender dysphoria or for transition efforts;

b. Performing surgeries to treat gender dysphoria or for transition efforts, including removing healthy organs from people who purport to identify as the opposite sex, nonbinary, or otherwise not as their sex;

c. Referring patients for any and all such interventions, procedures, services, or drugs, or affirming the same;

d. Saying in their professional opinions or through staff that these gender-transition efforts are the standard of care, are safe, are beneficial, are not experimental, are not cosmetic, or should otherwise be recommended;

e. Refraining from expressing views, options, policies, and opinions critical of transition efforts;

f. Treating and referring to patients according to gender identity and not sex, such as using patients' self-selected pronouns according to gender identity in communications or in writing (rather than using no pronouns or using pronouns based on sex);

g. Saying that males can be pregnant or give birth;

h. Allowing patients to access single-sex programs and facilities, such as restrooms, by gender identity rather than sex;

i. Repealing or modifying policies, procedures, and practices against the above procedures, drugs, and interventions for transition efforts; and

j. Providing assurances of compliance, express or implied certifications of compliance, and notices of compliant policies as to the OCR Rules' gender-identity requirements.

196. CMA members like Dr. Parker and Dr. Van Meter are actively practicing medicine and seeing patients. They provide services to patients reimbursed by federal financial assistance.

197. The OCR Rules impact CMA members in their practice of medicine as individual physicians who are regulated by the OCR Rules. And the OCR Rules impact some of these members as corporate principals and owners of medical practices that are regulated by the OCR Rules—for example in their duty to create, implement, and train staff on policies and to ensure compliance with the OCR Rules in their businesses' medical practices.

198. The OCR Rules impose the following no-win choice on CMA members: (1) abandon or violate their convictions on gender and incur the costs of compliance with the OCR Rules; (2) maintain their positions and practices but arguably falsify their policies, notices, and assurances of compliance to HHS and then risk continuing liability and investigative demands from OCR with no promise they will be deemed categorically exempt from the loss of eligibility for participation in Medicaid, Medicare, and CHIP, and other federal financial assistance programs; or (3) exit the medical field and abandon their patients.

199. If CMA members were to comply with the OCR Rules, they would lose their integrity and reputation of practicing with sound judgment and good medical ethics, making patients less likely to trust them, and driving patients and employees away from their practices.

200. If CMA members do not comply with the OCR Rules, CMA members will have to defend themselves from investigations and enforcement actions, losing time, money, and resources that they could use for medical care.

201. If CMA members do not comply with the OCR Rules, CMA members will find it difficult to be employed in the field of medicine, as almost all medical practices receive federal financial assistance from HHS.

202. It is no answer to say that entities may seek a religious or conscience exemption. Seeking such an assurance of exemption from HHS will cost time and money—$987.70 per entity according to HHS estimates—for uncertain results: there

is no guarantee that HHS will issue an assurance of exemption or will do so in time to avoid irreparable harm. 89 Fed. Reg. at 37,684.

203. Many CMA members like Dr. Parker and Dr. Van Meter live in states that restrict gender-transition procedures. Without an exemption, the OCR Rules force these doctors to choose between (a) following state law and their consciences and violating the OCR Rules, or (b) following the OCR Rules and violating state law and their consciences. They will not violate state law.

204. Dr. Parker is a board-certified OB/GYN hospitalist serving female Medicare and Medicaid patients in labor & delivery and emergency room ("ER") settings at OhioHealth Mansfield Hospital in Mansfield, Ohio. He works as an OB Hospitalist employed by Pediatrix Medical Group of Ohio, part of Pediatrix Medical Group.

205. In his past OB/GYN practice for females, he regularly provided medically indicated hysterectomies and provided medically indicated estrogen and testosterone hormones. He is board-certified to provide these services again in future clinical settings, but he cannot provide these services for gender-transition purposes.

206. Dr. Parker routinely records all OB/GYN patients as female. He uses the correct biological and binary pronouns: she/her. He does not facilitate male access to hospital restrooms designated for females, or vice versa, based on gender identity.

207. Dr. Parker at times treats patients who identify as transgender, non-binary, or otherwise contrary to their sex. He has cared for such a patient who was in labor having a baby. He does not—and will not—call a woman giving birth "a man."

In the past, hospital colleagues have said men could get pregnant and said that a certain patient was a man who was pregnant. Dr. Parker corrected them: the patient was a woman who was pregnant. Every time he encounters this issue, he wants to be free to explain that only females can get pregnant and give birth.

208. Dr. Parker does not wish to attend required training from his hospital or his physician group to follow a "nondiscrimination" policy on gender identity. He will attend such training as required but he will not agree to follow such a policy. He would rather be fired than harm his patients.

209. Dr. Van Meter is a pediatric endocrinologist seeing Medicaid and CHIP pediatric patients at his independent practice, Van Meter Pediatric Endocrinology, P.C., in Atlanta, Georgia. About seven percent of his patients are Medicaid patients, and if his patients need hospitalization, he provides care at two local hospitals that receive Medicaid and CHIP funding.

210. Dr. Van Meter regularly provides puberty blockers and sex hormones for medical reasons. He regularly cares for patients who identify as transgender, non-binary, or otherwise contrary to their sex, as well as patients who struggle with gender incongruence. He regularly receives patient requests to provide puberty blockers and cross-sex hormones for gender-transition purposes, but as a matter of sound medical judgment and good conscience, Dr. Van Meter does not and will not provide puberty blockers or hormones for gender-transition purposes.

211. Dr. Van Meter regularly provides his medical opinion against starting gender-transition procedures. He regularly uses pronouns for patients that accord with

biological and binary sex in conversation and in writing. He cannot use pronouns contrary to biology, even though he is regularly asked to do so.

212. Dr. Van Meter provides access to male and female restrooms for patients and their visitors based on biological and binary sex. Because of safety, dignity, privacy, and conscience concerns, he does not and will not ensure access to these facilities by gender identity.

213. Dr. Van Meter has adopted an official policy statement on his website encompassing these policies, and he does not wish to change this policy statement to be consistent with the OCR Rules, although he will do so in compliance with the OCR Rules if not protected by judicial relief. He does not wish to adopt or share a contrary policy or notice with patients. He will not reeducate his staff to comply with the OCR Rules, nor will he attend such training if required by his hospital.

214. Dr. Parker and Dr. Van Meter have already spent time and resources to avoid non-compliance with the OCR Rules, and if the OCR Rules go into effect, they will have to spend even more time and resources. Neither wants to stop seeing patients receiving federal financial assistance or to stop being affiliated with hospitals, but each would rather stop seeing patients receiving federal financial assistance and lose local hospital affiliations than adopt a policy under which they would harm a patient. Were they to lose their eligibility to serve in practices that serve patients receiving federal financial assistance, it would threaten their livelihoods and harm their patients, who would lose their established providers.

215. The OCR Rules threaten to drive similarly situated healthcare providers out of the medical profession, and it will dissuade students from choosing to practice medicine, reducing care for underserved, low-income, and rural patients.

COUNT I
(OCR Rules)

Violation of the Administrative Procedure Act
Agency Action Not in Accordance with Law, In Excess of Statutory Authority

216. Plaintiffs incorporate by reference paragraphs 1–215.

217. Defendants HHS and CMS are "agenc[ies]" under the APA. 5 U.S.C. § 551(1).

218. The 2024 Rules are a "rule" under the APA. 5 U.S.C. § 551(4).

219. The 2024 Rules are a "final agency action" subject to judicial review. 5 U.S.C. § 704.

220. Under the APA, a court must "hold unlawful and set aside agency action" that is "not in accordance with law, in excess of statutory authority, or limitations, or short of statutory right." 5 U.S.C. § 706(2)(A), (C).

221. The OCR Rules define discriminating "on the basis sex" in a manner that is contrary to Section 1557 and Title IX.

222. The Eleventh Circuit has held that "sex" in Title IX "unambiguously" means "biological sex," not "sexual orientation" or "gender identity," *Adams*, 57 F.4th at 812–15, so the same is true under Section 1557, *see Sex*, American Heritage Dictionary 1605 (5th ed. 2011) ("Either of two divisions, designated female and male,

by which most organisms are classified on the basis of their reproductive organs and functions.").

223. Relying on the reasoning in *Bostock*, which interprets a different statute, the 2024 Rules nevertheless define "on the basis of sex" to necessarily include discriminating based on "sexual orientation and gender identity."

224. But *Bostock* cannot apply here.

225. *First*, as *Adams* holds, because Title IX, and hence Section 1557, expressly permits specific kinds of sex group separation, such as separate living facilities for each sex, discriminating based on gender identity is not necessarily prohibited discrimination based on sex under Title IX.

226. *Second*, Section 1557 specifically excludes from its scope "transsexualism" and a "gender identity disorder" "not resulting from physical impairments." 42 U.S.C. § 18116(a) (prohibiting discrimination "on the ground prohibited under … section 794 of title 29"); 29 U.S.C. § 705(20)(F)(i) (providing "transsexualism" and "gender identity disorders not resulting from physical impairments" are not a "disability" under section 794). Those terms at the time were synonymous with having a transgender identity, so transgender persons that don't have a disorder of sex development—a physical impairment—don't have a "disability" and are excluded from "section 792 of title 29." The specific exclusion of transgender identity governs the general prohibitions of Section 1557, so the general term "based on sex" cannot be read to include discriminating based on transgender identity in Section 1557.

227. But even if *Bostock* applied here, its reasoning wouldn't authorize the OCR Rules. *Bostock*'s reasoning, if it applies at all, applies when an individual is requesting a health care treatment that is "to the [covered entity's mind], materially identical in all respects, except that one" service is sought by one sex, and not the other. *Bostock*, 590 U.S. at 660. That doesn't authorize the OCR Rules. Removing a testicle or uterus with cancer is not "materially identical" to removing a healthy testicle or uterus to address a psychological condition. In both cases, the surgery is requested by one sex: only males have testicles removed, only females have a uterus removed. The thing that changes is the therapeutic purpose. A covered entity's refusal to remove healthy reproductive organs discriminates instead based on clinical purpose, not a patient's sex. *Eknes-Tucker*, 80 F.4th at 1233–34 (Brasher, J., concurring); *L.W.*, 83 F.4th at 481–82. Thus, as the Eleventh Circuit has held, a State does not discriminate or stereotype "on the basis of sex" (the text used in Title IX) when it forbids a hormonal overdose or the removal of healthy organs for a gender transition. *Eknes-Tucker*, 80 F.4th at 1227–30 (Equal Protection Clause).

228. Similarly, prescribing testosterone to treat abnormally delayed puberty or low levels of testosterone (in men or women) is not medically the same thing as prescribing supraphysiological levels of testosterone to embark a minor or adult in a gender transition protocol. The treatment (hormone levels), clinical purpose, and risks of the treatment are materially different.

229. Because HHS's definition of discriminating "on the basis of sex" exceeds the prohibition of Title IX as defined by binding Eleventh Circuit precedent and the

scope of Section 1557, the OCR Rules are contrary to law and in excess of statutory authority.

230. Several other provisions of law and principles confirm that HHS has exceeded its statutory authority.

231. *First*, HHS's departure from text is confirmed by Section 1554 of the ACA, which prohibits any HHS rules that "violate the principles of informed consent and the ethical standards of health care professionals." 42 U.S.C. § 18114(5). In Florida, and many other places, principles of informed consent and ethical standards forbid precisely the kind of medical interventions HHS seeks to compel. Under our federal system of government, state legislatures and medical boards, not HHS, decide the principles of informed consent and the ethical standards of health care professionals. Section 1554 confirms that Section 1557 doesn't alter the federal structure with regard to state laws requiring informed consent or setting ethical standards of care.

232. *Second*, Congress must "enact exceedingly clear language if it wishes to significantly alter the balance between federal and state power." *U.S. Forest Serv. v. Cowpasture River Preservation Ass'n*, 590 U.S. 604, 622 (2020). States enjoy the "general power" of governing. *NFIB v. Sebelius*, 567 U.S. at 536. Moreover, "[t]here is no question that state and local authorities possess considerable power to regulate public health," and regulate the ethics and standards of medical professionals. *NFIB v. OHSA*, 595 U.S. 109, 121 (2022) (Alito, J., concurring). Vesting OCR with vast power to second-guess the judgments of state medical boards and determine what is "clinically

appropriate" seriously alters the balance of power between state and federal governments and intrudes upon the medical profession—an area traditionally regulated by the States.

233. *Third*, and relatedly, in areas traditionally regulated by the states, such as the medical profession, courts begin with the assumption "that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress." *Wyeth v. Levine*, 555 U.S. 555, 565 (2009). The 2024 Rules openly seek to preempt state laws or regulations reflecting the judgment that gender-transition interventions such as hormones and surgeries are not clinically appropriate to treat psychological distress arising from gender dysphoria. 89 Fed. Reg. at 37,535, 37,598. Section 1557 is an ordinary discrimination law; it does not clearly and manifestly preempt laws regulating the standard of medical care. Indeed, the ACA contains an express savings clause, confirming no broad "obstacle" preemption applies. *See* 42 U.S.C. § 18041 ("Nothing in this title shall be construed to preempt any State law that does not prevent the application of the provisions of this title.").

234. *Fourth*, Congress must "speak clearly when authorizing an agency to exercise powers of 'vast economic and political significance.'" *Ala. Ass'n of Realtors v. HHS*, 594 U.S. 758, 764 (2022) (cleaned up). Section 1557 doesn't clearly authorize the OCR Rules.

235. *Fifth*, because Section 1557 is a Spending Clause statute, Congress had to prohibit gender identity discrimination and prohibit disparate impacts

"unambiguously." *Adams*, 57 F.4th at 815. No clear statement appears on the face of the statute.

236. *Sixth*, the 2024 Rules violate Title IX's religious exemption. 20 U.S.C. § 1681(a)(3). The 2024 Rules exceed HHS's authority as cabined by Title IX and incorporated into Section 1557 because Section 1557 does not apply when it would violate the religious tenets of a covered entity.

237. *Seventh*, the 2024 Rules violate the Church Amendments, 42 U.S.C. § 300a-7, which protect the right of healthcare entities that receive federal funding to refuse to participate, perform, or assist with gender-transition procedures, including when it would be contrary to his religious beliefs or moral convictions.

COUNT II
(OCR Rules)

Violation of the Administrative Procedure Act
Arbitrary and Capricious

238. Plaintiffs incorporate by reference paragraphs 1–215.

239. Defendants HHS and CMS are "agenc[ies]" under the Administrative Procedure Act ("APA"). 5 U.S.C. § 551(1).

240. The OCR Rules are a "rule" under the APA. 5 U.S.C. § 551(4).

241. The OCR Rules are a "final agency action" subject to judicial review. 5 U.S.C. § 704.

242. Under the APA, a court must "hold unlawful and set aside agency action" that is "arbitrary [or] capricious." 5 U.S.C. § 706(2)(A).

243. An agency rule is arbitrary or capricious if it fails to "examine the relevant data and articulate a satisfactory explanation for its action including a rational connection between the facts found and the choice made." *Motor Vehicle Mfrs. Ass'n of U.S. Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 44 (1983). An agency rule is also 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." *Id.*

244. The OCR Rules are arbitrary and capricious for several reasons.

245. *First*, the OCR Rules never define "sex." But without defining sex, HHS cannot reasonably explain what it means to discriminate "based on" sex. HHS failed to adequately consider and find that, in medical practice as in education, sex is a biological reality.

246. *Second*, the OCR Rules' decision to embrace the WPATH and Endocrine Society Guideline runs counter to the evidence before the agency. Florida and other commenters put forth numerous studies and scholarly reviews showing these groups rely on weak evidence and that there is no consensus on gender-transition interventions.

247. *Third*, HHS failed to consider a significant aspect of the problem: the numerous negative side effects associated with "gender care." HHS never acknowledged, for example, that its preferred "standard of care" may render an untold

number of minors and adults infertile for life. HHS needs to consider that disadvantage.

248. *Fourth*, HHS arbitrarily departs from prior policy positions without adequate explanation. In the 2020 Rules, HHS said there was no medical or professional consensus that the benefits of gender-transition interventions outweighed the costs, as the evidence of a benefit was weak. HHS doesn't explain why the evidence is no longer weak.

249. *Fifth*, HHS improperly ignored the reliance interests of patients who want to keep receiving care from healthcare providers who object to gender transitions. HHS failed to adequately consider alternative policies.

250. Accordingly, the 2024 Rules' attempt to coerce covered entities into following a new federal standard of care for gender dysphoria is arbitrary and capricious and in violation of the APA.

COUNT III
(OCR Rules)

Violation of the Spending Clause

251. Plaintiffs incorporate by reference paragraphs 1–215.

252. Section 1557 is a Spending Clause statute. "[I]f Congress intends to impose a condition on the grant of federal moneys, it must do so unambiguously," so "States [can] exercise their choice knowingly." *Pennhurst State Sch. & Hosp. v. Halderman*, 451 U.S. 1, 17 (1981). "A safeguard of our federalist system is the demand

that Congress provide the States with a clear statement when imposing a condition on federal funding." *Adams*, 57 F.4th at 815.

253. "States cannot knowingly accept conditions of which they are 'unaware' or of which they are 'unable to ascertain.'" *Arlington Cent. Sch. Dist. Bd. of Educ. v. Murphy*, 548 U.S. 291, 296 (2006).

254. At the time that the ACA was passed in 2010, no federal courts or agencies interpreted "based on sex" in Title IX to include discrimination based on gender identity. *See Adams*, 57 F.4th at 815–17 (interpretation of Title IX that prohibits discrimination on the basis of gender identity cannot survive the Spending Clause's clear statement rule).

255. Nor does 1557 by its terms unambiguously prohibit refusals to provide medical interventions with a *different* clinical purpose.

256. Under the OCR Rules, Florida now faces the untenable choice of surrendering its power to protect the health and safety of Floridians or losing billions of dollars in federal funding without adequate notice that this would be part of the bargain.

257. Accordingly, the OCR Rules violate the Spending Clause.

COUNT IV
(CMS Rules)

Violation of the Administrative Procedure Act
Agency Action Not in Accordance with Law, In Excess of Statutory Authority

258. Plaintiffs incorporate by reference paragraphs 1–215.

259. Defendants HHS and CMS are "agenc[ies]" under the APA. 5 U.S.C. § 551(1).

260. The 2024 Rules are a "rule" under the APA. 5 U.S.C. § 551(4).

261. The 2024 Rules are a "final agency action" subject to judicial review. 5 U.S.C. § 704.

262. Under the APA, a court must "hold unlawful and set aside agency action" that is "not in accordance with law, in excess of statutory authority, or limitations, or short of statutory right." 5 U.S.C. § 706(2)(A), (C).

263. The CMS rules prohibit Medicaid and CHIP managed care organizations from having policies or practices that result in discrimination based on gender identity. 89 Fed. Reg. at 37,691, *to be codified at* 42 C.F.R. § 438.3(d)(4).

264. These rules are not authorized by Section 1557. For the reasons given above (Count I), Section 1557 doesn't protect against "gender identity" discrimination.

265. Section 1557 also requires intentional discrimination on the basis of sex: It prohibits different treatment based on animus, not facially neutral policies or practices that have "*the effect* of discriminating" on the basis of sex or gender identity. The law, like Title IX, prohibits discriminatory intentions, not just discriminatory consequences or outcomes.

266. Section 1902(a)(4) of the SSA, 42 U.S.C. § 1396a(a)(4), also does not give HHS authority to impose gender-identity non-discrimination rules on the states and its managed-care organizations. Non-discrimination rules are not "methods of

administration"; they are civil rights regulations. CMS's limitless reading of "methods of administration" is inconsistent with both text and statutory context, as well as the "clear notice" requirements for spending legislation and the major questions doctrine.

267. Section 2101(a) of the SSA, *id.* § 1397aa(a), also doesn't authorize this rule for CHIP. This vague statement of purpose doesn't grant any rulemaking authority or authorize CMS to legislate gender-identity non-discrimination rules. CMS's limitless reading of this statement of purpose is inconsistent with text and statutory context, as well as the "clear notice" requirements for spending legislation and the major questions doctrine.

268. The CMS rules also prohibit PACE organizations from discriminating against any participant based on gender identity. 89 Fed. Reg. at 37,692, *to be codified at* 42 C.F.R. §§ 460.98, 460.112.

269. Sections 1894(f)(A) and 1934(f)(A) of the SSA, 42 U.S.C. § 1395eee(f); *id.* § 1396u-4(f), similarly do not give CMS authority to legislate gender-identity non-discrimination rules for PACE. CMS's limitless reading of these rulemaking grants is inconsistent with the statutory context, as well as the "clear notice" requirements for spending legislation and the major questions doctrine.

270. The CMS rules also require that Medicaid and CHIP managed care organizations "promote the delivery of services in a culturally competent manner to all enrollees … regardless of sex which includes … gender identity." 89 Fed. Reg. at 37,691, *to be codified at* 42 C.F.R. § 438.206(c)(2).

271. Similarly, the CMS rules require that States' fee-for-service Medicaid programs "have methods to promote access and delivery of services in a culturally competent manner to all beneficiaries … regardless of sex which includes … gender identity." *Id.* at 37,692, *to be codified at* 42 C.F.R. § 440.262.

272. Further, the CMS rules require that State CHIP plans include methods for assuring that "access to and delivery of services in a culturally competent manner to all beneficiaries, as described in [42 C.F.R. § 440.262]." *Id.*, *to be codified at* 42 C.F.R. § 457.495(e).

273. All the "cultural competence" provisions appear to be intended to require that states require that transgender persons be referred to by pronouns that do not align with their sex.

274. The Social Security Act does not authorize CMS to impose speech codes or require adherence to a specific view of how to address transgendered individuals. Instead, the statute authorizes Medicaid rules specifying "methods of administration" that the Secretary concludes are "necessary for the proper and efficient operation of the plan." 42 U.S.C. § 1396a(a)(4). Requiring the use of pronouns that differ from the individual's sex does not advance the goal of "efficient" "administration" of the Medicaid program—it's about prescribing what should be orthodox in public discourse. That's beyond the reach of CMS's authority to publish rules that increase efficiency. Moreover, CMS's limitless reading of the term "methods of administration" is inconsistent with both text and statutory context, as well as the "clear notice" requirements for spending legislation and the major questions doctrine.

275. For similar reasons, Section 2101(a) of the SSA, *id.* § 1397aa(a), also doesn't authorize the CHIP version of this rule. This vague statement of purpose doesn't grant any rulemaking authority or authorize CMS to legislate pronoun rules. CMS's limitless reading of this statement of purpose is inconsistent with text and statutory context, as well as the "clear notice" requirements for spending legislation and the major questions doctrine.

276. Nor does Section 1902(a)(19) of the SSA, *id.* § 1396a(a)(19), authorize CMS to mandate the use of pronouns that differ from sex. That provision requires that State Medicaid plans contain safeguards that are "necessary to assure that" care and services are provided "in a manner consistent with simplicity of administration and the best interests of the recipients." *Id.* This general language doesn't grant any rulemaking authority or authorize CMS to legislate pronoun rules. CMS's limitless reading of this requirement of State Medicaid plans is inconsistent with text and statutory context, as well as the "clear notice" requirements for spending legislation and the major questions doctrine.

COUNT V
(CMS Rules)

Violation of the Administrative Procedure Act
Arbitrary and Capricious

277. Plaintiffs incorporate by reference paragraphs 1–215.

278. Defendants HHS and CMS are "agenc[ies]" under the APA. 5 U.S.C. § 551(1).

279. The CMS Rules are a "rule" under the APA. 5 U.S.C. § 551(4).

280. The CMS Rules are a "final agency action" subject to judicial review. 5 U.S.C. § 704.

281. Under the APA, a court must "hold unlawful and set aside agency action" that is "arbitrary [or] capricious." 5 U.S.C. § 706(2)(A).

282. An agency rule is arbitrary or capricious if it fails to "examine the relevant data and articulate a satisfactory explanation for its action including a rational connection between the facts found and the choice made." *State Farm*, 463 U.S. at 44. An agency rule is also 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." *Id.*

283. The CMS Rules are arbitrary and capricious for several reasons.

284. *First,* they never define "sex." But without defining sex, CMS cannot reasonably explain what it means to discriminate based on sex or to provide "culturally competent" care regardless of sex.

285. *Second*, CMS relied on factors that Congress never intended it to consider. Congress authorized regulations to improve the efficiency of Medicaid and CHIP administration. Congress did not intend CMS to require "pursuing health equity"—*i.e.*, gender ideology. 89 Fed. Reg. at 37,668.

286. *Third*, CMS failed to consider a significant aspect of the problem when promulgating its "culturally competent" care requirements: the risk that providers will

leave the Medicaid and CHIP programs if required to use pronouns that differ from sex, creating a shortage of providers that harms Medicaid and CHIP recipients.

COUNT VI
(CMS Rules)

Violation of the Spending Clause

287. Plaintiffs incorporate by reference paragraphs 1–215.

288. The SSA is a Spending Clause statute. "[I]f Congress intends to impose a condition on the grant of federal moneys, it must do so unambiguously," so "States [can] exercise their choice knowingly." *Pennhurst State Sch. & Hosp. v. Halderman*, 451 U.S. 1, 17 (1981). "A safeguard of our federalist system is the demand that Congress provide the States with a clear statement when imposing a condition on federal funding." *Adams*, 57 F.4th at 815.

289. "States cannot knowingly accept conditions of which they are 'unaware' or of which they are 'unable to ascertain.'" *Arlington Cent. Sch. Dist. Bd. of Educ.*, 548 U.S. at 296.

290. Neither the SSA nor the Public Health Service Act clearly authorize CMS to impose rules against discriminating on the basis of gender identity.

291. The SSA also does not clearly authorize CMS to impose rules requiring "culturally competent" care, especially when that appears to require the use of ungrammatical pronouns that differ from sex.

292. Accordingly, the CMS Rules violate the Spending Clause.

COUNT VII
(OCR Rules)

Violation of the First Amendment Guarantees of Free Speech and Association

293. Plaintiffs incorporate by reference paragraphs 1–215.

294. Under the First Amendment to the U.S. Constitution, "Congress shall make no law … abridging the freedom of speech … or the right of the people peaceably to assemble …." U.S. Const. amend. I.

295. CMA members' speech, association, and practice in healthcare are burdened in violation of the First Amendment.

296. The OCR Rules seek to restrict and compel speech and to regulate speech based on content and viewpoint. The OCR Rules require policies, opinions, referrals, and pronouns affirming gender-transition efforts, and they restrict speech taking a contrary view.

297. The OCR Rules violate CMA members' right of expressive association (or freedom of assembly) by coercing them to participate in facilities, programs, groups, and other healthcare-related endeavors that are contrary to their convictions and that express messages with which CMA members disagree.

298. The OCR Rules impose an unconstitutional condition on CMA members' receipt of federal funding.

299. The government lacks any compelling interest, and its mandates are not narrowly tailored to achieve any such interests.

300. If Section 1557 or Title IX is found to prohibit discrimination on the basis of gender identity, these statutes violate the First Amendment of the U.S. Constitution as applied to CMA members and all similarly situated healthcare professionals.

COUNT VIII
(OCR Rules)

Violation of the Religious Freedom (First Amendment and Religious Freedom Restoration Act)

301. Plaintiffs incorporate by reference paragraphs 1–215.

302. RFRA prohibits the federal government from substantially burdening a person's exercise of religion unless the government demonstrates that the burden is the least restrictive means of furthering a compelling government interest. 42 U.S.C. § 2000bb-1(a).

303. Under the First Amendment to the U.S. Constitution, "Congress shall make no law respecting an establishment of religion, or prohibiting the free exercise thereof …." U.S. Const. amend. I.

304. RFRA and the Free Exercise Clause apply to the OCR Rules, the statutes underlying them, and HHS's enforcement of them.

305. CMA members exercise their religious beliefs through providing healthcare and through expressing messages in their healthcare practices, including to low-income and underserved populations in Medicaid, Medicare, and CHIP.

306. CMA members' provision of healthcare in accord with their religious beliefs does not prevent anyone from obtaining services from other providers.

307. The OCR Rules substantially burden their exercise of religion.

308. The OCR Rules are not neutral or generally applicable.

309. The OCR Rules observe other statutory and informal exemptions.

310. The OCR Rules contemplate the possibility of exemptions for some religious providers but not others. The OCR Rules thus may favor some religious beliefs over others.

311. The OCR Rules further no compelling or legitimate governmental interest and are not the least restrictive means of furthering any interests.

312. Defendants' actions promulgating and enforcing the OCR Rules violate CMA members' religious-exercise rights and hybrid free-speech and religious-exercise rights under RFRA and the First Amendment. In the alternative, if Section 1557 or Title IX is found to prohibit discrimination on the basis of gender identity, these statutes violate RFRA and the First Amendment for the same reasons.

PRAYER FOR RELIEF

For these reasons, Plaintiffs ask the Court to:

a) Hold unlawful, set aside, and vacate the 2024 Rules;

b) Issue preliminary injunctive relief enjoining Defendants from enforcing the 2024 Rules during the pendency of this case, or, in the alternative, postpone the effective date of the 2024 Rules during the pendency of this case pursuant to 5 U.S.C. § 705;

c) Issue permanent injunctive relief enjoining Defendants from enforcing the 2024 Rules;

d) Declare that the 2024 Rules are contrary to law and arbitrary and capricious;

e) Declare that under any theory of Section 1557 and Title IX, Defendants may not require covered entities to:

i. Perform, provide, refer for, facilitate, affirm, or refrain from criticizing or from categorically rejecting "gender transition" interventions;

ii. Speak in ways that the entities contend inaccurately refers to a patient's sex, such as in pronoun usage, writing, or conversation, or be forced to say that men can get pregnant and give birth;

iii. Allow members of one sex into the healthcare programs or private spaces of the other sex in their facilities, such as by allowing males into female restrooms; or

iv. Make statements in their policies, notices, or website statements, or train staff, or speak to patients or visitors, or submit assurances or certifications of compliance, to the effect that the entity will not discriminate on the basis of gender identity.

f) Award Plaintiffs costs and reasonable attorneys' fees.

g) Award such other relief as the Court deems equitable and just.

May 6, 2024

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Dkt. 1-1

Exhibit 1

IN THE UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
TAMPA DIVISION

STATE OF FLORIDA; FLORIDA AGENCY FOR HEALTH CARE ADMINISTRATION; FLORIDA DEPARTMENT OF MANAGEMENT SERVICES, CATHOLIC MEDICAL ASSOCIATION, on behalf of its current and future members,

Plaintiffs,

No. 8:24-cv-_____

DEPARTMENT OF HEALTH AND HUMAN SERVICES; XAVIER BECERRA, in his official capacity as Secretary of the Department of Health and Human Services; MELANIE FONTES RAINER, in her official capacity as the Director of the Office for Civil Rights; THE CENTERS FOR MEDICARE AND MEDICAID; CHIQUITA BROOKS-LASURE, in her official capacity as Administrator of the Centers for Medicare and Medicaid,

Defendants.

DECLARATION OF KEN KNIEPMANN

I, Ken Kniepmann, declare as follows:

1. My name is Ken Kniepmann, and I have personal knowledge of the following statements. I am employed by the Florida Agency for Health Care Administration ("AHCA") as the Assistant Deputy Secretary for Medicaid Policy and Quality. As part of my duties, I oversee the bureau of Medicaid Policy, which is responsible for the development of all rules and policies for the Medicaid program in Florida.

2. AHCA is the single state agency responsible for the administration of the Medicaid program in Florida. *See* 42 U.S.C. § 1396a(a)(5). AHCA also administers the Children's Health Insurance Program ("CHIP") and Program of All-Inclusive Care for the Elderly ("PACE") in Florida.

Federal Funds for Florida CMS Programs

3. In State Fiscal Year 2022-2023, Florida expended $13,021,126,306 in state funds on the Medicaid program. The federal share expended was $24,436,629,368.

4. In State Fiscal Year 2023-2024, AHCA estimates that Florida will expend $14,643,127,054 in state funds on the Medicaid program. AHCA estimates that the federal share expended will be $20,306,042,621.

5. In State Fiscal Year 2022-2023, Florida expended $82,811,091 in state funds on the CHIP program. The federal share expended was $234,973,859.

6. In State Fiscal Year 2023-2024, AHCA estimates that Florida will expend $155,286,520 in state funds on the CHIP program. AHCA estimates that the federal share expended will be $355,219,776.

7. In State Fiscal Year 2022-2023, Florida expended $34,858,100 in state funds on the PACE program. The federal share expended was $68,038,237.

8. In State Fiscal Year 2023-2024, AHCA estimates that Florida will expend $100,688,395 in state funds on the PACE program. AHCA estimates that the federal share expended will be $147,802,215.

9. In total, the federal funds expended for these programs in Fiscal Year 2022-2023 was $24,671,603,227.

Florida Policy Regarding the Use of State Funds for Gender-Transitions

10. AHCA's state Medicaid program currently does not cover gender-transition interventions for the public at large. In August 2022, AHCA promulgated Rule 59G-1.050(7), Florida Administrative Code. That Rule provides that Florida Medicaid does not cover the following interventions for the treatment of gender dysphoria: (1) puberty blockers; (2) hormones and hormone antagonists; (3) gender-reassignment surgeries; and (4) any other procedures that are intended to alter primary or secondary sexual characteristics.

11. In May 2023, Governor Ron DeSantis signed into law Senate Bill 254, which prohibits the use of state funds for "sex-reassignment prescriptions or procedures"—including puberty blockers, hormones, hormone antagonists, or any medical procedure, including a surgical procedure, used "in order to affirm a person's perception of his or her sex if that perception is inconsistent with the person's sex." Fla. Stat. §§ 286.311, 456.001(9)(a). Therefore, AHCA's programs currently do not cover the cost of puberty blockers, hormones, hormone antagonists, or any medical procedure, including a surgical procedure, used as part of a gender-transition protocol.

12. The 2024 Rules purport to prohibit Florida's general prohibition on using state funds to pay for these gender-transition interventions. The 2024 Rules would generally require that state programs receiving funds from HHS cover gender-transition interventions for Medicaid and CHIP recipients. These changes are in direct

conflict with Florida law and regulations regarding these interventions, including AHCA's rules.

Fiscal Costs of Covering Gender-Transition

13. The 2024 Rules would impose significant fiscal costs on Florida by requiring coverage for gender-transition interventions.

14. Puberty blockers are expensive. Lupron Depot, a drug manufactured by AbbVie and used off-label for gender transitions in pubescent minors, typically costs thousands of dollars for a single, three-month shot. Because the drug is administered by clinics and hospitals, clinics and hospitals also charge hefty administration fees. Cross-sex hormones and endocrinologist visits are similarly expensive, costing thousands of dollars. And gender-change surgeries can cost many tens of thousands of dollars.

15. According to one paper relied on by HHS to downplay the cost of the rule in its economic impact analysis, based on data from the insurance plans offered to University of California employees and their dependents, including children, "the average cost of transition related care (surgery, hormones, or both) per person needing treatment was $29,929 over 6.5 years," or about $5,000 a year. Aaron Belkin, *Caring for Our Transgender Troops—The Negligible Cost of Transition-Related Care*, 373 New Eng. J. Med. 1089 (2015). However, even this low estimate would result in exorbitant costs to Florida.

16. According to the Williams Institute, Florida has roughly 95,000 adults who identify as "transgender," or 0.55% of the adult population in Florida, and 16,200 minors who identity as transgender, or 1.32% of the minor population in Florida.[1]

17. As of December 2023, some two-and-a-half million minors were enrolled in Florida Medicaid and CHIP. If 1.32% of this Medicaid population identifies as transgender, then approximately 33,000 transgender minors under 21 are enrolled in Florida Medicaid and CHIP.

18. Although not all transgender minors have gender dysphoria and seek gender-change interventions, assuming they do, the potential annual cost of treating all these minors with gender-change interventions—even using conservative cost estimates—may be roughly estimated at about $165,000,000 per year ($5,000/year × 33,000).

19. As of December 23, some one-and-a-half million adults were enrolled in Florida Medicaid. If 0.55% of this Medicaid population identifies as transgender, then approximately 8,250 transgender adults are enrolled in Florida Medicaid.

20. Although not all transgender adults have gender dysphoria and seek gender-change interventions, assuming they do, the potential annual cost of treating all these adults with gender-change interventions—even using conservative cost estimates—may be roughly estimated at about $41,250,000 per year ($5,000/year × 8,250).

[1] *See* https://williamsinstitute.law.ucla.edu/subpopulations/transgender-people/.

21. In total, using these rough estimates, the potential fiscal cost of covering gender-transition interventions under Florida Medicaid and CHIP is over $200,000,000 per year.

22. The utilization rate for these interventions has also risen rapidly in recent years. A study published in the JAMA Network Open details the meteoric rise of "gender affirming" surgeries in the United States over the past several decades. Jason D. Wright et al., *National Estimates of Gender-Affirming Surgery in the US*, 6 JAMA Netw Open. (Aug. 23, 2023). The number of such surgeries doubled between 2000 and 2005, and then doubled again between 2006 and 2011. These surgeries have kept increasing since then: the authors found these surgeries tripled between 2016 and 2019. *Id.* Despite significant pandemic-driven reductions for almost all elective surgeries in 2020, gender-transition surgeries remained steady near their 2019 high during the pandemic. *Id.* The study predicted that demand for these surgeries would continue to rise and warned of a shortage of qualified surgeons to meet this rapidly increasing demand. *Id.*

I declare under penalty of perjury that the foregoing is true and correct.

Executed on this 6th day of May 2024.

KEN KNIEPMANN

Dkt. 1-2

Exhibit 2

IN THE UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
TAMPA DIVISION

STATE OF FLORIDA; FLORIDA AGENCY FOR HEALTH CARE ADMINISTRATION; FLORIDA DEPARTMENT OF MANAGEMENT SERVICES; CATHOLIC MEDICAL ASSOCIATION, on behalf of its current and future members,

Plaintiffs,

No. 8:24-cv-_____

DEPARTMENT OF HEALTH AND HUMAN SERVICES; XAVIER BECERRA, in his official capacity as Secretary of the Department of Health and Human Services; MELANIE FONTES RAINER, in her official capacity as the Director of the Office for Civil Rights; THE CENTERS FOR MEDICARE AND MEDICAID; CHIQUITA BROOKS-LASURE, in her official capacity as Administrator of the Centers for Medicare and Medicaid,

Defendants.

DECLARATION OF TEELA SANDERS

I, TEELA SANDERS, declare as follows:

1. My name is Teela Sanders, and I have personal knowledge of the following statements.

2. I am employed by the Florida Department of Management Services ("DMS") as Director of the Division of State Group Insurance. I have been with the Division for five months and stepped into this role with extensive public sector health insurance experience.

3. DMS is a state agency charged with, among other things, the purchase of health insurance coverage for Florida's state employees under the State Group Health Insurance Program. The State Group Health Insurance Program covers active and retired employees, their eligible dependents, and surviving spouses from the executive, legislative, and judicial branches of the state government, state universities, and other statutorily defined Florida agencies. All but one of the insurance plans offered under the State Group Health Insurance Program are self-funded, wherein the State of Florida pays the cost of covered claims directly.

4. The State Group Health Insurance Program provides health insurance for Florida's state employees and offers employees the option to also insure their spouses and children up to age 26 (or older in certain circumstances). As of March 2024, the State Group Health Insurance Program had approximately 310,750 members.

5. I have reviewed the new Department of Health and Human Services ("HHS") "Nondiscrimination in Health Programs and Activities" rules (the "2024 Rules"), prohibiting covered entities from having or implementing a categorical coverage exclusion or limitation for all health services related to a gender-transition protocol. I understand that this requirement is applicable to entities operating health activities or programs, including health insurance issuers, receiving federal financial assistance from HHS.

6. As the State Group Health Insurance Program provides coverage to retirees, it is currently a recipient of federal financial assistance, such as the Retiree

Drug Subsidy ("RDS") from the Centers for Medicare and Medicaid Services ("CMS"), a part of HHS.

7. For over 40 years, the State Group Health Insurance Program has excluded coverage for gender-transition drugs and surgeries. Changes to coverage policies require prior approval of the Florida legislature.

8. As of 2023, using state funds on sex-reassignment prescriptions or procedures for the State Group Health Insurance Program is further prohibited by Florida law. Fla. Stat. § 286.311.

9. The plan, however, does provide for psychological counseling, including counseling for gender dysphoria, under the mental health benefit.

10. If Florida is now required by the 2024 Rules to cover such drugs and surgeries for gender transitions, then the State of Florida will incur increased costs for health insurance. The costs for such coverage can range from thousands of dollars to over six figures.

11. Even if in some individualized cases coverage can be denied without violating the 2024 Rules, under a case-by-case approach, the State of Florida will incur indirect administrative costs if the denial of a claim is appealed. Members may appeal the denial of a claim, first to the insurer and subsequently to an Independent Review Organization and the Division of State Group Insurance. A denial by the Division of State Group Insurance entitles the member to an administrative hearing. The resulting final order is then subject to judicial review. Associated administrative costs of the

appeal vary. The current exclusion, however, substantially reduces Florida's administrative costs.

12. Further, under the 2024 Rules, denying insurance coverage or claims for a gender-transition intervention would subject Florida to an increased risk of burdensome private lawsuits and OCR investigations for alleged "gender identity" discrimination, imposing litigation costs on Florida, and threating a devastating loss of federal financial assistance.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on this 6th day of May 2024.

DocuSigned by:
Teela Sanders
CBC0AE83663B495...

TEELA SANDERS

Dkt. 1-3

Exhibit 3

IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF FLORIDA
TAMPA DIVISION

State of Florida, et al. *Plaintiffs*, v. **U.S. Department of Health and Human Services**, et al., *Defendants*.	)	**Civil Action No.** _____

DECLARATION OF MARIO R. DICKERSON, M.T.S.

I, Mario R. Dickerson, M.T.S., declare as follows:

1. I am over 21 and I am fully competent to make this declaration.

2. These facts are true, correct, and within my personal knowledge. If called to testify, I could and would testify competently to them.

I. Background on the Catholic Medical Association

3. I serve as the Executive Director of the Catholic Medical Association ("CMA"). CMA is the largest association of Catholic individuals in healthcare. CMA is a national, physician-led community that includes about 2500 physicians and health providers nationwide in all fields of practice.

4. For our members, healthcare is not just a job but a sacred calling. Our members care for all people without discrimination on the basis of sex or any other characteristic prohibited by law. A patient with medical needs, such as a sore throat, broken arm, or cancer, should be given the best care possible, regardless of the patient's identity.

5. But we cannot harm or lie to our patients. Gender-transition efforts are impermissible and dangerous. Based on the Hippocratic Oath, on science, on medical ethics, on conscience, and on our religious faith, we

categorically exclude providing medical interventions or referrals for "gender transitions," and we categorically exclude facilitating or speaking in ways that affirm their legitimacy.

6. I am informed and aware of how the new Section 1557 OCR Rules challenged in this case would impact CMA's members in their medical practices and their exercise of religion.

7. The OCR Rules ignore clear biological truths – to the harm of doctors and patients alike. This rule tries to force doctors do evil in order to continue doing good. The OCR Rules claim that doctors who heal must also hurt. But doctors should never be forced to lie to their patients.

8. The OCR Rules infringe on our members in many ways. Providing, facilitating, referring for, or endorsing gender-transition efforts violates our core religious beliefs and our medical oath to "do no harm."

A. CMA's mission

9. CMA represents faithful Catholics in the healthcare field so that its members can grow in faith, maintain ethical integrity, and provide excellent healthcare in accordance with the teachings of the Catholic Church.

10. CMA members seek to be a voice of truth spoken in charity, defending the dignity of human life and showing how Catholic teachings on the human person improve the practice of medicine. CMA is a leading national voice on applying the principles of the Catholic faith to medicine. It publishes guidance on healthcare ethics, creates educational resources and events, and develops strategies for members to provide healthcare consistent with Catholic values. CMA advocates and litigates for members' freedoms.

CMA's position paper attached as Exhibit A explains the importance of protections from mandates to perform gender-transitions.[1]

B. CMA's membership

11. CMA is a Virginia nonprofit organization. CMA members join CMA voluntarily, help finance CMA activities with dues and donations, help elect CMA leaders, and serve in CMA leadership.

12. Our board of directors has twenty-nine medical doctors, a chaplain who is also a medical doctor, and a Catholic bishop who holds a doctorate of divinity.

13. CMA's 2024 national conferences will be held in Orlando, Florida, as was CMA's 2021 national conference.

14. CMA has local guilds (chapters) covering every region of the country and the military. CMA has a Florida statewide guild called the Florida Catholic Medical Association. CMA also has seven local Florida guilds, which are located in Gainesville, Miami, Orlando, Jacksonville, Palm Beach, Pensacola, and St. Petersburg/Tampa Bay.

15. CMA members mainly are physicians. We track each member's years in practice as well as whether the member has retired from practice.

16. We have separate membership categories for clergy, seminarians, medical students, dentists, nurse practitioners, nurses, physician assistants, other healthcare professionals, retirees, friends, and general supporters.

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[1] Ex. A, CMA, *Conscience* (Oct. 20, 2021), https://www.cathmed.org/resources/conscience/.

C. My role as Executive Director

17. I submit this declaration on my own behalf as CMA's Executive Director and on behalf of CMA as its corporate representative.

18. I hold a bachelor's degree in philosophy and theology from St. John's University and a master's in theological studies from Washington Theological Union. I have led other nonprofit organizations. I served as a Chaplain's Assistant at the National Naval Medical Center (Bethesda, MD), ministering to patients and doctors who faced tough ethical choices. I have published on faith in the workplace and have taught courses, including "Ethics in Ministry," at St. Charles Borromeo Seminary.

19. Given my frequent interactions with all aspects of the organization and its members, I have observed our organization's operations, membership, and views. As Executive Director, I participate in all activities of the CMA board of directors as a member. I ensure that our organizational leaders support CMA's mission at their local guild levels. I help ensure that CMA leaders implement CMA's mission and values, including that they ensure that local members share CMA's mission and values. I am responsible for increasing CMA membership and for advocating for healthcare ethics. I supervise member admission. At CMA events and activities, I observe CMA members' actions and statements, CMA members' motivations for their Catholic medical practices, CMA members' intent to observe CMA values in their medical practices, and CMA members' activities and plans. I ensure that members share CMA's positions. If I believe that a person does not share CMA's positions, I do not allow that person to become (or remain) a member. In my experience, CMA members share CMA's positions—that's why they joined CMA.

20. I have observed the operations and circumstances of CMA's members related to their commitment to operating within the Catholic values of CMA and related to the effect of the OCR Rules.

II. CMA's categorical positions on gender-transition procedures

21. CMA's members have deep, substantial, science-based and religious objections to gender-transition efforts.

A. CMA's scientific views on gender-transition procedures

22. We hold the categorical view that gender-transition procedures harm patients—particularly children—and can result in infertility, heart attacks, strokes, and other chronic illnesses, and that medical science does not support the provision of such procedures. We hold the categorical view that sex is a biological, immutable characteristic—a scientific reality, not a social construct. We hold the categorical view that to eliminate sex-specific private spaces violates fundamental rights to privacy, dignity, safety, and security.

23. One article illustrating our scientific concerns about gender interventions was published in a scholarly format in CMA's quarterly journal by Paul W. Hruz, M.D., Ph.D at the Washington University School of Medicine.[2] The article identifies a lack of high-quality scientific data for gender-identity interventions, such as the lack of randomized prospective trial design, a small sample size, recruitment bias, short study duration, high subject dropout rates, and reliance on opinion. It explains the serious deficits in understanding the cause of this condition or the reasons for the marked

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[2] Paul W. Hruz, *Deficiencies in Scientific Evidence for Medical Management of Gender Dysphoria*, 87 Linacre Quarterly (Issue 1) 34, 34–42 (Sept. 20, 2019), https://doi.org/10.1177/0024363919873762.

increase in people presenting for medical care. The article shows the risks of gender-transition interventions, including significant intervention-associated morbidity—raising concerns that suicide prevention is not achieved.

B. CMA's religious views on gender-transition procedures

24. Our concerns about gender-transition efforts reflect the best scientific expertise, but they also rest on much older foundations. The Catholic Church teaches that men and women are created in two sexes.[3] For thousands of years, Christian anthropology, with its roots in the narrative of human origins in the Book of Genesis, has taught that "God created man in his own image … male and female he created them." *Genesis* 1:27.

25. The Catholic Church categorically opposes invasive and drastic medical interventions promoted by modern gender ideology. Pope Francis recently issued a declaration, *Dignitas Infinita,* which explains that "any sex-change intervention, as a rule, risks threatening the unique dignity the person has received from the moment of conception."[4]

C. CMA's categorical positions against gender-transition procedures

26. CMA has a position paper, attached as Exhibit B, diving deeper into these scientific, theological, ethical, and technological considerations.[5]

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[3] *See, e.g.*, Catechism of the Catholic Church § 2333, 2393; Pope Francis, Encyclical Letter *Laudato Si': On Care for Our Common Home* ¶ 155 (May 24, 2015), https://perma.cc/AWY7-M8UH.

[4] Holy See Press Office, *Declaration of the Dicastery for the Doctrine of the Faith "Dignitas Infinita" on Human Dignity* (Apr. 8, 2024), https://press.vatican.va/content/salastampa/en/bollettino/pubblico/2024/04/08/240408c.html; *see also* Catechism of the Catholic Church § 2297.

[5] Ex. B, CMA, *The Ideology of Gender Harms Children* (Sept. 8, 2023), https://www.cathmed.org/resources/the-ideology-of-gender-harms-children/.

27. CMA officially resolved that it "does not support the use of any hormones, hormone blocking agents or surgery in all human persons for the treatment of Gender Dysphoria." CMA "members reject all policies that condition children to accept as normal a life of chemical and surgical impersonation of the opposite sex" as well as reject "the use of puberty blocking hormones and cross-sex hormones." In addition, "the Catholic Medical Association, in recognition of the dignity of the person, supports the continuation of gender-specific facilities in all public and private places. [6]

28. Our categorical exclusion of providing, facilitating, or affirming gender transitions, and our commitment to state law, precludes us from

A. Prescribing puberty blockers, cross-sex hormone therapies, or other similar ongoing interventions to treat gender dysphoria or for transition efforts;

B. Performing surgeries to treat gender dysphoria or for transition efforts, including:

   i. Removing healthy breasts, uteruses, or ovaries from females who purport to identify as males, nonbinary, or who otherwise do not identify as females (hysterectomies, mastectomies, and oophorectomies);

   ii. Removing healthy vaginal tissue from females who purport to believe themselves to be males, nonbinary, or otherwise not to be female, and creating for them a faux or cosmetic penis (phalloplasties and metoidioplasties);

   iii. Removing healthy testicles or scrotums from males who purport to believe themselves to be female (orchiectomies or scrotectomies);

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[6] CMA, Health Care Policy Resolutions, Family/Sexual Education, https://www.cathmed.org/programs-resources/health-care-policy/resolutions/familysexual-education/.

iv. Performing a process called "de-gloving" to remove the healthy skin of a male's penis and using it to create a faux vaginal opening or vulva (vaginoplasties and vulvoplasties);

v. Removing healthy internal or external genitals from any person to create a "smooth gender-neutral look" (nulloplasties or nullification surgeries); and

vi. Performing other procedures sought to make a person resemble the opposite sex or no sex, such as facial, chest, neck, skin, hair, or vocal modification;

C. Saying in our professional opinions or through staff that these transition efforts are the standard of care, are safe, are beneficial, are not experimental, are not cosmetic, or should otherwise be recommended;

D. Offering to perform, provide, or prescribe the above such transition interventions, procedures, services, or drugs, including in published statements;

E. Referring patients for any and all such interventions, procedures, services, or drugs;

F. Refraining from expressing our views, options, and opinions to patients when those views are critical of transition efforts;

G. Refraining from informing patients or the public that we do not provide transition procedures, including by refraining from sharing this information in patient conversations or on websites;

H. Treating and referring to patients according to gender identity and not sex;

I. Saying that sex or gender is nonbinary or on a spectrum;

J. Using language affirming any self-selected gender identity inconsistent with sex or the biological binary;

K. Asking patients to share their gender identity or pronouns beyond basic inquiries into the patient's sex;

L. Using patients' self-selected pronouns according to gender identity, rather than using no pronouns or using pronouns based on sex;

M. Creating medical records and coding patients and services according to gender identity not sex;

N. Saying that males can be pregnant or give birth;

O. Affirming or endorsing gender-transition efforts;

P. Allowing patients to access single-sex programs and facilities, such as well-woman and OB/GYN care, lactation training, induction, and medical care, breastfeeding support groups, educational sessions, maternity homes, changing areas, restrooms, communal showers, or other single-sex programs and spaces, by gender identity and not by sex;

Q. Repealing or modifying our policies, procedures, and practices of not offering to perform or prescribe the above procedures, drugs, and interventions for transition efforts; and

R. Providing assurances of compliance, compliance reports, express or implied certifications of compliance, and notices of compliant policies, or posting notices of compliant policies in prominent physical locations as to the OCR Rules' gender-identity requirements.

III. The OCR Rules' effect on CMA members

29. Most CMA members provide medical care in health programs and activities receiving federal financial assistance under 42 U.S.C. § 18116.

30. CMA has in good standing as CMA members Dr. Michael S. Parker of Mansfield, Ohio and Dr. Quentin L. Van Meter of Atlanta, Georgia,. Each member shares CMA's positions. They are representative of and are similarly situated to our members as a whole.

31. CMA thus seeks relief from the OCR Rules on behalf of its current and future members. Seeking such relief for all aspects of their practices is part of the mission of CMA as approved by its board of directors.

32. The OCR Rules impact our members in their practice of medicine as individual physicians who are regulated by the OCR Rules. And the OCR Rules impact some of these members as corporate principals and owners of medical practices that are regulated by the OCR Rules—for example in their duty to create, implement, and train staff on policies and to ensure compliance with the OCR Rules in their businesses' medical practices. Not

every CMA member is a recipient of federal funding within the meaning of the OCR Rules, although some are, and others are employees of recipients of the OCR Rules.

33. If our members were to comply with the OCR Rules, they would lose their integrity and reputation of practicing with sound judgment and good medical ethics, making patients less likely to trust them, and driving patients and employees away from their practices.

34. If our members do not comply with the OCR Rules, our members will have to defend themselves from investigations and enforcement actions, losing time, money, and resources that they could use for medical care.

35. If our members do not comply with the OCR Rules, our members will find it difficult to be employed in the field of medicine, as almost all medical practices receive federal financial assistance from HHS.

36. The OCR Rules threaten to drive doctors out of the medical profession, and they will dissuade students from choosing to practice medicine, reducing care for underserved, low-income, and rural patients.

I declare under 28 U.S.C. § 1746 and under penalty of perjury that this declaration is true and correct based on my personal knowledge.

Executed May 6, 2024 at Fort Washington, Pennsylvania.

Mario R. Dickerson

Mario R. Dickerson, M.T.S.

EXHIBIT A

October 20, 2021

Conscience

Conscience is a fundamental aspect of what it is to be human. Conscience is the ability to distinguish between good and bad action and strive to live in conformity with the virtue of integrity. The formation of conscience and its role in human actions is perhaps the most critical aspect of a person's character. Many religious and secular authorities agree that the protection of conscience is a fundamental human right. However, in an age of increasing moral relativism, conscience is relegated to a secondary status in the discussion of human rights. Instead, primary importance is placed on transitory cultural trends that are often disassociated from true moral goodness and the pursuit of the common good.

Conflicts between professional ethics and patient autonomy represent the height of this modern dilemma. Patients often request medical procedures that violate the sanctity of human life, the goodness of the created order, bodily integrity, and the protection of the vulnerable. Physicians, in the name of compassion, frequently are asked to facilitate acts of abortion, assisted suicide, euthanasia, sterilization, sexual promiscuity, transsexual surgery, assisted fertility procedures, etc. A robust argument against all these acts is articulated by the natural law, human experience and in the Catholic tradition—divine revelation. If a physician's conscience dictates not to participate in these requests, he or she ought to be defended by standards of practice, medical societies, and legislative action. Moreover, not only should physicians be exempt from participating in immoral practices, their rights to educate and exhort their patients and others as to the reasons for their ethical principles and positions also must be protected. Conscience protection is only the bare minimum expectation in a healthy society, and the right to convince others of the truth of one's moral insight should also be enshrined in a similar fashion. By its very nature, truth attracts. Therefore, the Catholic Medical Association supports conscience protection for all health care workers and facilities without compromise. Nothing less is acceptable.

If the patient, an employer or supervisor, or the law, insists on a referral/consultation for an immoral action or procedure, Catholic healthcare workers must not formally cooperate with such requests. They also may not participate in immediate material cooperation in which the assistance they provide is essential to the completion of the act. To avoid claims of patient abandonment, a physician may express an objection to the physician's supervisor for a change of assignment.If the patient is insistent on pursuing an immoral choice, the physician may be unable to prevent this, thus, necessitating a transfer of the patient to another health care provider chosen by the patient or the physician's supervisor. Ultimately, the patient is an independent moral agent who is free to decide where and from whom he or she will seek care. The physician is to make his or her objections known to the patient and must not indicate where the patient might go to receive the immoral procedure or otherwise direct the patient to it A general list of other providers or institutions based on geographic vicinity or even area of specialty might be provided; however, the list may not be developed based on the criterion of whether they are known or believed to offer the immoral procedure. In practice, this means that the list must include any providers or institutions that fit the chosen criterion (geography, specialty, both, or other) and also oppose the immoral practice. In the case of objections to contraception, for example, a list of local gynecologists should include those who offer only natural family planning.

The physician should release all medical records in accordance with statutory regulations. Ideally, health care institutions and the law should favor norms assuring morally questionable or objectionable consults can be arranged solely by patient request, exempting the objecting physician from any entanglement in the process of referral. The rights of the objecting physician should also apply to any health care worker with deeply held ethical or religious beliefs.

It must be stated emphatically that Catholic Medical Association stands by these principles not only to protect the rights of medical and other health care practitioners and Catholic facilities, but also because it believes immoral and unethical procedures are not in the patient's best interest and hurt patients physically, psychologically, and spiritually. This vision is holistic and fundamental to the entire tradition of Western medicine. Physicians are called to serve and love their patients by adhering to their well-formed conscience in the practice of medicine. Following their conscience is the sole guarantee of fulfilling that calling.

Approved by the Board – October 6, 2021

Categorised in:

Become a member

The Catholic Medical Association (CMA) is the largest association of Catholic individuals in health care. We help our members to grow in faith, maintain ethical integrity, and provide excellent health care in accordance with the teachings of the Church.

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EXHIBIT B

September 8, 2023

The Ideology of Gender Harms Children

Defining Terms and Understanding the Issue

"*Gender* is a term that refers to the psychological and cultural characteristics associated with biological sex. It is a psychological concept....*Gender identity* refers to an individual's awareness of being male or female, referred to as an individual's 'experienced gender'" (American College of Pediatricians, 2018). *Sex* is a biological term that refers to distinct and complementary roles for members of a species in relation to reproductive purpose. As there are only two gonads that contribute to human reproduction (testes and ovaries), sex is inherently binary. Gender awareness is based on thoughts and feelings whereas sex is a biological fact. The ideology of gender proposes the psychological awareness of an individual's gender may not be aligned with the person's biological sex. In cases of incongruence, the claim is made that psychological awareness predominates, negating the fact of the biological sex. *Intersex* is a term applied to disorders of sexual development. These disorders are very rare congenital defects frequently of genetic origin. It is a disease state, an objective medical condition. It is not an identity nor a third sex.

Dysphoria is defined as a state of dissatisfaction or unease about a given situation. *Gender dysphoria* (GD) is a psychological condition in which the individual feels an incongruence between his or her experienced gender and his or her biological sex. This condition is associated with varying levels of anxiety and unhappiness.

Human beings are born with a biological sex. The awareness of being male or female develops over time. As gender awareness develops during the early years of a child's life, there may be a time when the child may show confusion about his or her gender awareness. These pre-pubertal children may be diagnosed with gender dysphoria. W*hen GD occurs in the pre-pubertal child, it*

resolves in 80-90 percent of children by late adolescence as they naturally develop through puberty and gender awareness aligns with biological sex (Cohen-Kettenis, Delemarre-van de Waal, Gooren, 2008). Some of these adolescents may manifest same-sex attraction but without the desire to undergo sex reassignment.

The American Psychiatric Association (APA) explains in the fifth edition of the *Diagnostic and Statistical Manual of Mental Disorders* (DSM-5) that GD is listed as a mental disorder not because of the person's belief that they are someone they are not –– a break from reality –– but because of the emotional distress that is felt by the person and how this affects social functioning.

Once the distress is relieved, GD is no longer considered a disorder. The APA claims that the distress will be relieved by sex reassignment. A more recent document (DSM5-TR) reiterates the claims made by the prior document and insists that GD is not a mental disorder.

There are probably many paths that could lead to GD. There is no single-family dynamic or social situation that appears to be causative. There may be an association with adverse events in childhood including sexual abuse. Social reinforcement, parental psychopathology, family dynamics, and social contagion may all contribute to the development of GD in some children (American College of Pediatricians, 2018).

The traditional understanding of childhood GD had been that it reflected confused thinking on the part of the child. The standard approach was watchful waiting by the parents with the advice of a mental health specialist. The goals of therapy were to address family pathology when present, treat any psychosocial co-morbidities in the child, and aid the child in aligning gender identity with biological sex (American College of Pediatricians, 2018).

Medical Evidence Lacking in New Standard of Care

The traditional approach is no longer recommended. It is alleged that mental illness and suicide will be the consequences of withholding social affirmation of the child's confusion and allowing the child to grow through natural puberty. The American Academy of Pediatrics (AAP) has presented options for the suppression of normally timed puberty in affected children, and surgical interventions on a case-by-case basis for the adolescent child (Rafferty, 2018).

The American Medical Association (AMA) endorsed the Endocrine Society's position in passing a resolution to protect access to gender-affirming care for transgender and gender-diverse persons, which did not exclude youths (American Medical Association House of Delegates 2023). AMA cites the United States Department of Health and Human Services (HHS) for this decision. HHS indicates that gender-affirming care for transgender and non-binary people consists of "an array of services that may include medical, surgical, mental health, and non-medical services for transgender and non-binary people" (HHS, 2022). The so called "treatment" for GD in the US includes affirmation of the child's confusion, chemically blocking puberty, lifelong cross-sex hormones (testosterone for girls and estrogen for boys) and mutilating surgeries.

The protocol consists of affirming the child's confusion by using name and pronoun changes and facilitating the impersonation of the opposite sex as early as ages 3-4 years old. Then puberty is suppressed with GnRH (gonadotropin releasing hormone) analogues at ages 10- 11 years old. Puberty blocking hormones "arrest bone growth, decrease bone density, prevent the sex steroid dependent organization and maturation of the adolescent brain, and inhibit fertility" (American College of Pediatricians, 2018). Recently, the FDA placed a warning on the use of hormone puberty blockers because of several cases of pseudotumor cerebri (FDA, 2022). The pathological effects of puberty blockers are not easily reversed. The noxious psychological effect of not growing into adolescence together with one's peers is not reversible.

In 2018, the AAP in a statement from the Committee on Bioethics recognized that the research on the long-term effects of puberty blockers on children is limited. However, the AAP indicated it can cause harm to refrain from using puberty blockers on children with GD because of the resulting emotional distress of the children as they develop through physiologic puberty (Rafferty, 2018).

However, Great Britain, Sweden, Finland, France, and Denmark have recently restricted the use of puberty blocking drugs in children with GD (Lawless 2023; Nainggolan 2021; Smith 2021; Smith, 2022 and SEGM). Researchers in these countries posed the question that the treatment protocol could be ideology driven and not evidence based (Ludvigsson 2023). It was noted that children were given the diagnosis of GD with little clinical psychological oversight and rapidly placed on the sex reassignment protocol. This protocol is frequently set in motion by the demand and insistence of the children and their parents. Most children who undergo puberty suppression transition to cross-sex hormones and mutilating surgeries.

Cross-sex hormones are associated with dangerous health risks. Estrogen administration to boys will place them at risk of developing thromboembolism, elevated lipids, hypertension, decreased glucose tolerance, cardiovascular disease, obesity, and breast cancer. Girls provided with high-dose testosterone will be at risk of developing elevated lipids, insulin resistance, cardiovascular disease, obesity, polycythemia, and unknown effects on breast, endometrial, and ovarian tissues (American College of Pediatricians, 2018). Children who receive puberty blocking hormones followed by cross-sex hormones prior to completion of gonadal maturation risk permanent sterilization.

Mutilating surgeries for girls include bilateral mastectomy, hysterectomy, and removal of the ovaries. Girls as young as 14 have had completely healthy breasts removed (Rowe, 2016). Girls may undergo removal of skin from another part of the body for attachment to the pelvis to simulate a penis. Genital surgery for males includes removal of the testes and dissecting the penis and inverting it into a pelvic wound (American Society of Plastic Surgeons).

The claim that children with sexual confusion will commit suicide if they are not quickly affirmed and set on the path of sex reassignment is not scientifically supported. Sexually confused children frequently show significant psychiatric co-morbidities; the incidence of suicidality in this group corresponds to the psychiatric co-morbidities these children show. Scientific evidence suggests

that the transgender interventions do not reduce the risk of suicide. In fact, puberty blockers are associated with depression and other emotional disturbances related to suicide. Furthermore, data support that in the long run transitioning may even exacerbate the psychological distress that could lead to suicide (Robbins & Broyles).

Is the anxiety and suffering exhibited by persons with GD relieved by sex reassignment? Surveys show transgender adults express an initial sense of relief and satisfaction following the use of cross-sex hormones and sex reassignment surgery. Cross-sex hormone administration and surgeries to align appearance with a sex-discordant gender identity have been used in Sweden for many years. A thirty-year follow-up study of 324 sex reassigned adults found "substantially higher rates of overall mortality, death from cardiovascular disease and suicide, suicide attempts and psychiatric hospitalizations in post-surgical transsexuals as compared to a healthy control population" (Dhejne, et al., 2011).

Evidence of regret from so called de-transitioners, who have undergone sex reassignment procedures as children or adolescents is surfacing. These individuals claim they were coerced into sex reassignment when most vulnerable and immature, and when uninformed of consequences. Some are initiating lawsuits against medical practitioners and medical organizations who provided such interventions (Independent Women's Forum).

Children are the victims of this disturbing and irresponsible experiment, as misguided adults impose a confused ideology on the most innocent and vulnerable. Children cannot legally consent; they have neither the maturity nor the life experience to make decisions that will permanently affect them for the rest of their lives. A parent who convinces his or her child that he or she was born into the wrong body is committing a grievous error.

The U.S. Department of Health and Human Services Organization has stated that: "For transgender and non-binary children and adolescents, early gender affirming care is crucial to overall health and well-being as it allows the child or adolescent to focus on social transitions and can increase their confidence while navigating the health care system" (HHS, 2022). Promoting sex reassignment via public education and legal policies will further harm children and confuse parents.

Additional Considerations

Theological

Church doctrine is clear that human beings are created by God, male and female (Gn 1:27; CCC, nos. 355–357, 369, 373, 1604, 1701–1702, 2331). The two sexes are complementary; the union of their bodies results in a third human person; the species thrives (Gn 1:28, 2:18–24; CCC, nos. 369–372, 1604–1605, 1643, 1652, 2331–2335, 2360–2370). The body is an intrinsic dimension of our human nature (CCC, nos. 362, 364, 2289). To reject the essentiality of the body is to reject God's

gift and reflects the pretense of the confused human being through a pure act of the will. It is the ultimate form of rebellion against creation (CCC, nos. 2280, 2290).

Human beings are a body-and-soul unity with a single nature (USCCB 2023, no. 4). The body is a gift of God, created in His image, and therefore, declared to be very good (USCCB 2023, no. 7). The body is to be respected and cared for since it is intrinsic to the person. Sexual differentiation is an essential part of this embodiment (USCCB 2023, no. 5). All must respect the order and finality of this embodiment. No one, including patients, physicians, and researchers, have unlimited rights over the body. We are not owners of our bodies to use them as tools according to our will, to be manipulated just because we can (USCCB 2023, no. 7). Just because it can be done does not mean it should be done.

Ethical

The present "treatment" of GD is contrary to the nature of medicine. It denies the very essence of the human person who is an integrated entity of body and soul. Such a denial is perpetuated by language that negates this reality by the erroneous use of pronouns, and the fostering of dress and behaviors that are intended to affirm this denial. New developments in addressing gender dysphoria in children are concerning in terms of violating fundamental parental rights and upending long standing jurisprudence. Policies to undermine the rights and obligations of parents or guardians, particularly in the public-school systems, in no way are to be endorsed. Children lack the full decisional capacity for such serious issues and are dependent upon engaged parents/guardians to consent or refuse potentially life-altering psychological, medical, or surgical actions.

Technological

Furthermore, technology should never be used to mutilate the human person. Technology, whether medical or surgical, is properly used when repairing a defect caused by injury or illness or to sacrifice a part for the whole. To allow a part to be sacrificed, three conditions must be fulfilled: (1) "The retention or functioning of a particular organ causes serious damage to it or constitutes a threat" to the whole organism. (2) "This damage cannot be avoided, or at least appreciably diminished, otherwise than by the mutilation in question and the effectiveness of the mutilation is well assured." It is a last resort. (3) "It can reasonably be expected that the negative effect, i.e., the mutilation and its consequences, will be compensated for by the positive effect: removal of the danger for the whole organism, lessening of suffering, etc." (USCCB 2023, no. 12). This loss is recognized as an evil to be tolerated.

The present medical and surgical "treatments" of GD do not meet these criteria. The organs are not causing serious damage nor threatening the whole organism and so none of the conditions are fulfilled. There is no defect because the organs are physiologically healthy and functioning normally. Nor is this a reluctant sacrifice of a body part, such as orchiectomy to treat prostate cancer. It is a deliberate, intentional attempt to transform the body to mimic the characteristics of

the opposite sex by mutilating it. In effect, the functioning of the healthy organs (reproduction) is destroyed, and the mutilation effects a cosmetic function if any at all. It is the refusal to recognize that the sexual organs have essential roles within the embodiment of the human person.

Authentic Health Care

This attempt to address surgically and with hormones what should be treated psychiatrically with counseling is not authentic health care. Health care professionals must not affirm what is not true. Cognitive Based Therapy (CBT) has been shown to be useful in treating other body dysphoria disorders associated with increased risk of death, such as anorexia nervosa. Persons with GD would benefit from such treatment of depression and anxiety along with aggressive counseling and medications directed to those conditions.

A health care professional who counsels a parent and child seeking support in the sex reassignment process needs to inform the parent of the risks and side effects of puberty blockers and cross-sex hormones, and of sex-reassignment surgeries. The plan of care should involve both physician and mental health specialist. It is inappropriate to refer the child to a “Gender Clinic.” This likely will result in rapid enrollment of the child into the sex reassignment process, frequently with little mental health oversight.

Sex reassignment does not respect the fundamental order of the human person with a body-and-soul unity. Treatments that do not respect this unity ultimately harm the human person. The ideology underlying GD is harmful since it declares that people can remake themselves according to how they feel. Solutions must be found that promote human flourishing, respect one’s own bodily integrity and are in concordance with the sex inscribed in one’s body. This is especially true for Catholic health care which is part of the healing ministry of Jesus. That means providing treatments directed to the healing of the whole person: physical, mental, and spiritual.

A first principle of medicine is “First, do no harm.” The sex reassignment movement is a vast, unregulated experiment based on studies with a high drop-out rate, non-randomized control studies, and no long-term studies past the first five years for interventions that are structurally and/or functionally mutilating and have long term and irreversible consequences.

Responding with Unconditional Love

Parents and guardians must show unconditional love if confronted with a child who professes to be transgender and demands affirmation which denies the reality of biological sex. Parents and guardians must be free to determine how best to address lovingly this challenge through informed consent that is not obstructed by policies that deny that right. It is best to enter into dialogue and allow the child to tell his or her story. At the same time, the parent should gently inform the child of the correct scientific data.

It is essential that concurrent treatment be given by a mental health specialist who will address the mental disorder of the child according to correct understanding of the nature of the human

person. Parents should unite and work together to advocate for appropriate and effective treatments that affirm truths about the integrity of the human person as a sacred unity of body and soul.

Call to Action

The Catholic Medical Association calls on the medical organizations that promote the practice of sex reassignment of children with GD to reverse their decision. These organizations should consider the profoundly harmful long-term physical and psychological damage that awaits these children as they grow into adulthood.

GD is a psychiatric disorder that should be treated by a mental health specialist with the cooperation of loving parents. The practice of sex reassignment as the treatment of choice for children who show confusion with their sexuality is not ethically permissible and should be discontinued.

Furthermore, physicians and other health care professionals of conscience, who wish to promote the best interest of their patients, must be free to do so without policies that threaten their ability to practice medicine (Catholic Medical Association, 2021). As with all conflicts in medical ethics, the conscience of a clinician, enlightened by Catholic teaching on the sacredness of human life and the dignity of human persons, should never be coerced to violate the clinician's medical and moral judgement in the care of a patient.

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Revised and Approved by the Executive Committee – October 16, 2023

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Dkt. 1-4

Exhibit 4

IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF FLORIDA
TAMPA DIVISION

State of Florida, et al., *Plaintiffs*, v. **U.S. Department of Health and Human Services,** et al., *Defendants*.	)	**Civil Action No. _____**

DECLARATION OF MICHAEL S. PARKER, M.D.

I, Michael S. Parker, M.D., declare:

1. I am over 21 and I am fully competent to make this declaration.

2. These facts are true, correct, and within my personal knowledge. If called to testify, I could and would testify competently to them.

3. I am a board-certified OB/GYN hospitalist serving female Medicare and Medicaid patients in labor & delivery and emergency room (ER) settings at OhioHealth Mansfield Hospital in Mansfield, Ohio. I work as an OB Hospitalist employed by Pediatrix Medical Group of Ohio, part of Pediatrix Medical Group. My hospital collects patient insurance information, and my physician group handles insurance reimbursement.

4. I helped establish the Order of Malta Center of Care in Columbus, Ohio. We give free medical care to the homeless and underserved.

5. I am a member of the Catholic Medical Association (CMA) and the American Association of Pro-Life Obstetricians and Gynecologists (AAPLOG) but I am not a member of the Christian Employers Alliance, or the Christian Medical & Dental Associations. I share CMA's and AAPLOG's positions. I have served CMA as President, and I am now its Assistant

Parliamentarian.

6. I provide care with respect and without unlawful discrimination.

7. I will not provide or refer for "gender transitions."

8. I categorically object to providing, referring for, or affirming any procedures to "transition" a patient's gender.

9. I categorically oppose asking for or using a patient's self-selected gender identity or pronouns for any purpose, including for coding or charting.

10. I categorically oppose allowing males in female private spaces, or vice versa, or following a policy that says (or is interpreted by federal rules to mean) that I do not "discriminate" based on gender identity.

11. I hold these positions as a matter of sound medical judgment, Catholic religious exercise, and conscience. I want to be free to follow and share my views. I do not want to be coerced to do wrong and I cannot harm my patients.

12. In my past OB/GYN practice for females, I regularly provided medically indicated hysterectomies and provided medically indicated estrogen and testosterone hormones. I am board-certified to provide these services and I may do so again in the future if the clinical setting presents itself. I do not and will not provide these services for gender-transition purposes. Nor will I violate Ohio state law regulating these procedures.

13. I routinely record all my OB/GYN patients as female. My regular practice is to use the correct biological and binary pronouns: she/her.

14. I at times treat patients who identify as transgender, non-binary, or otherwise contrary to their sex. I have cared for such a patient who was in labor having a baby. I also see female ER patients identifying as males. These patients may expect me to describe them in ways contrary to sex. In conversation, I use the patient's preferred name and avoid pronouns. In

charts, I use biological pronouns, while noting that the patient is a biological female who identifies as male or who has gender dysphoria.

15. I do not—and will not—call a woman giving birth "a man." In the past, hospital colleagues have said men could get pregnant and said that a certain patient was a man who was pregnant. I corrected them: the patient was a woman who was pregnant. Every time I encounter this issue, I want to be free to explain that only females can get pregnant and give birth.

16. At my hospital we provide patients with access to male, female, and unisex restrooms. I do not and will not facilitate male patient access to restrooms designated for females, or vice versa, based on gender identity.

17. I serve a rural, underserved population with high unemployment and drug addiction. Most female patients are of reproductive age.

18. I have spent time planning to avoid liability under the new rule.

19. The rule will force my hospital and my physician group to require me to follow a "nondiscrimination" policy on gender identity and to attend training on such a policy. But for the rule, this would not be a condition of my employment. I will not agree to follow this policy. I would rather be fired than harm my patients.

20. I do not want to attend training on this policy. But I will attend training on such a policy as required or scheduled. If the rule did not require this training, I would not attend.

21. When I have to decide whether to follow the rule—or risk losing my job and my patients—I won't know whether the federal government will exempt my hospital, my physician group, or me.

I declare under 28 U.S.C. § 1746 and under penalty of perjury that this declaration is true and correct based on my personal knowledge.

Executed this 5 day of May, 2024 at Galena, Oh.

Michael S. Parker, M.D.

Dkt. 1-5

Exhibit 5

IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF FLORIDA
TAMPA DIVISION

State of Florida, et al. *Plaintiffs*, v. **U.S. Department of Health and Human Services**, et al., *Defendants*.	)	**Civil Action No. _____**

DECLARATION OF QUENTIN L. VAN METER, M.D.

I, Quentin L. Van Meter, M.D., declare as follows:

1. I am over 21 and I am fully competent to make this declaration.

2. These facts are true, correct, and within my personal knowledge. If called to testify, I could and would testify competently to them.

3. I am a pediatric endocrinologist seeing Medicaid and CHIP pediatric patients at my independent practice, Van Meter Pediatric Endocrinology, P.C., in Atlanta, Georgia. If my patients need hospitalization, I provide care at two local hospitals that receive Medicaid and CHIP funding.

4. I hold a medical degree from the Medical College of Virginia. I completed a pediatric internship and a pediatric residency at the Naval Regional Medical Center in Oakland through the University of California, San Francisco. I completed a pediatric endocrinology fellowship at Johns Hopkins University School of Medicine. I am a former adjunct associate professor of pediatrics at Emory University School of Medicine and a former clinical associate professor of pediatrics at Morehouse School of Medicine.

5. I am a member of the Catholic Medical Association (CMA) and the American College of Pediatricians (ACPeds) but I am not a member of the

Christian Employers Alliance or the Christian Medical & Dental Associations. I share CMA's and ACPeds' positions. I am ACPeds' Past President, and I serve on its board. Through ACPeds and CMA, I have long been a prominent international advocate against the harms of "gender-transition" procedures.

6. I care for all patients with respect and without unlawful discrimination. No matter how a patient identifies, I am his or her advocate and friend.

7. But I will not provide or refer for gender-transition procedures. It is a scientific fact, which informs my medical judgment, that puberty blockers and cross-sex hormones combined will sterilize many youth and cause them to develop serious chronic illnesses such as diabetes, heart disease, stroke, and cancers.

8. I categorically object to providing, referring for, or affirming any procedures to "transition" a patient's gender.

9. I categorically oppose asking for or using a patient's self-selected gender identity or pronouns for any purpose, including for coding or charting.

10. I categorically oppose allowing males in female private spaces or vice versa.

11. I categorically oppose adopting, following, or providing a policy or notice that says (or is interpreted by federal rules to mean) that I do not "discriminate" based on gender identity.

12. I hold these positions as a matter of sound medical judgment as well as sincere Catholic religious exercise and conscience. If the government requires me to speak or act against these positions, it would seek to stop me from speaking and acting in the way my medical judgment and my religious faith requires of me.

13. I regularly provide puberty blockers and sex hormones for medical reasons. I prescribe puberty blockers to treat precocious puberty. I prescribe hormone replacement therapy for delayed puberty or for children who will never go through puberty on their own due to a deficiency. But as a matter of sound medical judgment and good conscience, I do not and will not provide puberty blockers or hormones for gender-transition purposes.

14. I have cared and continue to regularly care for patients who identify as transgender, non-binary, or otherwise contrary to their sex, as well as patients who struggle with gender incongruence. I reasonably expect to see more future patients who identify in this way walk in my office door. I provide the same high-quality medical care to these patients as I do to all my patients, whether it is for diabetes or any other medical condition.

15. I have received patient requests to provide puberty blockers and cross-sex hormones for gender-transition purposes. I have been asked to give puberty blockers or cross-sex hormones to at least twelve pubertal children. About half of the parents asked for puberty blockers, and about half asked for both puberty blockers and cross-sex hormones as a pair. I expect to keep receiving similar patient requests, but I could not provide such procedures with sound medical judgment or in good conscience.

16. Families at times seek my medical opinion when they wish to evaluate whether a child should start gender-transition procedures. I have freely shared my complete medical judgment on such procedures with these patients. I explain that there are no sound studies or reliable data proving that such procedures are safe or helpful. I want to remain free in my practice to follow and share my views. I will not self-censor my medical opinions in patient consultations.

17. I regularly use pronouns for patients that accord with biological and binary sex. I code and chart patients by sex. I do not and will not ask for self-selected pronouns. I do not and will not use pronouns contrary to biology.

18. I am regularly asked by patients to use self-selected pronouns contrary to a patient's sex in conversation or in medical records. Because I am the patient's advocate, when I speak with these patients, I try to use names or nicknames for such patients, and I try to avoid pronouns, but I do not always succeed at avoiding pronouns in these conversations. Outside the presence of the patient, I speak about the patient using biological pronouns.

19. I provide access to male and female restrooms for patients and their visitors. Within our medical building, I have a single unisex restroom in my office, and I provide access to male and female restrooms in the hallway outside of my office. On the doors of these restrooms, it says "men" and "women." I understand these signs to refer to a person's biological and binary sex. Because of safety, dignity, privacy, and conscience concerns, I do not and will not ensure access to these facilities by gender identity. I do not and will not facilitate male patient access to restrooms designated for females, or vice versa, based on gender identity.

20. I left a multi-specialty clinic in 2003 to found my own practice to better care for the increasing number of pediatric patients with endocrine needs. We have several staff members. I am proud to say that my youngest daughter works as a nurse practitioner in my office.

21. I direct and manage all operations within my office. No person other than me exercises oversight over medical care for patients. I am solely responsible for office policy and for deciding what notices to give patients.

22. With the administrative help of my staff, my practice bills for Medicaid. My affiliated hospitals also serve Medicaid patients. To the best of

my knowledge, each time when we signed up to obtain credentials to receive Medicaid funding, we provided all required paperwork, including signing any required assurances of compliance with federal regulations.

23. I have adopted an official policy statement for my office that explains that I do not offer, refer for, or endorse gender-transition efforts.[1] I have attached this policy statement to this declaration as Exhibit A.[2]

24. I currently inform patients and potential patients on my office website that I do not offer, refer for, or endorse gender-transition efforts by posting my policy statement.

25. I want to, but out of compliance with the rule on its specified dates, will no longer inform patients and potential patients about this policy on my website. If the court does not protect me from the rule, I will remove my policy statement from my office website in compliance with the rule.

26. The rule forces me to adopt a new "nondiscrimination" policy for my office. This new policy must be consistent with the redefinition of sex to include gender identity, and I must revise all my policies to ensure that they are consistent with following the rule's requirements.

27. The rule will make me force all my employees to follow such a policy. Then my staff and I will have to give patients notice of such a policy and post the policy prominently in our office. My affiliated hospitals also must adopt and make me follow such a policy. I will refuse to adopt, post, or

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[1] Our policies for patients seeking information and guidance are available on our office policies page: Van Meter Pediatric Endocrinology, Office Policies, https://www.pediatricendo.com/policies.

[2] Ex. A, Van Meter Pediatric Endocrinology, https://www.pediatricendo.com/_files/ugd/68c6d3_1606b8fdc36e4d948bb0dd7733291ef5.pdf.

follow such a policy. Nor will I make my staff members, including my daughter, do so.

28. The rule will force me to provide training on such a "nondiscrimination" policy to myself and to all employees to ensure my office's compliance with the rule's mandatory gender-identity policy. My affiliated hospitals also must make me attend training on such a policy. But for the rule, this training would not be a condition of federal funding or of my admitting privileges.

29. I will not arrange or provide this training. I will not reeducate myself, nor will I reeducate my employees, including my daughter. Nor will I attend this training when scheduled by my hospitals on the rule's mandatory gender-identity policy.

30. I adamantly object to attending training on such a policy. The government should respect the views of a doctor like me. But the purpose of this government-ordered training is to target my deeply held views for elimination from the medical profession. By this mandate, the government seeks to make me a captive audience, to pressure me publicly at length to change my medical practice, and to coerce me to adopt a policy at odds with my beliefs. I will not undergo this coercion. Indeed, given my uncompromising international public advocacy against gender-transition procedures, the message I would risk sending by submitting to this training is that I yield to the rule's policy. This message would compromise my integrity, including the integrity of my public advocacy. Being forced to provide or attend this training thus would substantially burden me in the free exercise of my medical judgment, my conscientious objections, and my religious beliefs.

31. If the rule goes into effect, each time I request Medicaid payment, the federal government will deem me to be certifying that my office complies with the rule. But we will not be in compliance with the rule's gender-identity

requirements. So arguably neither I, nor any other person, can make a certification on my behalf without making a misleading statement. I will not knowingly make a false statement or claim to the government.

32. Because I earn income based on the number of patients I see, I will bear the financial cost of the rule's compliance requirements in terms of my lost hours and productivity (not to mention lost staff productivity). I typically receive $350 per hour in income for my time. So, for example, if the training takes me away from patients for an hour, I will lose $350 in lost income. Or, for instance, if I have to work overtime to revise policies and plan training, I will personally lose the same value for each hour of extra uncompensated work.

33. I have already spent time and resources to learn about the rule. It has taken me at least an hour to read the rule, to obtain compliance guidance, and to form plans (as described in this declaration) to significantly change my daily medical practice to avoid noncompliance. My preparations to avoid noncompliance with the rule already resulted in $350 in lost value for my time. (This figure does not count time preparing for CMA to litigate on my behalf.)

34. If the rule goes into effect, I will spend even more resources to avoid noncompliance. I estimate that it would take me at least two hours to revise my policies to comply with the rule, at least one hour to plan training and create an attendance sign-up sheet, and at least one hour to provide training to staff on new policies. I estimate that it then would take me an hour over the next year to keep training records and patient grievance records. I would not spend my time in this way but for the rule.

35. Georgia restricts gender-transition procedures. The rule forces me to choose between following the rule or following state law. I will not violate state law or harm my patients.

36. I also will not knowingly violate federal regulations or my conscience. So if a court does not protect me from the rule and I am not exempt, I will have no choice but to take steps to stop seeing Medicaid and CHIP patients.

37. I have a well-established medical practice with many ongoing patients. My patients rely on me for specialist care for endocrine conditions like diabetes, and I rely on them, on insurance, and on Medicaid for revenue. I rely on my affiliated hospitals as an avenue for me to hospitalize patients as needed. About seven percent of my patients are Medicaid patients.

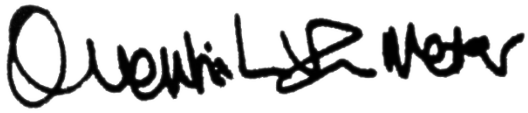
38. I do not want to stop seeing Medicaid or CHIP patients or to stop being affiliated with local hospitals, but I would rather stop seeing Medicaid or CHIP patients and lose my local hospital affiliations than adopt a policy under which I would harm a patient.

39. If I cannot participate in Medicaid or CHIP, if I lose my hospital affiliations, or if I have to close my office doors due to the burdens of government regulations, investigations, and penalties, my patients would suffer the loss of their trusted doctor and I would lose my income derived from Medicaid or CHIP, which will cause me a significant financial loss. My patients will be unexpectedly without care at a time when there is already a nationwide shortage of doctors accepting Medicaid patients.

40. When I have to decide whether to follow the rule—or risk losing my Medicaid and CHIP patients, my hospital affiliations, and my livelihood—I won't know whether my hospitals and my practice will be required to follow the rule's requirements.

I declare under 28 U.S.C. § 1746 and under penalty of perjury that this declaration is true and correct based on my personal knowledge.

Executed May 5, 2024 at Atlanta, Georgia



Quentin L. Van Meter, M.D.

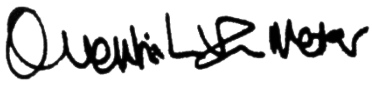
EXHIBIT A

Office Policy 2024 Regarding Patients seeking information and guidance on abortion

1. We value all human lives equally. We oppose prematurely ending the life of any child at any stage of development from conception to natural death.
2. We will not refer pregnant patients for abortion to any abortion facility. We will, instead, caringly give such patients information about prenatal care, including, if needed, information about a pregnancy care center.
3. We will not prescribe mifepristone as an abortifacient and will reserve its use to treatment of adrenal disease.

Office Policy 2024 Regarding Patients under the age of 18 years who identify as the opposite sex

1. We treat all patients and visitors with respect. No matter how a patient identifies, we are the patient's advocate and friend.
2. We will welcome, compassionately, all patients who are experiencing gender dysphoria.
3. We will follow the best evidence-based standards of care including appropriate physical examinations.
4. We will use our discretion in ordering any bloodwork and x-rays.
5. We will request that the patient's family give their consent to share the records of other care providers who have treated the patient.
6. We will take extensive medical and mental health histories with specific attention to documentation of all adverse childhood experiences (ACE's). We will refer patients to vetted mental health care professionals if they have had no prior mental health assessment, or if we feel the current mental health professionals are pushing for social, medical, or surgical interventions for the purpose of changing the patient's persona.
7. No long-term study demonstrates the safety or efficacy of puberty blockers, cross-sex hormones and surgeries for youth who identify as the opposite sex or as non-binary. These "gender-transition" procedures are experimental, and therefore, neither parents nor minors can provide informed consent. Moreover, the best long-term evidence we have among adults shows that medical intervention fails to reduce suicide.
8. Our focus will be on the well-being of the patient using the Hippocratic principle of Do No Harm. Therefore, we will not prescribe GnRH agonists to interrupt normally timed puberty, and we will not use wrong-sex hormones or refer to surgeons who intend to remove healthy body parts.
9. We will use correct biological and binary terminology to refer to patients in conversation and in medical records, and we will not use biologically incorrect pronouns. We welcome all patients and visitors to our facility based on the patient's sex as a biological male or female.



Quentin L. Van Meter, M.D.

Dkt. 12

IN THE UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
TAMPA DIVISION

STATE OF FLORIDA; FLORIDA AGENCY FOR HEALTH CARE ADMINISTRATION; FLORIDA DEPARTMENT OF MANAGEMENT SERVICES; CATHOLIC MEDICAL ASSOCIATION, on behalf of its current and future members,

Plaintiffs,

No. 8:24-cv-1080-WFJ-TGW

DEPARTMENT OF HEALTH AND HUMAN SERVICES; XAVIER BECERRA, in his official capacity as Secretary of the Department of Health and Human Services; MELANIE FONTES RAINER, in her official capacity as the Director of the Office for Civil Rights; CENTERS FOR MEDICARE AND MEDICAID SERVICES; CHIQUITA BROOKS-LASURE, in her official capacity as Administrator of the Centers for Medicare and Medicaid Services,

Defendants.

MOTION FOR STAY OR PRELIMINARY INJUNCTION

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INTRODUCTION

In the Affordable Care Act ("ACA"), Congress incorporated by reference several anti-discrimination provisions, including Title IX's prohibition against discriminating "on the basis of sex." Title IX includes many permissible sex-based distinctions. For example, it allows covered entities to separate living spaces based on sex. The Department of Health and Human Services ("HHS") now claims to have discovered in this ordinary non-discrimination law the extraordinary power to promulgate rules (1) *forbidding* longstanding policies or practices of separating private medical spaces based on sex whenever that policy or practice comes into conflict with an individual's "gender identity," and (2) *compelling* States to allow and even pay for controversial "gender-transition" interventions, including the removal of healthy reproductive organs.

HHS's attempt to drastically expand the contours of sex discrimination runs headlong into binding Eleventh Circuit precedent. The Eleventh Circuit has held that (1) Title IX unambiguously does not protect gender identity, and (2) banning gender-transition interventions is not discriminating "on the basis of sex," the same words used in Title IX. *See Adams ex rel. Kasper v. Sch. Bd. of St. Johns Cnty.*, 57 F.4th 791 (11th Cir. 2022) (en banc); *Eknes-Tucker v. Governor of Ala.*, 80 F.4th 1205 (11th Cir. 2023). At a minimum, the ACA does not clearly authorize HHS's new rules, as required under Congress's spending power. The rules will also impose immediate and irreparable harm on Plaintiffs by forcing them to incur irrecoverable costs and by

unlawfully pressuring Florida to surrender its sovereign interests. The rules should be stayed, or Defendants should be enjoined.

BACKGROUND

I. Section 1557

Congress has "power under the Spending Clause of the Constitution to set the terms on which it disburses federal funds." *Cummings v. Premier Rehab Keller, P.L.L.C.*, 596 U.S. 212, 216 (2022). Using this power, "Congress has passed a number of statutes prohibiting recipients of federal financial assistance from discriminating based on certain protected characteristics." *Id.*

Section 1557 of the ACA is such a statute. *Id.* at 218. Section 1557 prohibits discriminating in health programs or activities "on the ground prohibited under," among other laws, "title IX of the Education Amendments of 1972 (20 U.S.C. 1681 et seq.)." 42 U.S.C. § 18116(a). Title IX, in turn, prohibits discriminating "on the basis of sex." 20 U.S.C. § 1681(a).

II. The 2024 Rules

On May 6, 2024, HHS promulgated rules purporting to implement Section 1557. Ex. A, 89 Fed. Reg. 37,522 (May 6, 2024) ("2024 Rules") (excerpts). HHS declines to "define 'sex'" in the 2024 Rules, *id.* at 37,575, but nevertheless interprets "[d]iscrimination on the basis of sex" to include discriminating based upon, among other things, "[g]ender identity," *id.* at 37,699, *to be codified at* 45 C.F.R. § 92.101(a)(2). HHS does not define "gender identity" either, *id.* at 37,577, but explains that the term can encompass a "full range of identities," *id.* at 37,592, including "transgender,"

"nonbinary," "gender nonconforming," "genderqueer," or "genderfluid," 87 Fed. Reg. 47,824, 47,867 (Aug. 4, 2022) ("NPRM").

HHS then uses this definition of sex discrimination as a launching pad to decide matters of significant public debate. Specifically, the 2024 Rules purport to prohibit separating private spaces in healthcare facilities based on sex, and threaten any covered entity that opposes "gender-transition" interventions—such as puberty blockers, hormones, and "bottom" surgeries—that may lead to infertility and other harms to public health. Anyone in the health care sector who disagrees with HHS on these contentious medical and ethical questions, including States, now risks the loss of all HHS federal financial assistance. Compl. ¶¶ 43–46, 154, 189. The 2024 Rules also add controversial prohibitions against discriminating based on gender identity in the Medicaid and Children's Health Insurance Program ("CHIP") regulations. 89 Fed. Reg. at 37,667–68. HHS claims its rules will "preempt" any conflicting state law. *Id.* at 37,535.

A. Separate Facilities

Florida, like many other States, holds to the longstanding view that separating intimate private spaces in public buildings based on male or female sex, or providing single-occupant facilities, best protects the safety and privacy of its residents. *See* Fla. Stat. § 553.865(5), (12).[1]

[1] Sex means male or female as determined by biology. *See* Fla. Stat. § 553.865(3)(*l*); *Adams*, 57 F.4th at 812; Compl. ¶¶ 62–63. It should not be confused with "gender identity." Compl. ¶ 64.

HHS disagrees and attempts to stretch Section 1557 to force compliance with its policy views. The 2024 Rules interpret "on the basis of sex" to forbid "any policy or practice" that prevents an individual from being treated "consistent with the individual's gender identity," if this causes the individual more than *de minimis* harm, a malleable concept that includes emotional or dignitary harm. 89 Fed. Reg. at 37,701, *to be codified at* 45 C.F.R. § 92.206(b)(3). HHS notes that preventing a male who identifies as a woman from sharing a dual-occupancy hospital room with a female "would result in more than *de minimis* harm." *Id.* at 37,593; NPRM, 87 Fed. Reg. at 47,866–67 (same).

B. Gender-Transition Interventions

1. The Debate

In recent years, a growing number of individuals, especially minors, have been diagnosed with "gender dysphoria," Compl. ¶ 84, a condition previously known as a "gender identity disorder," Compl. ¶¶ 68–71. Gender dysphoria is defined as distress resulting from a discordance between a person's sex and sense of "gender identity." Compl. ¶ 69.

There is an ongoing "debate" about how best to treat gender dysphoria and related conditions, especially in minors. *See L.W. v. Skrmetti*, 83 F.4th 460, 471–72 (6th Cir. 2023). Advocacy groups such as the World Professional Association for Transgender Health ("WPATH") promote what they call "gender-affirming care," a protocol of social, hormonal, and surgical interventions aimed at altering a person's physical characteristics to better accord with the person's sense of "gender identity."

Compl. ¶¶ 72–108. But "the WPATH Standards of Care reflect not consensus, but merely one side in a sharply contested medical debate." *Gibson v. Collier*, 920 F.3d 212, 221 (5th Cir. 2019). Many experts, States, and countries, while supporting mental health treatment and compassion, believe the gender-transition protocol recommended by WPATH and other organizations is experimental, harmful, and unethical. Compl. ¶¶ 106–29.

WPATH claims these interventions are necessary to promote mental wellbeing and prevent self-harm, but "no one disputes that these treatments carry risks or that the evidence supporting their use is far from conclusive." *L.W.*, 83 F.4th at 489; Compl. ¶¶ 85–108 (noting risks). Indeed, HHS noted just four years ago that there is a "lack of high-quality scientific evidence supporting such treatments." 85 Fed. Reg. 37,160, 37,187 (June 19, 2020); *see also Vazzo v. City of Tampa*, 415 F. Supp. 3d 1087, 1103–04 (M.D. Fla. 2019) (Jung, J.) ("Formal epidemiologic studies on gender dysphoria in children, adolescents, and adults are lacking").

Florida's public health authorities, its legislature, and its medical boards, have concluded that the putative psychological benefits of gender-transition interventions are too speculative to justify the health risks, particularly for minors lacking the ability to consent. Compl. ¶¶ 109–29. Florida has therefore enacted laws, standards of medical care, and regulations limiting these experimental interventions, promoting informed consent, and preventing public spending on interventions that, in Florida's considered judgment, do more harm than good. *See* Fla. Stat. §§ 286.311, 456.001,

456.52; Fla. Admin. Code r. 59G-1.050(7), r. 64B8-9.019, r. 64B15-14.014; *see also* Compl. ¶¶ 109–29 (describing these laws and regulations).

2. The 2024 Rules

In the 2024 Rules, HHS seeks to end any debate by establishing gender-transition as *the* uniform, federal standard of medical care. *See* NPRM, 87 Fed. Reg. at 47,868 & n.423 (asserting covered entities "should follow clinical practice guidelines and professional standards of care" and citing WPATH). The 2024 Rules make it presumptively discriminatory for covered entities, such as hospitals, clinics, medical practices, and pharmacies, to "[d]eny or limit" puberty blockers, cross-sex hormones, or surgeries "sought for purpose of gender transition," so long as those entities provide the services for "other purposes." 89 Fed. Reg. at 37,701, *to be codified at* 45 C.F.R. § 92.206(b)(4). For example, if a surgeon performs an orchiectomy (surgical removal of the testicles) to treat testicular cancer, he is presumptively required to remove healthy testicles for a "gender transition." *Id.*; *see also* NPRM, 87 Fed. Reg. at 47,867.

A covered entity that refuses to further a gender transition may avoid sanctions only if HHS deems a refusal "clinically appropriate *for a particular individual*." 89 Fed. Reg. at 37,701, *to be codified at* 45 C.F.R. § 92.206(c) (emphasis added). Repeatedly, HHS emphasizes that covered entities must make an "*individualized* clinical judgment." *Id.* at 37,575, 37,595–97 (emphasis added). A general policy against gender-transition interventions is necessarily not "individualized," and would therefore risk enforcement proceedings and punishment.

Confirming this understanding, HHS says that speech referring to gender-transition interventions as "experimental or cosmetic" would alone "be considered evidence of pretext because this characterization is not based on current standards of medical care"—i.e., WPATH's say-so. NPRM, 87 Fed. Reg. at 47,874. And covered entities must have "demonstrated a willingness to refer or provide accurate information about gender-affirming care." 89 Fed. Reg. at 37,598. In other words, doctors must assist gender-transitions through referrals and avoid advice HHS might deem "disinformation."

Similarly, States and insurers must subsidize gender transitions. The 2024 Rules make it presumptively discriminatory for insurers and other entities—including States—to set "limitations or restrictions" on claims "for specific health services related to gender transition" if doing so "*results in* discrimination on the basis of sex." 89 Fed. Reg. at 37,701, *to be codified at* 45 C.F.R. § 92.207(b)(5) (emphasis added); *see also id.* at 37,691, *to be codified at* 42 C.F.R. § 438.3(d)(4) (requiring Medicaid service contracts to prohibit policies or practices with a discriminatory "effect" on "gender identity").

An insurer or State may avoid sanctions by showing no "medical necessity" in a particular case. But the 2024 Rules prohibit a "categorical coverage exclusion … for all health services related to gender transition." 89 Fed. Reg. at 37,701, *to be codified at* 45 C.F.R. § 92.207(b)(4), (c). In other words, HHS has already determined that "gender transition" is medically necessary, and that disagreeing with HHS's view on this issue is discriminating on the basis of sex.

ARGUMENT

A party seeking a preliminary injunction must show that "(1) it has a substantial likelihood of success on the merits; (2) irreparable injury will be suffered unless the injunction issues; (3) the threatened injury to the movant outweighs whatever damage the proposed injunction may cause the opposing party; and (4) if issued, the injunction would not be adverse to the public interest." *Siegel v. LePore*, 234 F.3d 1163, 1176 (11th Cir. 2000) (en banc). To establish a "substantial likelihood of success on the merits," Plaintiffs need only show its claims are "*likely* or probable" to succeed. *Schiavo ex rel. Schindler v. Schiavo*, 403 F.3d 1223, 1232 (11th Cir. 2005).

The Administrative Procedure Act ("APA") also provides that "to the extent necessary to prevent irreparable injury, the reviewing court … may issue all necessary and appropriate process to postpone the effective date of an agency action." 5 U.S.C. § 705. The same standard that governs preliminary injunctions governs a stay. *Sampson v. Murray*, 415 U.S. 61, 68 n.15 (1974); *Cook Cnty. v. Wolf*, 962 F.3d 208, 221 (7th Cir. 2020).

I. Plaintiffs Are Likely To Prevail on the Merits

A. "Gender Identity" Is Not Protected by Section 1557

1. Eleventh Circuit precedent on Title IX controls this case

The 2024 Rules are premised on the notion that Title IX, and hence Section 1557 (which incorporates Title IX by reference), prohibits any discrimination based on "gender identity." 89 Fed. Reg. at 37,699, *to be codified at* 45 C.F.R. § 92.101(a)(2). That premise is inconsistent with binding precedent. *See Adams.*, 57 F.4th at 813–14.

In *Adams*, the Eleventh Circuit squarely confronted the question at issue here. The transgender plaintiff there argued that separating bathrooms based on sex, and thus denying access to a bathroom consistent with an individual's "gender identity," was discriminating based on sex under Title IX. *Id.* at 811. The plaintiff argued this followed from *Bostock v. Clayton County*, which held that an employer discriminates "because of sex" under Title VII of the Civil Rights Act of 1964 when he fires a male for no reason other than identifying as a woman, but "retains an otherwise identical employee" who is a female. 590 U.S. 644, 659–60 (2020).

The Eleventh Circuit rejected the argument. The Court began by noting that "sex" in Title IX, and hence in Section 1557, unambiguously means "biological sex" (male and female), and not "gender identity." *Adams*, 57 F.4th at 812–13. And although *Bostock* proceeded on the assumption that "sex" means biological sex, "the statutory context of Title IX" required a different result. *Id.* at 813. As the Court noted, Title IX is an equal-opportunity statute that, among other things, permits separating living facilities based on sex, which is inconsistent with protecting "gender identity." *Id.* at 814–15 & n.7. Specifically, Title IX provides that "nothing contained [in Title IX] shall be construed to prohibit any [covered entity], from maintaining separate living facilities for the different sexes." 20 U.S.C. § 1686; *Adams*, 57 F.4th at 811. If Title IX were read to protect "gender identity," then this provision "would be rendered meaningless" whenever it came "into conflict with a transgender person's gender identity." *Id.* at 813–14. "That conclusion cannot comport" with Title IX. *Id.* at 814. For the same reason, the Court rejected the transgender plaintiff's argument that

separating facilities based on sex is prohibited sex "stereotyping." *Id.* at 813. *Adams* therefore makes it "pellucid" that unlike Title VII, Title IX doesn't protect "gender identity." *D.N. by Jessica N. v. DeSantis*, No. 0:21-cv-61334, 2023 WL 7323078, at *13 (S.D. Fla. Nov. 6, 2023).

The Court also noted that Title IX, unlike Title VII, was enacted under the "Spending Clause." *Adams*, 57 F.4th at 815. "A safeguard of our federalist system is the demand that Congress provide the States with a clear statement when imposing a condition on federal funding." *Id.* That "clear-statement" rule provided an independent basis for rejecting the transgender plaintiff's argument, as Title IX certainly does not *clearly* protect gender identity.

HHS recognizes that "Section 1557 is best read to incorporate existing interpretations of what constitutes sex discrimination under title IX, including regulatory interpretations *and case law*." 89 Fed. Reg. at 37,638 (emphasis added). That case law includes *Adams*. The 2024 Rules, however, expand the concept of sex discrimination beyond the unambiguous text of Title IX, as interpreted by the Eleventh Circuit. Plaintiffs are therefore likely to prevail on the argument that the 2024 Rules are contrary to law.

2. HHS's attempts to avoid Title IX precedent fail.

HHS implicitly recognizes that *Adams* precludes HHS's reading of Section 1557. *See* 89 Fed. Reg. at 37,574 n.116 (citing *Adams* with a "*but cf.*"). Nevertheless, HHS attempts to circumvent that precedent by arguing that Section 1557's reference to "the ground prohibited under … title IX of the Education Amendments of 1972 (20 U.S.C.

1681 et seq.)," 42 U.S.C. § 18116(a), incorporates only the phrase "on the basis of sex," 20 U.S.C. § 1681(a), but "does not incorporate provisions of title IX or that statute's regulations that do not define or interpret what constitutes a ground of discrimination or an enforcement mechanism," 89 Fed. Reg. at 37,639. In other words, HHS believes Section 1557 adopts just Title IX's lone provision barring sex discrimination, shorn from Title IX's surrounding provisions explaining what sex discrimination means in context.

That approach doesn't withstand scrutiny. HHS acknowledges that Section 1557 "incorporate[s] existing interpretations of what constitutes sex discrimination under title IX, including … case law." 89 Fed. Reg. at 37,638. And as explained, that Title IX "case law" includes *Adams*, which "define[s]" what it means to discriminate on the basis of sex. *Id.* at 37,638–39. Section 1686, also at issue in *Adams,* defines how "on the basis of sex" "shall be construed" in Title IX, so it is relevant to defining the scope of the prohibited ground of discrimination. 20 U.S.C. § 1686. *Adams* is therefore relevant "case law" even under HHS's selective reading of Section 1557. 89 Fed. Reg. at 37,638. And *Adams* concludes that gender identity is not a protected ground of discrimination under Title IX. 57 F.4th at 814. "Because Title IX does not protect … 'gender identity' status, neither does Section 1557." *Neese v. Becerra*, 640 F. Supp. 3d 668, 684 (N.D. Tex. 2022).

In any event, Section 1557 is a Spending Clause statute, which means restrictions on funds must be clearly stated, and "the needed clarity under the Spending Clause 'must come *directly from the statute*.'" *West Virginia v. U.S. Dep't of Treasury*, 59

F.4th 1124, 1147 (11th Cir. 2023) (emphasis added). The Eleventh Circuit has already held that "on the basis of sex" in Title IX unambiguously does *not* include "gender identity," the exact opposite of clearly doing so. *Adams*, 57 F.4th at 814–15. Nor does Title IX *clearly* forbid separating private spaces based on sex. In fact, it expressly allows separating living facilities based on sex, and *Adams* held it allows separate bathrooms too. Therefore, even if there is some doubt about to what extent Section 1557 imports Title IX, Plaintiffs are still likely to prevail.

3. Even setting aside precedent, HHS's interpretation of Section 1557 is wrong.

The Court need go no further, but Plaintiffs nonetheless explain why HHS's reading of Section 1557 is wrong, even setting aside *Adams*.

It would have been quite easy for Congress to say in Section 1557 that any sex-based distinction is barred. But it didn't. Congress expressly incorporated *all* of "title IX" by reference, including not just the general prohibition against sex discrimination (20 U.S.C. § 1681(a)) but also the numerous separate provisions allowing for sex-based distinctions, insofar as they could be relevant to health programs and activities. *See* 20 U.S.C. §§ 1681(a)(2), 1681(a)(6)(B), 1681(a)(7)(A), 1681(a)(8), 1686. Congress even used "et seq.," which means "and the following," to confirm that the remaining provisions of Title IX applied. *Franciscan All., Inc. v. Burwell*, 227 F. Supp. 3d 660, 690 (N.D. Tex. 2016). HHS suggests Congress thoughtlessly put "et seq." in the statute, and that it has no "substantive" content. 89 Fed. Reg. at 37,532. Courts, however, do not lightly assume that statutory text is "meaningless." *Adams*, 57 F.4th at 813. When

Congress transplanted "title IX" into the ACA, it brought Title IX's "soil" with it, including its exceptions (and case law such as *Adams*). *SuVicMon Dev., Inc. v. Morrison*, 991 F.3d 1213, 1224 (11th Cir. 2021). Moreover, Congress knows how to reference only a single section of a law: it did so in Section 1557 itself. 42 U.S.C. § 18116(a) (incorporating "section 794 of title 29," part of the Rehabilitation Act of 1973). This difference must be presumed intentional. *Russello v. United States*, 464 U.S. 16, 23 (1983).

Incorporating Title IX makes good sense: Congress wanted to ensure a uniform regime with ready-made case law to promote clarity and certainty for funding recipients. There is no daylight between the scope of "on the basis of sex" in Title IX and Section 1557. Because Title IX does not protect "gender identity" status, neither does Section 1557.

B. Rejecting Gender-Transition Interventions Is Not Sex Discrimination.

Plaintiffs are likely to prevail for the independent reason that even if Section 1557 incorporates only Title IX's general prohibition against discriminating based on sex, the Eleventh Circuit has held that a State "does not discriminate based on sex" when it forbids hormonal treatments and surgeries for a gender transition. *Eknes-Tucker*, 80 F.4th at 1228. Although *Eknes-Tucker* involved the Equal Protection Clause, the Court's reasoning is binding here.

1. Eknes-Tucker's Reasoning Is Binding.

Eknes-Tucker involved a challenge to an Alabama law prohibiting gender-transition interventions in minors, particularly puberty blockers and cross-sex

hormones. *Eknes-Tucker*, 80 F.4th at 1210, 1227. The plaintiffs argued the law discriminated based on sex by referencing sex in the statute and by stereotyping based on gender "nonconformity." *Id.* at 1228.

The Eleventh Circuit held that "the statute does not discriminate based on sex." *Id.* As the Court noted, the law prohibited drugs used for a specific therapeutic purpose: "treating discordance between biological sex and sense of gender identity." *Id.* Any reference to sex or difference in treatment was due to the therapeutic purpose of the drugs coupled with basic biological facts about sex, which is not a stereotype. *Id.* at 1229. Only females can take supraphysiologic levels of testosterone for a gender transition, and only males can take supraphysiologic levels of estrogen for a gender transition. *Id.* at 1213, 1228. But acknowledging this reality is not discriminating.

Nor did the law stereotype based on sex by prohibiting interventions sought only by "gender nonconforming individuals." *Id.* at 1229. As the Court held, "the regulation of a course of treatment that only gender nonconforming individuals can undergo" is not stereotyping "based on sex" "unless the regulation were a pretext for invidious discrimination against such individuals." *Id.* at 1228–30. *Eknes-Tucker* therefore holds that absent a showing of animus, a ban on gender-transition interventions doesn't discriminate "based on sex," even when a law restricts interventions that are necessarily "sex-based." *Id.* at 1228.

The Court also distinguished *Bostock* on two grounds. First, the Court emphasized that the text of the Equal Protection Clause is different than the text of

Title VII, the law at issue in *Bostock*. *Eknes-Tucker*, at 1228–29. But second, and more important here, the Court emphasized the "different factual context" involved in *Eknes-Tucker* and *Bostock*—*Eknes-Tucker* involved a law regulating specific medical treatments, not a rule penalizing a transgender individual for no reason other than being transgender. *Id.* at 1229.

Eknes-Tucker's reasoning is binding here. Title IX, like the Equal Protection Clause, prohibits only "intentional sex discrimination." *Jackson v. Birmingham Bd. of Educ.*, 544 U.S. 167, 173 (2005). Section 1557, therefore, also requires "a discriminatory intent or motive." *Ricci v. DeStefano*, 557 U.S. 557, 577 (2009) . So, when *Eknes-Tucker* says that a ban on gender-transition interventions doesn't intentionally discriminate "on the basis of sex," the very same words used in Title IX and imported into Section 1557, that reasoning also carries over to Title IX and Section 1557.[2]

2. The 2024 Rules Conflict With Eknes-Tucker.

The 2024 Rules conflict with *Eknes-Tucker* in at least two ways. *First*, the 2024 Rules make it presumptively discriminatory for covered entities to "[d]eny or limit"

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[2] The Eleventh Circuit recently held that an employer violates Title VII when it excludes all denies health insurance coverage for gender-transition interventions. *Lange v. Hous. Cnty.*, No. 22-13626, slip op. at 9 (11th Cir. May 13, 2024). But *Lange* (like *Bostock*) interprets Title VII, which is not a Spending Clause statute like Title IX (at issue here). *Fitzpatrick v. Bitzer*, 427 U.S. 445, 458 (1976) (Brennan, J., concurring). So unlike Section 1557, Title VII need not satisfy the Spending Clause's stringent requirement of clear and unambiguous notice. *Adams*, 57 F.4th at 815. In any event, to the extent *Lange* conflicts with *Eknes-Tucker*, *Eknes-Tucker* controls. *Burke-Fowler v. Orange Cnty.*, 447 F.3d 1319, 1323 n.2 (11th Cir. 2006).

puberty blockers, cross-sex hormones, or surgeries "sought for purpose of gender transition," so long as those entities provide the services for "other purposes." 89 Fed. Reg. at 37,701, *to be codified at* 45 C.F.R. § 92.206(b)(4); *see also id.*, *to be codified at* 45 C.F.R. § 92.207(b)(1) (requiring services "typically or exclusively" associated with one sex). Any covered entity that categorically refuses to provide interventions "sought for purpose of gender transition" is a sex discriminator. NPRM, 87 Fed. Reg. at 47,867; Compl. ¶¶ 8, 140.

The 2024 Rules therefore prohibit discriminating based on therapeutic purpose, which is inherent in the practice of medicine and is not intentional sex discrimination. *Eknes-Tucker*, 80 F.4th at 1228. To see why, consider the following otherwise identical patients:

(a) A male seeks an orchiectomy (removal of testicles) to treat testicular cancer;

(b) A male who identifies as a woman seeks an orchiectomy to treat testicular cancer;

(c) A male who identifies as a woman seeks an orchiectomy to "transition."

If a surgeon provides the medical treatment to patient (a) but not (b), discrimination based on gender stereotypes may be afoot, as no other "reasonable distinction can be found between those favored and those not favored." *CSX Transp., Inc. v. Ala. Dep't of Revenue*, 562 U.S. 277, 286 (2011); *Discrimination*, Black's Law Dictionary 534 (9th ed. 2009) (same).

But a surgeon who treats patient (a) but not (c) is not presumably discriminating based on sex: the surgeon is instead discriminating based on the patient's medical

condition or diagnosis. *See Eknes-Tucker*, 80 F.4th at 1228; *id.* at 1233 (Brasher, J., concurring) (same); *L.W.*, 83 F.4th at 481–82 (same in equal protection case); *Kadel v. Folwell*, No. 22-1721, 2024 WL 1846802, at *31–33, *35 n.19 (4th Cir. Apr. 29, 2024) (Richardson, J., dissenting) (same in equal protection and Section 1557 case). To use *Bostock*'s language, removing reproductive organs with cancer is not "to [the doctor's mind], materially identical in all respects" to removing healthy reproductive organs for a gender transition. *Bostock*, 590 U.S. at 660. That's because, in medicine as in pharmacy, the "therapeutic purpose" is material to a course of treatment. *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 142 (2000). Because the medical diagnosis is different, not "materially identical," intentional sex discrimination cannot be presumed. *Eknes-Tucker*, 80 F.4th at 1228; *Bostock*, 590 U.S. at 660.

Second, the 2024 Rules prohibit a facially neutral reimbursement policy or practice limiting gender-transition interventions if the policy or practice merely "*results in* sex discrimination." 89 Fed. Reg. at 37,701, *to be codified at* 45 C.F.R. § 92.207(b)(5). HHS claims that limiting coverage for a gender transition intentionally discriminates on the basis of gender nonconformity "because transgender individuals are the only individuals who seek transition-related care." NPRM, 87 Fed. Reg. at 47,871. But *Eknes-Tucker* rejected that same argument: "the regulation of a course of treatment that only gender nonconforming individuals can undergo" is not stereotyping "based on sex" (the same words used in Title IX) "unless the regulation were a pretext for invidious discrimination against such individuals." *Eknes-Tucker*, 80 F.4th at 1228–30.

For example, only women have abortions, but refusing to perform an abortion is not presumptive proof of misogynism. *Bray v. Alexandria Women's Health Clinic*, 506 U.S. 263, 270 (1993).

Nor are gender-transition interventions "such an irrational object of disfavor" that intentional discrimination on the basis of gender nonconformity can be presumed. *Id.* According to HHS, any covered entity that believes that "gender transition" interventions are "experimental or cosmetic" is displaying animus. *See* 89 Fed. Reg. at 37,701; NPRM, 87 Fed. Reg. at 47,874. Not so. "The unsettled, developing, in truth still experimental, nature of treatments in this area surely permits more than one policy approach." *L.W.*, 83 F.4th at 488. As numerous health organizations, States, and even western European nations have now recognized, gender-transition interventions have serious health risks, and it is far from settled that the therapeutic benefits outweigh the risks. Comp. ¶¶ 85–108. Opposing gender-transition interventions as experimental and harmful is therefore "rational." *Eknes-Tucker*, 80 F.4th at 1225. Section 1557 doesn't answer this debate by preempting state ethical standards of care restricting gender-transition interventions. *See* 42 U.S.C. § 18114(5) (ACA rules must not "violate the principles of informed consent and the ethical standards of health care professionals").

C. The Social Security Act Does Not Authorize Rules Forbidding Disparate Impacts on Gender Identity.

What cannot be done through Section 1557, HHS seeks to accomplish through the Social Security Act ("SSA"). In addition to purporting to implement Section 1557, the 2024 Rules also amend the standard contract requirements under Medicaid and

CHIP to require prohibiting any policy or practice that has the *"effect of* discriminating" based on an individual's "gender identity." 89 Fed. Reg. at 37,691, *to be codified at* 42 C.F.R. §§ 438.3(d)(4) (emphasis added), 457.1201(d). But as explained above, Section 1557 doesn't prohibit discriminating based on gender identity, nor does it forbid discriminatory effects. So, for purported additional statutory authority, HHS invokes the SSA, which was also enacted under the Spending Clause. *See* 89 Fed. Reg. at 37,668. HHS's attempt fails.

First, HHS invokes its authority to adopt "methods of administration" for Medicaid that are "necessary for the proper and efficient operation of the [state Medicaid] plan." 42 U.S.C. § 1396a(a)(4). But novel civil rights laws are not "methods of administration." Congress offered examples of "methods of administration," giving "more precise content" to the term. *United States v. Williams*, 553 U.S. 285, 294 (2008) (*noscitur a sociis*). It includes setting "personnel standards" and providing for "medical personnel" and transporting patients. 42 U.S.C. § 1396a(a)(4). That humdrum list of *administrative* tasks looks nothing like the power to declare new civil rights guarantees that will transform the practice of medicine. When the SSA was enacted, States had no "clear" "notice" from the face of the statute that HHS could force their contractors into the gender-transition business. *Adams*, 57 F.4th at 815. HHS's attempts to do so therefore exceed its statutory authority.

Second, HHS invokes a CHIP provision stating that the "purpose of" the CHIP program "is to provide funds to States to enable them to initiate and expand the provision of child health assistance … in an effective and efficient manner." 42 U.S.C.

§ 1397aa(a). But that anodyne statement of purpose provides no authority to HHS, and certainly, it doesn't clearly authorize these rules. *Adams*, 57 F.4th at 815. In any event, imposing effects-based liability on contractors does nothing to improve the "efficiency" of the CHIP program. *See* "Efficient," *Am. Heritage Dictionary* (5th ed. 2022) ("Acting or producing effectively with a minimum of waste, expense, or unnecessary effort"). If anything, disparate impact requirements increase burdens and costs on the delivery of services by putting "undue pressure" on contractors "to adopt inappropriate prophylactic pressures." *Watson v. Fort Worth Bank & Tr.*, 487 U.S. 977, 992 (1988).

II. Plaintiffs Will Suffer Irreparable Injury

Absent intervention from this Court, the 2024 Rules will be effective on Friday, July 5, 2024. 89 Fed. Reg. at 37,522. If they go into effect, Florida will face an untenable choice: renounce its sovereign interest in protecting the health and safety of its citizens and suffer irrecoverable costs, or lose federal financial assistance from HHS, an untenable option. *See* Compl. ¶ 168. Without temporary relief, Florida will remain caught between the 2024 Rules and Florida law, facing "actual and imminent" injury to its sovereign interests and unrecoverable monetary loss. *Ne. Fla. Chapter of Ass'n of Gen. Contractors v. City of Jacksonville*, 896 F.2d 1283, 1285 (11th Cir. 1990). The 2024 Rules also leaves doctors such as the members of Plaintiff Catholic Medical Association ("CMA") in legal and professional jeopardy, forcing them to incur unrecoverable costs to avoid non-compliance. Plaintiffs are irreparably harmed in multiple ways.

First, the 2024 Rules purport to preempt any state law that requires covered entities to separate private spaces in public buildings based on sex. Florida has such a law. *See* Fla. Stat. § 553.865(5), (12). The 2024 Rules also unlawfully attempt to preempt Florida's laws, regulations, and standards of care restricting gender-transition interventions and preventing the use of public funds for these purposes. Compl. ¶¶ 109–28, 174, 181–84.

That is irreparable harm. "A state retains a sovereign interest in enacting and enforcing state law, and the 'inability to enforce [the State's] duly enacted plans clearly inflicts irreparable harm on the State.'" *Florida v. Nelson*, 576 F. Supp. 3d 1017, 1039 (M.D. Fla. 2021) (quoting *Abbott v. Perez*, 585 U.S. 579, 602 n.17 (2018)); *see also Texas v. Becerra*, 577 F. Supp. 3d 527, 557 (N.D. Tex. 2021) ("irreparable harm exists when a federal regulation prevents a state from enforcing its duly enacted laws"). The harm is also imminent and concrete. Indeed, the federal government has already argued that Florida's Medicaid rule restricting public spending on these interventions, Fla. Admin. Code r. 59G-1.050(7), is preempted by Section 1557, asserting that HHS's then-proposed (and now final) rules make this clear by prohibiting "categorical" limits on gender-transition interventions. Brief for the United States as Amicus Curiae at 26 n.10, *Dekker v. Fla. Agency for Health Care Admin.*, No. 23-12155 (11th Cir. Dec. 4, 2023), https://perma.cc/9UYG-SVPL.

Second, if the 2024 Rules go into effect and Florida is forced to abandon its health and safety laws and regulations while this suit is pending, the resulting harms to the "health and welfare of [Florida's] citizens" could never be "repair[ed]" by

"monetary damage." *Texas v. Biden*, 589 F. Supp. 3d 595, 621 (N.D. Tex. 2022). The 2024 Rules will compel health institutions, including institutions for the intellectually and developmentally disabled, to allow "nonbinary" males into disabled female residents' private spaces, increasing the risk of harm to Florida's citizens. Ex. B, Bailey Dec. ¶¶ 31–41 Some of Florida's citizens, including minors, would also suffer irreversible infertility and other health harms while the suit is pending. Compl. ¶¶ 92–97.

Third, if the 2024 Rules go into effect, Florida would have to amend the State Group Health Insurance Program to cover gender-transition interventions, suffering irrecoverable monetary losses to administer and fund such payments while this suit proceeds. Compl. ¶¶ 169–70 & Ex. 2. Similarly, Florida would be pressured to amend its laws and regulations limiting funding for these interventions, which would require Florida to incur irrecoverable costs under Medicaid and CHIP while this litigation is pending. Compl. ¶ 179 & Ex. 1 ¶¶ 12–22.

Fourth, if the 2024 Rules go into effect, it would force CMA doctors—on pain of ineligibility to participate in Medicare, Medicaid, and CHIP—to adopt, follow, and be trained on policies that harm patients, and to provide, refer for, or affirm, unethical gender-transition procedures. Ex. C, Akey Decl. ¶¶ 25–36; Ex. D, Kaiser Decl. ¶¶ 17–21; Compl. Ex. 3, Dickerson Decl. ¶¶ 32–36; Compl. Ex. 4, Parker Decl. ¶¶ 19–21; Compl. Ex. 5, Van Meter Decl. ¶¶ 23–40. CMA members likewise separate bathroom facilities by sex, regardless of gender identity. Compl. Ex. 3, Dickerson Decl. ¶ 28; Compl. Ex. 4, Parker Decl. ¶ 16; Compl. Ex. 5, Van Meter Decl. ¶ 19. The rule's

"'substantial pressure'" on doctors to upend their practices and violate their conscience "constitutes an irreparable injury." *Navy Seal 1 v. Austin*, 586 F. Supp. 3d 1180, 1204 (M.D. Fla. 2022).

III. Balance of Harms and Public Interest Favor Plaintiffs

The balance of harms and public interest factors merge when the government is the defendant, *Gonzales v. Governor of Ga.*, 978 F.3d 1266, 1271 (11th Cir. 2020); *cf. Nken v. Holder*, 556 U.S. 418, 435 (2009), and they strongly favor Plaintiffs. Absent an injunction, Plaintiffs will suffer serious imminent harm to their interests and unrecoverable monetary loss.

By contrast, HHS has no legitimate interest in an unlawful rule, because "our system does not permit agencies to act unlawfully even in pursuit of desirable ends." *Ala. Ass'n of Realtors v. HHS*, 594 U.S. 758, 766 (2021); *see also BST Holdings v. OSHA*, 17 F.4th 604, 618 (5th Cir. 2021) ("Any interest [the government] may claim in enforcing an unlawful [rule] is illegitimate."). Section 1557, moreover, is self-executing, so staying or enjoining enforcement of the 2024 Rules won't interfere with HHS's legitimate law-enforcement interests. If the 2024 Rules are stayed, HHS will be able to continue enforcing Section 1557 to prevent actual intentional sex discrimination, as well as prohibited intentional discrimination based on race, disability, or age. But it won't be able to enforce the misreading of Section 1557 embodied in the 2024 Rules.

IV. A Stay Is the Proper Remedy

The APA expressly authorizes courts to issue all "necessary and appropriate process to postpone the effective date of an agency action or to preserve statutes or rights pending conclusion of the review proceedings." 5 U.S.C. § 705. Courts may thus stay the effective date of a rule, and this relief need not be "party-specific." *Career Colls. & Sch. of Tex. v. U.S. Dep't of Educ.*, 98 F.4th 220, 255 (5th Cir. 2024). At the same time, a stay should be no broader than needed to prevent the irreparable harm. *Id.* Plaintiffs are irreparably harmed by HHS's interpretation of Title IX as incorporated by Section 1557, and HHS's reading of the SSA. The Court should therefore stay the effective date of the provisions of the 2024 Rules that implement HHS's reading of Title IX as incorporated in Section 1557, as well as its reading of the SSA to prohibit disparate impacts. *See* 89 Fed. Reg. at 37,698–701, *to be codified at* 45 C.F.R. §§ 92.101, 92.206, 92.207; *id.* at 37,691, *to be codified at* 42 C.F.R. § 438.3(d)(4).

CONCLUSION

Plaintiffs are likely to succeed on the merits, will suffer imminent and irreparable injury absent temporary relief, and the balance of harms favors Plaintiffs. Accordingly, this Court should enter an order postponing the effective date of the 2024 Rules for Plaintiffs while this suit proceeds, as expressly authorized by the APA. 5 U.S.C. § 705. In the alternative, this Court should preliminarily enjoin Defendants from enforcing the 2024 Rules. Because this case is complex, an oral hearing would assist the Court.

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CERTIFICATE OF SERVICE

I hereby certify that on May 15, 2024, a true and correct copy of the foregoing was filed with the Court's CM/ECF system, which will provide service to all parties who have registered with CM/ECF and filed an appearance in this action. I also sent a copy by email to the following U.S. Department of Justice attorney assigned to this matter:

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/s/ R. Trent McCotter
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Dkt. 12-1

EXHIBIT A

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 438, 440, 457, and 460

Office of the Secretary

45 CFR Parts 80, 84, 92, 147, 155, and 156

RIN 0945–AA17

Nondiscrimination in Health Programs and Activities

AGENCY: Office for Civil Rights, Office of the Secretary, Department of Health and Human Services; Centers for Medicare & Medicaid Services, Department of Health and Human Services.

ACTION: Final rule and interpretation.

SUMMARY: The Department of Health and Human Services (HHS or the Department) is issuing this final rule regarding section 1557 of the Affordable Care Act (ACA) (section 1557). Section 1557 prohibits discrimination on the basis of race, color, national origin, sex, age, or disability in certain health programs and activities. Section 1557(c) of the ACA authorizes the Secretary of the Department to promulgate regulations to implement the nondiscrimination requirements of section 1557. The Department is also revising its interpretation regarding whether Medicare Part B constitutes Federal financial assistance for purposes of civil rights enforcement. Additionally, the Department is revising provisions prohibiting discrimination on the basis of sex in regulations issued by the Centers for Medicare & Medicaid Services (CMS) governing Medicaid and the Children's Health Insurance Program (CHIP); Programs of All-Inclusive Care for the Elderly (PACE); health insurance issuers and their officials, employees, agents, and representatives; States and the Exchanges carrying out Exchange requirements; agents, brokers, or web-brokers that assist with or facilitate enrollment of qualified individuals, qualified employers, or qualified employees; issuers providing essential health benefits (EHB); and qualified health plan issuers.

DATES: *Effective date:* July 5, 2024.

Applicability dates: Unless otherwise specified, the provisions of this final rule apply on or after July 5, 2024. See the **SUPPLEMENTARY INFORMATION** section for additional information.

FOR FURTHER INFORMATION CONTACT:

Office for Civil Rights

Daniel Shieh, Associate Deputy Director, HHS Office for Civil Rights (202) 240–3110 or (800) 537–7697 (TDD), or via email at *1557@hhs.gov*, for matters related to section 1557.

Centers for Medicare & Medicaid Services

John Giles, (410) 786–5545, for matters related to Medicaid.

Meg Barry, 410–786–1536, for matters related to CHIP.

Timothy Roe, (410) 786–2006 for matters related to Programs of All-Inclusive Care for the Elderly.

Becca Bucchieri, (301) 492–4341 or Leigha Basini, (301) 492–4380, for matters related to 45 CFR 155.120, 155.220, 156.125, 156.200, and 156.1230.

Lisa Cuozzo, (410) 786–1746, for matters related to 45 CFR 147.104.

Hannah Katch, (202) 578–9581, for general questions related to CMS amendments.

Assistance to Individuals With Disabilities in Reviewing the Rulemaking Record: Upon request, the Department will provide an accommodation or appropriate auxiliary aid or service to an individual with a disability who needs assistance to review the comments or other documents in the public rulemaking record for the final rule. To schedule an appointment for this type of accommodation or auxiliary aid, please call (202) 240–3110 or (800) 537–7697 (TDD) for assistance or email *1557@hhs.gov*.

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I. Background

Section 1557 of the Affordable Care Act (ACA) (section 1557), 42 U.S.C. 18116, prohibits discrimination on the basis of race, color, national origin, sex, age, or disability in a health program or activity, any part of which is receiving Federal financial assistance, including credits, subsidies, or contracts of insurance, except where otherwise provided in title I of the ACA. Section 1557 also prohibits discrimination on the basis of race, color, national origin, sex, age, or disability under any program or activity that is administered by an executive agency, or any entity established under title I of the ACA or its amendments. The statute cites title VI of the Civil Rights Act of 1964 (title VI), 42 U.S.C. 2000d *et seq.,* title IX of the Education Amendments of 1972 (title IX), 20 U.S.C. 1681 *et seq.,* the Age Discrimination Act of 1975 (Age Act), 42 U.S.C. 6101 *et seq.,* and section 504 of the Rehabilitation Act of 1973 (section 504), 29 U.S.C. 794, to identify the grounds of discrimination prohibited by section 1557. The entities to which section 1557 and this final rule apply (*i.e.,* recipients of Federal financial assistance, the Department, and title I entities) are collectively referred to as ''covered entities.'' The statute further specifies that the enforcement mechanisms provided for and available under title VI, title IX, the Age Act, or section 504 shall apply for purposes of violations of section 1557, 42 U.S.C. 18116(a). The statute authorizes the Secretary of the U.S. Department of Health and Human Services (HHS or the Department) to promulgate implementing regulations for section 1557, 42 U.S.C. 18116(c).

A. Regulatory History

On August 1, 2013, the HHS Office for Civil Rights (OCR) published a Request for Information in the **Federal Register**, 78 FR 46558,[1] followed by issuance of a notice of proposed rulemaking (NPRM) on September 8, 2015 (2015 NPRM), 80 FR 54171.[2] OCR finalized the first section 1557 regulation on May 18, 2016 (2016 Rule), 81 FR 31375. On June 14, 2019, the Department published a new section 1557 NPRM (2019 NPRM), 84 FR 27846, proposing to rescind and replace large portions of the 2016 Rule.[3] On June 12, 2020, OCR publicly posted its second section 1557 final rule (2020 Rule), which was published in the **Federal Register** on June 19, 2020, 85 FR 37160. The 2020 Rule remains in effect, save for the parts enjoined or set aside by courts, until the effective date of this final rule. In the meantime, entities that are subject to the 2020 Rule must continue to comply with the parts of the 2020 Rule that remain in effect.

On January 5, 2022, the Department proposed to amend CMS regulations such that Exchanges, issuers, and agents and brokers would be prohibited from discriminating against consumers based on their sexual orientation or gender identity in the HHS Notice of Benefit and Payment Parameters for 2023 NPRM, 87 FR 584 (January 5, 2022). CMS did not finalize the amendments in the Notice of Benefit and Payment Parameters for the 2023 final rule, 87 FR 27208 (May 6, 2022); instead, CMS proposed to make the amendments to its regulations in forthcoming Departmental rulemaking.

On July 25, 2022, OCR publicly posted the section 1557 NPRM associated with this rulemaking (2022 NPRM or Proposed Rule), which was published in the **Federal Register** on August 4, 2022, 87 FR 47824. OCR invited comment on the Proposed Rule by all interested parties. The comment period ended on October 3, 2022. In total we received 85,280 comments on the Proposed Rule.[4] Comments came from a wide variety of stakeholders, including but not limited to: civil rights/advocacy groups, including language access organizations, disability rights organizations, women's advocacy organizations, and organizations serving lesbian, gay, bisexual, transgender, queer, or intersex (LGBTQI+) individuals; health care providers; consumer groups; religious organizations; academic and research institutions; reproductive health organizations; health plan organizations; health insurance issuers; State and local agencies; and tribal entities. Of the total comments, 79,126 were identified as being submitted by individuals. Of the 85,280 comments received, 70,337 (80 percent) were form letter copies associated with 30 distinct form letter campaigns.

B. Overview of the Final Rule

Section 1557

This preamble is divided into multiple sections: section II describes changes to the section 1557 regulation and contains four subparts: subpart A sets forth the rule's general provisions; subpart B contains the rule's nondiscrimination provisions; subpart C describes specific applications of the prohibition on discrimination to health programs and activities; and subpart D describes the procedures that apply to enforcement of the rule. Section III provides official notice of HHS's change in interpretation that Medicare Part B meets the definition of ''Federal financial assistance.'' Section IV describes changes to CMS regulations.

OCR has made some changes to the Proposed Rule's provisions, based on the comments we received. Among the changes are the following:

OCR modified proposed § 92.4 (Definitions) to include new definitions for telehealth, State, relay interpretation, and patient care decision support tools.

OCR modified proposed § 92.201 (Meaningful access for individuals with limited English proficiency) to change ''limited English proficient individual'' to ''individual with limited English proficiency'' where applicable in this provision and elsewhere where the term is used. The text for proposed § 92.201(a) was updated to include ''companions with limited English proficiency'' for clarity and parity with the rule's effective communication

[1] Responses are available for public inspection at *https://www.regulations.gov/docket/HHS-OCR-2013-0007/comments.*

[2] The 2015 NPRM received roughly 2,160 comments, which are available for public inspection at *https://www.regulations.gov/docket/HHS-OCR-2015-0006/comments.*

[3] The 2019 NPRM received roughly 198,845 comments, which are available for public inspection at *https://www.regulations.gov/document/HHS-OCR-2019-0007-0001.* This count includes bundled submissions, including petitions and form letter campaigns, which were counted as individual comment submissions.

[4] This count includes bundled submissions, including petitions. The number of submission entries in the Federal Docket Management System is 75,254 submissions. Responses are available for public inspection at *https://www.regulations.gov/docket/HHS-OS-2022-0012.*

provision. OCR also modified proposed § 92.201(f) and proposed § 92.201(g) to address concerns that audio and video remote interpreting may not be appropriate to provide meaningful access in certain circumstances.

OCR modified proposed § 92.206 (Equal program access on the basis of sex) to clarify a covered entity's ability to raise legitimate and nondiscriminatory reasons for the denial of care under this provision, while stating that the basis for a denial or limitation must not be based on unlawful animus or bias, or constitute a pretext for discrimination.

OCR modified the text of proposed § 92.207 (Nondiscrimination in health insurance coverage and other health-related coverage), consistent with changes to § 92.206(c) to clarify that covered entities may raise a legitimate, nondiscriminatory reason for denials or limitations of health services in benefit design and in individual cases, while stating that the basis for a denial or limitation must not be based on unlawful animus or bias, or constitute a pretext for discrimination.

OCR revised proposed § 92.210 (Nondiscrimination in the use of clinical algorithms in decision-making) to change ''clinical algorithms'' and ''clinical algorithms in decision-making'' to ''patient care decision support tools.'' OCR further specified the scope of the application of this provision and the requirement that covered entities take reasonable steps to mitigate discrimination once made aware of the potential for discrimination resulting from use of these tools.

OCR modified proposed § 92.302 (Notification of views regarding application of Federal religious freedom and conscience laws) to clarify the application of religious freedom and conscience laws, and aspects of the administrative process set forth in the provision, including that a recipient may request an assurance of an exemption under such laws, the availability of a temporary exemption, and the availability of an administrative appeal process.

CMS Amendments

In response to comments, CMS is finalizing the proposed amendments to the CMS regulations with a revision to scope of sex discrimination to be consistent with section 1557's regulatory text at § 92.101(a)(2).

II. Provisions of the Proposed Rule and Analysis and Responses to Public Comments

Subpart A—General Provisions

Purpose and Effective Date (§ 92.1)

In the 2022 NPRM, proposed § 92.1(a) explained that the purpose of 45 CFR part 92 is to implement section 1557, which prohibits discrimination in certain health programs and activities on the ''ground[s] prohibited'' under title VI, title IX, the Age Act, or section 504. Section 1557 adopts the grounds of these statutes and prohibits discrimination based on race, color, national origin, sex, age, or disability.[5]

Proposed § 92.1(b) provided that the effective date of the section 1557 implementing regulation shall be 60 days after the publication of a final rule in the **Federal Register** and provided a delayed implementation date (referred to as ''applicability date'' in this final rule) for provisions of this part that require changes to health insurance or group health plan benefit design.

The comments and our responses regarding the purpose and effective date are set forth below.

Comment: Several commenters noted that the regulatory purpose described in the 2022 NPRM strengthens nondiscrimination protections in health care, and appropriately aligns with section 1557's statutory text and Congressional intent.

Response: As commenters noted, the 2022 NPRM's purpose is to prohibit discrimination in accordance with section 1557's statutory text. The Proposed Rule mirrors the statutory text and clarifies that the purpose of this rule is to regulate health programs and activities conducted and funded by the Department and those of title I entities. Thus, we maintain the regulatory language for § 92.1(a) as proposed in the 2022 NPRM.

Comment: One commenter observed that, in addition to title IX's general prohibition of discrimination on the ground of ''sex,'' section 904 of title IX (20 U.S.C. 1684) also prohibits discrimination on the ground of blindness or severe vision impairment.

Response: Both HHS's and the Department of Education's title IX regulations define title IX to exclude section 906. *See* 45 CFR 86.2(a); 34 CFR 106.2(a). While 20 U.S.C. 1684 prohibits certain forms of discrimination on the ground of blindness or severe vision impairment, such conditions are disabilities and section 1557 prohibits discrimination on the basis of disability as it is the ''ground'' of discrimination prohibited by the statute's reference to section 504. Accordingly, we decline to revise the regulatory text at § 92.1(a).

Comment: OCR received many comments about the proposed 60-day effective date for requirements other than those related to health insurance or group health plan coverage benefit design. Commenters identified several tasks covered entities would need to accomplish to comply with the final rule requirements within the proposed 60 days, including updating existing policies and procedures; developing and reviewing new content; developing written communications with members and distributing written documents, including preparing additional mailings; and familiarizing themselves with new requirements and OCR-provided tools and resources.

Most of these commenters expressed concern that covered entities would not be able to develop and implement the required policies and procedures (§ 92.8) and notices (§ 92.10, § 92.11), or complete the proposed training requirement (§ 92.9) within the allotted 60 days. A variety of commenters argued that the 60-day effective date for §§ 92.7 through 92.11 would be unreasonable for all covered entities, requesting that OCR consider allowing covered entities more time to come into compliance with the final rule.

Commenters' recommended compliance timeframes varied widely, from 180 days to three years following publication of the final rule in the **Federal Register**. One commenter asked that, for the first 18 to 24 months following publication of the final rule in the **Federal Register**, OCR's section 1557 enforcement efforts, including complaint investigations, primarily focus on providing covered entities technical assistance with respect to their section 1557 obligations.

Response: OCR appreciates comments regarding the effective date and commenters' identification of factors influencing feasibility of a single effective date for all section 1557 requirements. We are maintaining the overall 60-day effective date related to the general prohibition on discrimination on the basis of race, color, national origin, sex, age, and disability. This is consistent with the approach taken with respect to the effective date of our previous

[5] *See Schmitt* v. *Kaiser Found. Health Plan of Wash.*, 965 F.3d 945, 953 (9th Cir. 2020) (''Section 1557(a) incorporates only the prohibited 'ground[s]' and '[t]he enforcement mechanisms provided for and available under' the four civil rights statutes. A prohibited 'ground' for discrimination . . . is simply the protected classification at issue.'').

distinctions exempt from the Age Act are also exempt from section 1557 enforcement.

Response: OCR appreciates commenters' request for clarity and directs commenters to § 92.101(b)(1) of this regulation, which adopts by reference the permissible uses of age located in the Department's Age Act regulations at 45 CFR part 91 (subpart B).

Comment: Some commenters argued that the Proposed Rule is inappropriate for the Indian Health Services (IHS) facilities because these are not open to members of the public but reserved for patients who are eligible beneficiaries as citizens of Tribal Nations, and as such, tribally operated IHS health facilities [21] should be exempt. These commenters stated that the 2022 NPRM failed to recognize the unique nature of the Indian Health Care System, which is the health care system for members of federally recognized Tribes in the United States. Commenters recommended that OCR acknowledge American Indian/Alaska Native (AI/AN) as a political classification, and not as a race-based classification. Commenters further opined that the 2022 NPRM failed to recognize the diplomatic, nation-to-nation relationship between Tribal Nations and the United States.

Response: OCR appreciates these comments. Similar concerns were raised during the 2022 NPRM Tribal Consultation held on August 31, 2022, pursuant to Executive Order 13175. The IHS, an agency within the Department, is responsible for providing health services to members of federally recognized tribes in 37 states, arising out of the special government-to-government relationship between the Federal Government and Indian tribes.[22]

Membership or eligibility in a federally recognized tribal entity is a political classification rather than a racial classification.[23] Preferences based upon the unique relationship between the United States and federally recognized tribal entities are distinct from the forms of discrimination prohibited by Federal civil rights laws, which aim to protect all individuals on the basis of race, color, or national origin (including AI/AN individuals, regardless of political affiliation).[24] The Department's regulations implementing title VI provide that an individual shall not be deemed subjected to discrimination by reason of their exclusion from benefits limited by Federal law to individuals of a different race, color, or national origin. 45 CFR 80.3(d) (Indian Health and Cuban Refugee Services). IHS is mentioned in the Department's title VI regulation as an example of such a program. *Id.* In § 92.101(b), the final rule adopts this provision by reference, and OCR will fully apply it, as well as other applicable exemptions or defenses that may exist under Federal law.

Programs of the IHS are administered by IHS and tribes, including through self-determination contracts or self-governance compacts, and we intend to address any restrictions on application of the law to IHS programs in the context of individual complaints.

Comment: Some commenters requested that OCR develop an online tool that would help covered entities determine whether the final rule applies either directly or indirectly to an organization or other health program or activity.

Response: OCR provides various tools on our website to help covered entities determine their covered entity status and will continue to ascertain what tools would help the industry ensure widespread compliance. OCR notes that the Department's Office of Grants operates a website that tracks obligated Department grant funds, *https://taggs.hhs.gov/*, which allows the public to identify recipients of Department funding.

Summary of Regulatory Changes

For the reasons set forth in the Proposed Rule and considering the comments received, we are finalizing the provisions as proposed in § 92.2, with modification. We are revising § 92.2(a)(3) to add the modifier ''health'' to ''program or activity administered by a title I entity.'' We are also revising § 92.2(b) to state that the provisions of this part shall not apply to any employer ''or other a plan sponsor of a group health plan, including but not limited to, a board of trustees (or similar body), association or other group,'' with regard to its employment practices, including the provision of employee health benefits.

Treatment of the Title IX Religious Exception

In the 2022 NPRM, OCR proposed to not import the title IX religious exception into the section 1557 regulation. The title IX statute states that the nondiscrimination requirements ''shall not apply to an educational institution which is controlled by a religious organization'' to the extent that such application ''would not be consistent with the religious tenets of such organization.'' 20 U.S.C. 1681(a)(3), *as amended* Public Law 100–259, section 3(b), Mar. 22, 1988, 102 Stat. 29. The title IX statutory definition of ''program or activity'' further limits the nondiscrimination requirements, in that they do not apply to ''any operation of an entity which is controlled by a religious organization if the application of section 1681 of this title to such operation would not be consistent with the religious tenets of such organization.'' *Id.* at 1687(4).

In the 2022 NPRM, we said that under the most natural understanding of section 1557's text, which bans discrimination ''on the ground prohibited under . . . title IX,'' the statutory term ''ground prohibited'' is best understood as incorporating only the bases on which discrimination is prohibited in the referenced statutes (*i.e.,* ''sex'' in title IX). 87 FR 47839. Rather than import the title IX exception for ''educational institution[s]'' that are controlled by ''religious organization[s],'' OCR proposed that the best way to address religious objections to the application of this rule—and the way most consistent with section 1557's statutory text and structure—would be through the process provided in proposed § 92.302. We sought comment on this approach. We particularly invited comments from covered entities controlled by or affiliated with religious organizations, providers employed by such entities, and people who receive health care from religiously affiliated medical providers.

The comments and our responses regarding this request for comment are set forth below.

Comment: Commenters provided mixed responses to OCR's proposal not to import the title IX religious exception into this rule. Many commenters supported OCR's statutory interpretation that section 1557

[21] Titles I and V of the Indian Self-Determination and Education Assistance Act, Pub. L. 93–638, as amended, provide Tribes the option of exercising their right to self-determination by assuming control and management of programs previously administered by the Federal Government. Since 1992, the IHS has entered into agreements with tribes and tribal organizations to plan, conduct, and administer programs authorized under section 102 of the Act. Today, over sixty percent of the IHS appropriation is administered by tribes, primarily through self-determination contracts or self-governance compacts. U.S. Dep't of Health & Hum. Servs., Indian Health Servs., *IHS Profile, https://www.ihs.gov/newsroom/factsheets/ihsprofile/.*

[22] U.S. Dep't of Health & Hum. Servs., Indian Health Servs., *About IHS, https://www.ihs.gov/aboutihs/.*

[23] *See Morton* v. *Mancari,* 417 U.S. 535, 553 & n.24 (1974).

[24] *See Morton* v. *Mancari,* 417 U.S. 535, 550 (1974) (''[a] provision aimed at furthering Indian self-government by according an employment preference withing the [Bureau of Indian Affairs] for qualified members of the governed group can readily co-exist with a general rule prohibiting employment discrimination on the basis of race.'').

incorporated the title IX statute only with respect to the ground of discrimination prohibited (sex) and its enforcement mechanisms (*e.g.,* termination of Federal financial assistance and other means authorized by law). Several commenters stated that this reading is most consistent with the statutory structure, because if Congress intended for the title IX religious exception to apply, the statute would also require the importation of the other title IX exceptions, many of which are by their terms plainly inapplicable in the context of health care.

Several commenters also stated that if Congress wanted to include the title IX religious exception, it could have either explicitly referenced or listed the exception in the section 1557 statutory text. Many commenters stated that any silence regarding the title IX exceptions was not an oversight by Congress, but an intentional decision. Many commenters contended that importing the title IX religious exception is contrary to the purpose of section 1557 and the goal of the ACA: to expand access to health care coverage. Additionally, many commenters said that importing the title IX religious exception is unnecessary given the numerous other Federal laws that allow religious organizations and providers to invoke a conscience or religious objection to providing certain kinds of medical services and care.

Many other commenters disagreed with OCR's interpretation, claiming that Congress intended to incorporate the entire title IX statutory scheme by including the signal ''*et seq.*'' Several commenters also argued that title IX's prohibition on sex discrimination cannot be read separate and apart from all the exceptions included in the title IX statute, in which Congress authorized certain conduct—*i.e.,* otherwise prohibited sex discrimination. Accordingly, several commenters maintained that it is arbitrary and capricious for OCR to rely upon title IX's implementing regulations as a guide to prohibit discrimination on the basis of sex, such as those related to pregnancy-related conditions, or when distinguishing a marital, parental, and family status, while not importing the statute's religious exception.

A few commenters maintained that the differences between educational and health care institutions provide an unconvincing argument for nonimportation of the title IX religious exception because under the Title IX Common Rule of 2000 (Common Rule),[25] title IX already applies to recipients of Federal financial assistance that provide health care. Many commenters also asserted that the court in *Franciscan Alliance* v. *Burwell,* 227 F. Supp. 3d 660 (N.D. Tex. 2016), found that the decision not to import the title IX religious exception into the 2016 Rule, without explanation, was contrary to law. Several commenters also pointed to that court's determination that the Department had previously ''provide[d] that when cross-referencing the provisions of Title IX's use of 'student,' the term 'individual' should be used in the healthcare context.'' *Id.* at 691. Commenters asserted that this finding by the court undermines the Department's claim that the title IX religious exception is specific to education and cannot be adopted more broadly in the health care context.

Response: Title IX applies to ''any education program or activity'' operated by recipients of Federal financial assistance, and the statute creates an exception from coverage for the education programs and activities of ''an educational institution which is controlled by a religious organization if the application of [title IX's prohibition on sex discrimination in education programs and activities] would not be consistent with the religious tenets of such organization.'' 20 U.S.C. 1681(a)(3). In addition, the Civil Rights Restoration Act of 1987 (CRRA)[26] statutorily defined ''program or activity'' for title IX to exclude from coverage ''any operation of an entity which is controlled by a religious organization if the application of section 1681 of this title to such operation would not be consistent with the religious tenets of such organization.'' 20 U.S.C. 1687(4). The preamble to the 2020 Rule stated that section 1557 ''incorporates the statutory scope of Title IX, so it is appropriate for this rule to incorporate the Title IX statutory language concerning religious institutions.'' 85 FR 37208.

OCR notes that as an initial matter, the CRRA's exclusion of any operation of religiously controlled entities from the application of title IX to the extent such operation is inconsistent with the religious tenets of the organization is not incorporated into section 1557. As we explain further in the discussion of ''health program or activity,'' section 1557 includes its own coverage provision that does not incorporate the CRRA's definitions of ''program or activity.'' Moreover, unlike title VI, section 504, and the Age Act,[27] title IX modifies ''program or activity'' with ''education,'' 20 U.S.C. 1681(a), which limited title IX's prohibition on sex discrimination to the ''education'' context; the definitions of ''program or activity'' under title VI, section 504, or the Age Act do not include any comparable exclusion for the operations of religiously controlled entities.[28] Thus, the CRRA's limitation to the application of certain operations of religious entities from title IX's coverage applies only in the ''education'' context and is not part of the definition of ''program or activity'' as that term is used in civil rights statutes more generally. Further, it is inapplicable to the definition of ''health program or activity'' adopted in section 1557. As a result, the sole question is whether the exclusion in title IX, 20 U.S.C. 1681(a)(3), of certain applications of the statute to ''educational institution[s] which [are] controlled by a religious organization'' carries over into section 1557.

Although title IX's prohibition of sex discrimination applies to some health-related activities of covered education programs—such as programs training future health workers—the range of exceptions provided in section 1681(a) are plainly tied to the educational setting (*e.g.,* the membership practices of social fraternities and sororities, YMCA, Girls Scouts, Boys Scouts; voluntary youth service organizations; father-son and mother-daughter activities; and beauty pageant-based scholarships, as well as educational admissions practices). All of these exceptions have little if any application to health programs and activities. Further, exceptions listed in that subsection include limitations regarding ''educational institution[s],'' ''institution[s] of public higher education,'' or ''institution[s] of higher education.'' 20 U.S.C. 1681(a)(1)–(9).

[25] *Nondiscrimination on the Basis of Sex in Education Programs or Activities Receiving Federal Financial Assistance,* 65 FR 52857 (Aug. 30, 2000) (multiagency rulemaking adopting consistent title IX implementing regulations).

[26] Public Law 100–259, 102 Stat. 28 (Mar. 22, 1988).

[27] *See* 42 U.S.C. 2000d (title VI, prohibiting ''discrimination under any program or activity receiving Federal financial assistance''); 42 U.S.C. 6101 (the Age Act, prohibiting discrimination ''in programs or activities receiving Federal financial assistance''); 29 U.S.C. 794(a) (section 504 prohibiting ''discrimination under any program or activity receiving Federal financial assistance or under any program or activity conducted by any Executive agency or by the United States Postal Service'').

[28] S. Rep. No. 100–64, 100th Cong., 1st Sess. (1987), *as reprinted in* 1988 U.S.C.C.A.N. 3, 6, 1987 WL 61447, at *18 (discussing ''education limitation in Title IX''); *see also id.* at *20–*21 (''[The CRRA] leaves the religious tenet exemption in Title IX intact and clarifies that the exemption is as broad as the Title IX coverage of *education programs and activities.*'' (Emphasis added)).

The language and subject matter of the exceptions suggest that Congress, in enacting title IX, did not intend those exceptions to define the statute's basis of discrimination—what section 1557 calls the ''ground prohibited''—under title IX. Title IX prohibits discrimination on the basis of sex, so the ''ground prohibited'' under that statute is sex. Congress intended these exceptions to delineate certain contexts in which otherwise prohibited sex discrimination in the educational context would be excluded from the statute's coverage. Congress could have chosen to draft section 1557 to incorporate additional elements from title IX and the other referenced civil rights statutes (*e.g.,* those statutes' applicability provisions), but did not do so, instead narrowly specifying that only the ''ground[s] prohibited'' are incorporated.

OCR further notes that the inclusion of ''*et seq.*'' is simply part of an ordinary citation to the title IX statute. Congress frequently appends ''*et seq.*'' to statutory citations as a matter of course when legislation includes a generalized reference to a previously enacted statute.[29] Including ''*et seq.*'' does not change the substantive meaning of section 1557, which incorporates only the grounds of prohibited discrimination and the enforcement mechanisms of each referenced statute. Further, section 1557 includes similar parenthetical citations with ''*et seq.*'' for the other referenced civil rights statutes in both 42 U.S.C. 18116(a) and (b). This underscores that Congress merely intended to provide the general, ordinary citation to the statutes being referenced, including title IX.

Section 1557's role as a health care statute further reinforces our reading of the statutory text and Congressional intent. Section 1557 was enacted as part of the ACA, in part, to expand access to health insurance and increase consumer protections. Title IX, as we have explained, relates specifically to education programs and activities. The title IX religious exception in that statute allows some entities to engage in certain conduct without requiring any consideration or mitigation of harm to third parties. If a similar standard were imported into this rule, it could undermine a key purpose of section 1557—ensuring access to health care. And as discussed below, unlike educational settings such as colleges and universities where there is more choice, individuals often have far fewer choices when accessing health care. In the federally funded health care context, the array of statutory conscience provisions enacted by Congress, as well as the general requirements of the First Amendment and the Religious Freedom Restoration Act (RFRA), provide a better fitting approach to addressing the relevant interests. This final rule has been revised to include regulatory text at § 92.3(c) recognizing that, insofar as the application of any rule requirement would violate applicable Federal protections for religious freedom and conscience, such application shall not be required. Also, we have strengthened the process for raising religious freedom and conscience protections under this final rule at § 92.302.

The fact that title IX and agency implementing regulations apply to *some* health programs and activities—those that are part of educational programs and activities [30]—does not suggest that the exceptions set forth in the statute or implementing regulations apply to health programs and activities that are not a part of an educational program. Title IX's limitation to a recipient's education programs and activities has long been established.[31] For example, the Common Rule (adopted by more than 20 Federal agencies) included the statute's limitation that the prohibition on sex discrimination applied *only to the educational components* of a covered entity's program.[32] As we have explained, it is inconsistent with the text and purpose of section 1557, as well as the text and structure of title IX, to apply the title IX exceptions outside of the educational setting. Although the title IX regulations are relevant to informing what constitutes sex discrimination for purposes of this final rule—and we have looked to them for that purpose—that is because section 1557 incorporates the ''ground prohibited'' under title IX. But section 1557 does not incorporate any of the title IX exceptions. 87 FR 47839.

OCR disagrees with the *Franciscan Alliance* decision vacating portions of the 2016 Rule, and in any event, that decision does not prohibit OCR from not importing the title IX religious exception in this final rule. The promulgation of this final rule constitutes new rulemaking, and OCR has provided a detailed explanation for the decision to not import the title IX religious exception and has taken important steps to address religious freedom and conscience protections beyond those in the 2016 Rule. These steps include revisions at § 92.3(c) to recognizes that, ''[i]nsofar as the application of any requirement under this part would violate applicable Federal protections for religious freedom and conscience, such application shall not be required,'' adoption of a voluntary assurance of exemption process based on these protections at § 92.302, and the Department's issuance of a final rule entitled *Safeguarding the Rights of Conscience as Protected by Federal Statutes,* 89 FR 2078 (Jan. 11, 2024).

OCR notes that this final rule does not alter or eliminate a recipient's ability to maintain, seek, claim, or assert a title IX religious exception under title IX if it meets the applicable criteria.[33] And to the extent the recipient is entitled to a religious exception under title IX, OCR's analysis will consider the entire statute, including title IX's specific limitation to the context of educational programs and activities.

Comment: Many commenters supported OCR's proposal not to import the title IX religious exception, highlighting what they characterized as the dangers of doing so in the context of health care and the potential consequences on people's access to health care it might have. For example, many commenters expressed concerns that providers would be able to deny essential health care services based on disapproval of a particular group, thereby putting at risk the health and well-being of already vulnerable individuals. Many commenters asserted that entities have invoked religious beliefs to deny individuals access to health care and coverage for a broad range of health care services. Commenters said that in urgent or emergency care situations, individuals may be unable to identify or use the services of an alternate provider when an institution withholds care based on religious tenets, even when the

[29] *See, e.g.,* 20 U.S.C. 1689(a)(1) (requesting a task force ''provide pertinent information . . . with respect to campus sexual violence prevention, investigations, and responses, including the creation of consistent, public complaint processes for violations of title IX of the Education Amendments of 1972 (20 U.S.C. 1681 *et seq.*)[.]''); *accord id.* 1689(a)(8), (b)(1), (c).

[30] *See, e.g., Doe* v. *Mercy Cath. Med. Ctr.,* 850 F.3d 545, 555 (3d Cir. 2017) (holding that a hospital's residency program was an educational program or activity under title IX).

[31] *See O'Connor* v. *Davis,* 126 F.3d 112, 117 (2d Cir. 1997), *cert. denied,* 522 U.S. 1114 (1998) (under title IX a program or activity must be ''such that one could reasonably consider its mission to be, at least in part, educational''); *see also Jeldness* v. *Pearce,* 30 F.3d 1220, 1224–25 (9th Cir. 1994); *Klinger* v. *Dep't of Corrs.,* 107 F.3d 609, 613–16 & n.5 (8th Cir. 1997); *Roubideaux* v. *North Dakota Dep't of Corrs. & Rehab.,* 570 F.3d 966, 976–79 (8th Cir. 2009).

[32] *Nondiscrimination on the Basis of Sex in Education Programs or Activities Receiving Federal Financial Assistance,* 65 FR 52858, 52868 (Aug. 30, 2000).

[33] 20 U.S.C. 1681(a)(3); 45 CFR 86.12.

individual is aware of such objections by an institution.

Many commenters highlighted the difference between education and health care. Multiple commenters stated that unlike certain health care settings, many parents have the choice to send their children to religious schools, whereas individuals often lack meaningful choices when seeking a health care provider, particularly for time-sensitive care. For example, numerous commenters stated that choice is especially limited in rural areas, and some patients may only have local access to religiously affiliated providers. Commenters worried that importing the title IX religious exception into this rule could have dire implications for health outcomes.

Response: As previously noted, this rule's application to the health care context is central to OCR's interpretation of section 1557. OCR appreciates that religiously affiliated hospitals and health care facilities play an important role in the health care system and recognizes the critical patient care needs they provide, including in underserved communities and areas which otherwise lack access to quality health care. At the same time, OCR believes that Congress chose not to import the title IX religious exception into section 1557 due to concerns about the impact such an action could have on access to health care. The importation of the title IX religious exception would raise unique concerns in the health care context that are not typically present in education programs and activities. As OCR discussed in the 2022 NPRM, health care settings differ from educational settings with respect to both the ability of affected parties to choose (or avoid) certain religiously affiliated health care institutions and the urgency of the need for services provided by the covered entities. 87 FR 47840. While students and families normally make a deliberate choice to attend a religious educational institution, in many cases specifically due to its religious character, individuals seeking health care are far more likely to be driven by other considerations such as availability, urgency, geography, insurance coverage, and other factors unrelated to whether the provider is controlled by or affiliated with a religious organization. *See id.* Rather than importing the title IX religious exception into section 1557, where Congress referenced only the ''ground prohibited under'' and the ''enforcement mechanisms provided'' for in title IX, the process set forth in § 92.302 respects religious freedom and conscience protections. As this final rule makes clear at § 92.3(c), insofar as the application of any requirement under this rule would violate applicable Federal protections for religious freedom and conscience, such application shall not be required. Under § 92.302, recipients may rely on these protections or seek assurance of these protections from OCR, if they wish. In this process, OCR will comply with the applicable legal standards of the governing statutes, which include the protections in the ACA itself, 42 U.S.C. 18023; the Church, 42 U.S.C. 300a–7, Coats-Snowe, 42 U.S.C. 238n, and Weldon Amendments, *e.g.,* Consolidated Appropriations Act, 2024, Public Law 118–47, div. H, tit. V, sec. 507(d)(1), 138 Stat. 460, 703 (Mar. 23, 2024); the generally applicable requirements of RFRA, 42 U.S.C. 2000bb–1; and other applicable Federal laws.

Comment: Many commenters who supported OCR's proposal not to import the title IX religious exception raised concerns that its importation could discourage individuals from seeking necessary medical care. Many commenters also discussed various State laws recently enacted to further expand religious exemptions from health care requirements and how such laws have specifically affected communities with limited access to care. These commenters argued that the effects of these laws further support OCR's goal of ensuring patients have broad access to nondiscrimination protections.

Response: OCR appreciates commenters' concerns regarding the potential harms to individuals with limited or restricted access to health care. OCR appreciates that many religiously affiliated hospitals and providers are providing vital services in areas where people are in the most need and are often motivated by their faith to provide this important care. However, OCR maintains that Congress did not choose to import the title IX religious exception into section 1557. Importing the title IX exception would be inconsistent with the text, structure, and purpose of both title IX and section 1557. Rather, Congress has enacted protections for conscience in the ACA itself; the Church, Coats-Snowe, and Weldon Amendments, among others; the generally applicable requirements of RFRA, and other applicable Federal laws as the means to protect religious freedom and conscience in this context. We are committed to affording full effect to Congress's protections of conscience and religion, as detailed in § 92.302 and the Department's issuance of its final rule, Safeguarding the Rights of Conscience as Protected by Federal Statutes. 89 FR 2078.

Comment: Multiple commenters opposed OCR's proposal not to import the title IX religious exception, stating that doing so would harm providers and hospital systems by compelling covered entities to provide abortion or other care that is contrary to their religious beliefs or that they believe will be harmful to their patients. Various commenters said that compelling such actions would turn many individuals and institutions of faith away from the medical profession.

Several commenters expressed confusion about available religious exceptions and how certain rule requirements would apply to religiously affiliated covered entities. These commenters said that including the title IX religious exception would clarify protections for religious entities.

Some commenters expressed concern that this regulation demonstrated OCR's intent to use section 1557 to force religious hospitals to dispense medication and perform procedures that are prohibited by their faith. Several commenters objected to the inclusion of cites in the 2022 NPRM that explain the increased prevalence of religiously affiliated health care systems and opined that this demonstrated hostility toward faith-based providers. According to these commenters, including these cites prejudices OCR's review of providers' religious exemption requests. Instead, these commenters urged OCR to make clear that providers will not be compelled to perform, cover, or promote procedures or medical interventions to which they have moral or religious objections.

Response: OCR appreciates commenters' concerns and respects their opposition to the proposal not to import the title IX religious exception. OCR reiterates, consistent with the 2022 NPRM, that this final rule does not promote any particular medical treatment, require provision of particular procedures, mandate coverage of any particular care, or set any standard of care; rather, the final rule implements the nondiscrimination requirements of section 1557. *See* 87 FR 47867–68. The full protections of all Federal religious freedom and conscience laws continue to apply.

Additionally, OCR makes clear that the decision not to import the title IX religious exception does not compel any individual provider or covered entity with religious or conscience-based objections to provide abortion or any other care to the extent doing so would conflict with a sincerely-held belief. The ACA itself provides that ''[n]othing in this Act shall be construed to have any

effect on Federal laws regarding—(i) conscience protection; (ii) willingness or refusal to provide abortion; and (iii) discrimination on the basis of the willingness or refusal to provide, pay for, cover, or refer for abortion or to provide or participate in training to provide abortion.'' 42 U.S.C. 18023(c)(2)(A). As discussed further below, section 1557 prohibits discrimination on the basis of race, color, national origin, sex, age, or disability in covered health programs or activities. A covered entity does not engage in discrimination prohibited by section 1557 if it declines to provide abortions based on religious or conscience objections to performing the procedure. In addition, any recipient that believes that it is exempt from certain provisions of this rule due to the application of a Federal conscience or religious freedom law may rely on those provisions, as referenced in § 92.3(c), or choose to seek assurance of the applications of those provisions pursuant to the process provided in § 92.302.

In light of § 92.302 and 42 U.S.C. 18023(c)(2)(A) (section 1303 of the ACA), OCR maintains that although some recipient providers and hospitals may decline to participate in federally funded health programs as a result of this rule, most will choose to continue to participate. To avoid confusion, we have further clarified the process for seeking assurance of an exemption based on religious freedom and conscience laws at § 92.302 and are committed to making available trainings and other resources to assist covered entities in understanding their obligations under section 1557 and the process by which they may seek assurance of an exemption under § 92.302.

Again, OCR appreciates that religiously affiliated hospitals and health care facilities play an important role in the health care system and recognizes the critical patient care needs they provide, including in underserved communities and areas which otherwise lack access to quality health care. Any discussion relating to the prevalence of religiously affiliated care is relevant for OCR to evaluate access issues that patients seeking certain procedures or care could potentially face, although OCR does not assume that all religiously affiliated entities' refusals to provide certain forms of care would result in such access issues. As previously stated, the 2022 NPRM provided factual findings with respect to health care accessibility in the United States based upon health care capacity of providers, population demands, and geographic limitations. 87 FR 47840. A detailed discussion of these considerations can be found in the Regulatory Impact Analysis (RIA).

Summary of Regulatory Changes

For the reasons set forth in the Proposed Rule and considering the comments received, OCR is finalizing the rule as proposed, without importing the title IX religious exception.

Relationship to Other Laws (§ 92.3)

In § 92.3, we provided an explanation of the relationship of the proposed regulation to existing laws. Proposed § 92.3(a) provided that neither section 1557 nor this part shall be interpreted to apply lesser standards for the protection of individuals from discrimination than the standards under title VI, title IX, section 504, the Age Act, or the regulations issued pursuant to those laws.

In § 92.3(b), we proposed that nothing in this part shall be interpreted to invalidate or limit the existing rights, remedies, procedures, or legal standards available under the Federal civil rights laws cited in 42 U.S.C. 18116(b) (title VI, title VII, title IX, section 504, and the Age Act), consistent with 42 U.S.C. 18116(b).

In § 92.3(c), we proposed that nothing in this part shall be interpreted to invalidate or limit the existing rights, remedies, procedures, or legal standards available under Federal religious freedom and conscience laws. Though not specifically referenced in the Proposed Rule, these include the protections in the ACA itself; the Church, Coats-Snowe, and Weldon Amendments; the generally applicable requirements of RFRA; and other applicable Federal laws.

The comments and our responses to this provision are set forth below.

Comment: Commenters expressed a mix of viewpoints regarding the ''lesser standard'' language included in proposed § 92.3(a), concerning civil rights statutes referenced in section 1557. Some commenters recommended removing the ''lesser standard'' language because it is not included in the section 1557 statute. Commenters stated that this language ignores Congress's decision to employ a particular standard to each of the civil rights laws incorporated, such that it would allow OCR to redefine bases for discrimination and improperly preempt State law affecting such categories.

Response: In this final rule, OCR seeks to give all laws their fullest possible effect. OCR appreciates these comments but declines to remove the ''lesser standard'' language included in § 92.3(a). As the 2016 Rule recognized, 81 FR 31381, this interpretation is consistent with a natural reading of section 1557's statutory text that explicitly states that section 1557 shall not be construed to ''invalidate or limit the rights, remedies, procedures, or legal standards'' of the referenced statutes (and title VII) ''or to supersede State laws that provide additional protections against discrimination,'' 42 U.S.C. 18116(b). OCR accordingly reaffirms that the civil rights laws referenced in section 1557 establish the grounds of prohibited discrimination, and nothing in this final rule is intended to provide lesser protections than those found under title VI, title IX, section 504, or the Age Act, or their implementing regulations.

Comment: Several commenters supported the inclusion of the ''lesser standard'' language in § 92.3(a) but suggested that § 92.3(c), concerning Federal religious freedom and conscience laws, is unnecessary and, if included without any limitations, undermines this ''lesser standard'' language of § 92.3(a) and could encourage discrimination.

Response: We decline to remove § 92.3(c), concerning Federal religious freedom and conscience laws. These laws remain applicable and removing the language runs contrary to the Department and OCR's stated commitment to protect the rights of individuals and entities under Federal conscience or religion freedom laws. Indeed, the ACA itself contains a similar provision at 42 U.S.C. 18023(c)(2)(A)(i), which provides that ''[n]othing in this Act shall be construed to have any effect on Federal laws regarding—conscience protection[.]'' As discussed later in this section, we have revised § 92.3(c) to provide additional specificity regarding the application of Federal religious freedom and conscience protections.

Comment: Some commenters suggested that OCR clarify that section 1557 does not limit the rights of individuals to any of the protections afforded under title VI, title IX, section 504, or the Age Act. These commenters suggested that section 1557 is a distinct law and, while it is intended to work in tandem with other civil rights laws, section 1557 stands on its own. Several other commenters requested that the final rule include language that clarifies that administrative exhaustion is not required to bring any claim under section 1557 in Federal court, where for example a claim may involve age as one basis of discrimination among several (*e.g.,* alleging discrimination on the bases of age, sex, and disability at the same time) but the Age Act has a

statutory requirement that claimants first exhaust their administrative remedies.

Response: Section 92.3(b) clearly states that this part does not limit or invalidate the rights, remedies, procedures, or legal standards under the statutes referenced (*i.e.,* title VI, title VII, title IX, section 504, and the Age Act), consistent with the statutory text of section 1557 at 42 U.S.C. 18116(b). In addition to incorporating the ''ground[s] prohibited'' by these other statutes, section 1557 incorporates the ''enforcement mechanisms'' of the statutes. 42 U.S.C. 18116(a). Though the section 1557 rule is informed by the title VI, title IX, Age Act, and section 504 implementing regulations, section 1557 provides an independent basis for regulation of discrimination in covered health programs and activities that is distinct from these statutes. Section 1557's nondiscrimination requirements do not in any way limit or impact the interpretation of those statutes. *See id.* at 18116(b). Section 1557 is a distinct civil rights authority.

Courts have long recognized that section 1557 authorizes a private right of action under any of the bases for discrimination. While we appreciate concerns raised by commenters regarding the heightened risks associated with unnecessary delays in the context of health care, we decline to revise regulatory text to adopt a stance on the appropriate standards that apply to private litigants. This is an issue appropriately addressed by the Federal judicial branch and not via agency rulemaking. Comments and responses regarding OCR procedures for conducting its own administrative enforcement are provided in §§ 92.303 (Procedures for health programs and activities conducted by recipients and State Exchanges) and 92.304 (Procedures for health programs and activities administered by the Department).

Comment: Many commenters raised concerns about the potential conflicts of State and Federal laws. Some commenters expressed that any conflict between State and Federal law or policy would be inconsistent with the principles of federalism. Some commenters had specific concerns regarding the final rule's application to State laws that prohibit transgender patients from receiving certain medically necessary gender-affirming care or those that protect religious freedom and conscience. Other commenters suggested that OCR should include a subsection in the final rule that addresses the interaction between section 1557 and State or local laws, making explicit that a State may set more rigorous standards for nondiscrimination in the provision of health care but not lesser protections than those of section 1557. To the extent State or local law offers lesser protections these commenters recommended OCR make explicit that such laws are preempted by Federal law, consistent with the general preemption standard for title I of the ACA, codified at 42 U.S.C. 18041(d).

Response: OCR appreciates these comments regarding the rule's interaction with State and other Federal laws. We agree with commenters who observed that Federal laws, as a general matter, preempt conflicting State laws. *See* U.S. Const. art. 6, cl. 2. We also note that title I of the ACA itself contains a preemption provision, which courts have interpreted to preempt State laws that serve as an obstacle to or frustrate the purpose of the ACA.[34] *See* 42 U.S.C. 18041(d). Accordingly, we decline to alter the regulation to include any additional language under this provision addressing preemption. OCR recognizes that some States may have laws impacting health programs and activities that are contrary to the final rule's nondiscrimination protections, and as discussed later regarding § 92.206 (Equal program access on the basis of sex), section 1557 preempts those laws, though OCR will consider the specific facts of each case and any other relevant factors in determining whether the recipient has a legitimate, nondiscriminatory reason for taking actions that conflict with section 1557. OCR is adding § 92.3(d) regarding State and local laws to provide: ''Nothing in this part shall be construed to supersede State or local laws that provide additional protections against discrimination on any basis described in § 92.1.''

Comment: Commenters recommended that OCR include in the final rule clarification that the Emergency Medical Treatment and Labor Act (EMTALA) protects emergency care for pregnancy and related conditions, including termination of pregnancy.

Response: This rule concerns section 1557 and does not purport to interpret or enforce EMTALA—indeed, OCR does not enforce EMTALA, nor does EMTALA limit or expand the civil rights protections found in section 1557.

Summary of Regulatory Changes

For the reasons set forth in the Proposed Rule and considering the comments received, we are finalizing the provisions as proposed in § 92.3, with modifications. We are revising § 92.3(c) to provide that, insofar as the application of any requirement under the part would violate applicable Federal protections for religious freedom and conscience, such application shall not be required. For example, 42 U.S.C. 18023 provides (among other things) that, nothing in section 1557 shall be construed to have any effect on Federal laws regarding conscience protection; willingness or refusal to provide abortion; and discrimination on the basis of the willingness or refusal to provide, pay for, cover, or refer for abortion or to provide or participate in training to provide abortion. We are also adding a new § 92.3(d) to provide that nothing in the part shall be construed to supersede State or local laws that provide additional protections against discrimination on any basis described in § 92.1.

Definitions (§ 92.4)

In § 92.4 of the Proposed Rule, we set out proposed definitions of various terms. The comments and our responses regarding § 92.4 are set forth below.

Auxiliary aids and services. The term auxiliary aids and services was defined in the 2016 Rule and has not been changed substantively. The proposed definition is consistent with the Americans with Disabilities Act (ADA) regulations at 28 CFR 35.104 and 36.303(b) and provides examples of auxiliary aids and services.

Comment: Commenters generally supported the definition of ''auxiliary aids and services.'' Some commenters recommended that the final rule clarify that ''similar services and actions'' are available for all individuals with disabilities, not just for individuals who are deaf or hard of hearing and individuals who are blind or have low vision.

Response: OCR appreciates this comment; however, effective communication requirements are addressed in § 92.202(a). As § 92.4 is simply providing a definition for the term auxiliary aids and services, which is used in § 92.202(b), we do not believe

[34] *See St. Louis Effort for AIDS* v. *Huff,* 782 F.3d 1016, 1021, 1024 (8th Cir. 2015) (partially affirming lower court preliminary injunction because Missouri law ''frustrates Congress' purpose'' and ''pose[s] an obstacle to the accomplishment and execution of the full purposes and objectives of Congress''); *Coons* v. *Lew,* 762 F.3d 891 (9th Cir. 2014), *as amended,* (Sept. 2, 2014) (''The Affordable Care Act presents a classic case of preemption by implication because the Arizona Act 'stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.' ''), *quoting Gade* v. *Nat'l Solid Wastes Mgmt. Ass'n,* 505 U.S. 88, 98 (1992).

§ 92.11(c)(5)(ix) to read: ''Communications related to the cost and payment of care with respect to an individual, including medical billing and collections materials, and good faith estimates required by section 2799B–6 of the Public Health Service Act.'' We are also making technical revisions, including replacing ''limited English proficient individual'' with ''individual with limited English proficiency,'' consistent with modifications elsewhere.

Data Collection

We solicited comments on requiring covered entities to collect additional data, beyond those required by the referenced statutes and their regulations, on race, ethnicity, language, sex, gender, gender identity, sexual orientation, disability, and age, to inform a final rule and OCR's overall civil rights work.

We also sought comment on whether covered entities are already collecting disaggregated demographic data in their health programs and activities and, if so, for which categories of data, through what systems, and at what cost. We also invited comment on how a section 1557 civil rights data collection requirement could impact current data collection efforts, either positively or negatively. We also requested comment on whether the adoption of a regulatory standard for a recurring civil rights data collection would benefit civil rights enforcement, as well as how frequently the data should be submitted to OCR. We also sought comment on whether the data collection requirements should vary by type of entity, as recipients of Federal financial assistance include a variety of entities, including State and local agencies, health insurance issuers, providers, health care facilities and clinics, hospitals, Federally Qualified Health Centers, and health-related educational and training programs. Accordingly, we invited comment on which types of recipients (if any) should be covered; if recipients under a certain size should be exempt from the data collection requirement, and if so, whether that exemption should be based on employee number, the number of beds (if relevant), or some other metric; what types of data should be collected; what definitions should be used; the potential costs associated with such a requirement; and the potential benefits of such a requirement.

The comments and our responses regarding data collection are set forth below.

Comment: Some commenters recommended that OCR not mandate the collection of data, with some strongly suggesting that we minimize provider burden and utilize existing data collection systems.

Response: OCR is not including a data collection requirement in the final rule. OCR has the authority independent of this rulemaking to conduct data calls to ensure recipient compliance with Federal civil rights laws.[98] OCR is actively engaged with other agencies within the Department and throughout the Federal Government related to responsible data collection and recognizes the importance of data collection to meet its mission. We will continue to work with covered entities and beneficiaries to determine whether an additional data collection requirement is needed in a future rulemaking.

Comment: Some commenters recommended that OCR adopt data collection standards. They noted that with any demographic data collection requirement, OCR must provide appropriate training and technical assistance resources to programs and grantees and make clear that data cannot be used for negative actions such as immigration or law enforcement, redlining, or targeting of specific groups.

Response: OCR appreciates the comments regarding standards and safeguards to ensure that programs and grantees have the appropriate training. OCR also understands the concerns that some commenters have regarding data being used for adverse actions. While OCR is not including a data collection requirement in the final rule, OCR will continue to research the benefits of civil rights data collection and how to mitigate potential negative impacts.

Comment: Some commenters urged OCR to require covered entities to collect data regarding a core set of disaggregated categories to include race, ethnicity, language, sex, gender, gender identity, sexual orientation, pregnancy status, sex characteristics, disability, and age from patients and providers. Commenters stated that data are essential to identify and address unmet needs, and for many populations data remain largely uncollected. Some commenters also noted that collecting disaggregated data could allow OCR to distinguish the impact of intersectional discrimination on those seeking access to health care. Some commenters also urged that if individuals volunteer such information, it should be self-reported to ensure accuracy and privacy.

Response: OCR agrees that better standards and practices for collecting data can have a positive impact on reducing disparities. OCR will continue to work to ensure that any civil rights data collection yields accurate data that adequately protects the privacy of individuals.

Summary of Regulatory Changes

For the reasons set forth above and considering the comments received, we are finalizing the rule without a data collection provision.

Subpart B—Nondiscrimination Provisions

In subpart B, OCR proposed provisions related to the prohibition of discrimination on the basis of race, color, national origin, sex, age, and disability in covered health programs and activities.

Discrimination Prohibited (§ 92.101)

In § 92.101(a), we proposed a general prohibition of discrimination on the basis of race, color, national origin, sex, age, or disability under any health program or activity to which section 1557 or the part applies and provided additional detail regarding what constitutes discrimination on the basis of sex.

In § 92.101(a)(1), we proposed general prohibitions on discrimination under section 1557 by restating the core objective of section 1557. In § 92.101(a)(2), we clarified that discrimination on the basis of sex includes discrimination on the basis of sex stereotypes; sex characteristics, including intersex traits; pregnancy or related conditions; sexual orientation; and gender identity.

In § 92.101(b), we identified several specific forms of prohibited discrimination under section 1557. Proposed § 92.101(b)(1)(i) specifically referred to recipients of Federal financial assistance and State Exchanges; proposed § 92.101(b)(1)(ii) referred to the Department's health programs and activities, including Federally-facilitated Exchanges.

In § 92.101(b)(2), we proposed that the enumeration of specific forms of discrimination in 92.101(b) does not limit the general application of the prohibition in proposed § 92.101(a).

The comments and our responses regarding § 92.101 are set forth below.

Comment: Numerous commenters supported the Proposed Rule's nondiscrimination provisions, stating that these provisions would promote the health equity for communities of color and increase access to coverage and care for those who have been historically underserved because of race, ethnicity, language, age, disability, and sex. Many commenters stated that OCR should finalize the provisions without delay.

[98] *See, e.g.,* 45 CFR 80.6(b).

Another commenter supported the proposed discrimination prohibitions as consistent with the ACA, and another requested that more support be provided for educating the public about the nondiscrimination obligations of health programs and activities.

Response: OCR agrees that the nondiscrimination provisions are one important tool to address health disparities and advance health equity. OCR will continue to provide technical assistance and public education related to compliance with section 1557 and encourages covered entities to continue to visit our website for technical assistance materials.

Comment: Numerous commenters stated that section 1557's explicit prohibition on discrimination based on multiple grounds fills a critical gap by protecting patients who may experience multiple forms of discrimination. Commenters provided numerous examples of simultaneous discrimination on more than one protected basis, including, but not limited to, discrimination against LGBTQI+ individuals of color, with disabilities, with LEP, or who are immigrants; and Black and Hispanic/Latino older adults. Numerous commenters recommended that OCR revise § 92.101(a)(1) to include ''or any combination thereof'' to explicitly account for intersectional discrimination within the regulatory text.

Response: OCR agrees that simultaneous discrimination on multiple prohibited bases, is important to account for and is prohibited by section 1557. As we noted in the Proposed Rule, a recent study examined disability and pregnancy as intersecting traits and how this may impact risk for maternal morbidity and mortality, underscoring the importance of ensuring nondiscrimination against women with disabilities. 87 FR 47837. The Proposed Rule also provided information regarding Black maternal health and the alarming disparities in maternal mortality rates for Black women and American Indian/Alaska Native women. 87 FR 47832.

Therefore, to account for the fact that individuals can experience discrimination based on two or more protected bases (race, color, national origin, sex, age, and disability), we have amended the language of § 92.101(a)(1) to include ''or any combination thereof.'' This language has also been amended throughout the final rule for consistency. The addition intends to clarify that an individual is protected from discrimination on more than one protected basis that occurs at the same time.

Comment: A commenter provided a discussion of the harms and unaddressed discrimination faced by patients with rare diseases and requested that OCR explicitly prohibit discrimination against patients with rare diseases. Some commenters requested that specific recognition also be made for patients with liver diseases. A commenter requested that the proposed regulatory text or accompanying guidance provide examples of discrimination on the basis of disability.

Response: Discrimination against an individual with a rare or specific disease that meets the definition of ''disability'' will be addressed under section 1557's prohibition on discrimination on the basis of disability, which already appears in the rule. The commenter's request for further guidance will be taken into consideration. For additional information related to disability discrimination, please see the discussions under subpart C. OCR also provides guidance and examples, as well as answers to frequently asked questions related to disability discrimination on our website.

Comment: A number of commenters asked that vaccination status be added as a ground of prohibited discrimination, stating that their right to make their own health care decisions should be protected.

Response: Section 1557 prohibits discrimination on the basis of race, color, national origin, sex, age, and disability. To the extent vaccination status is not related to these prohibited bases of discrimination specified by Congress in section 1557, we decline to include it as a ground of prohibited discrimination under this rule.

Comment: Some tribal organizations recommended that OCR acknowledge American Indian/Alaska Native (AI/AN) people as holding a political classification as compared to a race-based classification and to exempt Tribal health programs from the final rule. These commenters stated that recognizing the political classification of AI/AN people allows AI/AN providers to only serve AI/AN patients, which commenters said is necessary because of logistical capacity constraints.

Response: As discussed at § 92.2, OCR recognizes the unique relationship between the United States and federally recognized tribal entities. Federal Government preferences based on an individual's membership or eligibility in a federally recognized tribal entity are based on political classifications. Such classifications are not race-based. As such, preferences on this basis do not violate the Equal Protection Clause,[99] title VI,[100] or section 1557. As discussed at § 92.2, preferences based on the unique relationship between the United States and federally recognized Tribes are distinct from the protections afforded under Federal civil rights laws, which protect all individuals from discrimination on the basis of race, color, or national origin (including AI/AN individuals, regardless of tribal enrollment or affiliation). This final rule adopts by reference the Department's title VI regulatory provision at 45 CFR 80.3(d), which provides that an individual shall not be deemed subjected to discrimination by reason of their exclusion from benefits limited by Federal law—such as the Indian Health Service—to individuals of a different race, color, or national origin. OCR will fully apply this provision as well as other applicable exemptions or defenses that may exist under Federal law. OCR intends to address any restrictions on application of section 1557 to Tribal entities in the context of individual complaints or compliance reviews.

Comment: A commenter suggested that nondiscrimination protections should be extended to health care workers, indicating that health care workers often experience discrimination, especially on the basis of race and that additional protections are needed.

Response: While OCR acknowledges that health care workers can face discrimination as they provide health care, OCR does not have jurisdiction over patients who may discriminate against health care workers, as patients are not covered entities under section 1557. Separately, and as previously noted, OCR does not intend for this rule to apply to employment discrimination. If OCR receives a complaint from a health care worker, we will determine if we have jurisdiction to investigate. Complaints received by OCR from health care workers alleging discrimination experienced in the context of employment will be referred to an appropriate agency, per §§ 92.303(b) and 92.304(a) (incorporating 45 CFR 85.61(e)), as this regulation does not apply to employment practices.

Comment: Many commenters expressed support for the explicit references to discrimination on the basis of sex stereotypes; sex characteristics, including intersex traits; pregnancy or related conditions; sexual orientation; and gender identity as forms of

[99] *See Morton* v. *Mancari,* 417 U.S. 535 (1974).

[100] 45 CFR 80.3(d).

discrimination on the basis of sex in § 92.101(a)(2). Commenters pointed to evidence of health disparities and barriers to accessing health care faced by LGBTQI+ people, and how ongoing health care discrimination contributes to higher rates of substance use, mental health conditions, HIV, cancer, and cardiovascular disease for LGBTQI+ people relative to non-LGBTQI+ people.[101] Several commenters stated that § 92.101(a)(2)'s prohibitions should be mirrored in the CMS regulations addressed in section IV.

Response: It is well documented that LGBTQI+ people face significant health disparities and barriers to health care and insurance coverage,[102] and section 1557's protections are critical tools to combat those disparities. We appreciate commenters' view that CMS regulations within this rulemaking should mirror the language provided in § 92.101(a)(2), and we refer readers to section IV (CMS Amendments).

Comment: A number of comments addressed discrimination in the context of organ transplantation. Several commenters noted that people with disabilities are routinely denied access to organ transplants due to stereotypical assumptions about compliance with post-operative care and policies that deny transplants to otherwise eligible individuals with disabilities.[103]

Several commenters noted that existing practices in organ transplants appear to discriminate against Black, Hispanic/Latino, and Native American/Alaska Native individuals, as those individuals are more likely to develop end stage renal disease but are less likely to receive a kidney transplant than white individuals.[104] Another commenter stated that providers may discriminate against immigrant patients during the assessment process by assuming they lack social support or the ability to care for themselves after organ transplantation, resulting in a denial of care.[105]

Response: Discrimination on the basis of disability and race in the provision of health care, including organ transplantation, is a continuing issue that limits opportunities for life-saving treatment. This final rule provides OCR with a powerful tool to help address this ongoing issue. While section 1557 does not prohibit discrimination on the basis of immigration status, section 1557's protections apply regardless of someone's citizenship or immigration status, and individuals who believe they have been discriminated against based on certain characteristics such as race, color, and national origin can file a complaint. We will continue to address discrimination in organ transplantation through robust enforcement of not only section 1557, but all Federal civil rights laws.[106]

Comment: Numerous commenters generally supported the inclusion of the prohibition of discrimination on the basis of gender identity and sexual orientation as prohibited types of sex discrimination in proposed § 92.101(a)(2). They maintained that inclusion was consistent with *Bostock* v. *Clayton County,* 590 U.S. 644 (2020), in which the Supreme Court held that title VII's prohibition of discrimination because of sex includes discrimination on the basis of sexual orientation and gender identity. Commenters supported the application of the reasoning in *Bostock* to title IX by citing several cases, DOJ resource materials, and Executive Order (E.O.) 13988.[107] Another commenter cited several cases stating that courts have treated title VII and title IX protections as consistent with one another in support of the application of *Bostock* to title IX.[108] A few commenters cited *City of Los Angeles Department of Water and Power* v. *Manhart,* 435 U.S. 702 (1978), as indicating that, for decades, sex discrimination prohibitions have covered sex stereotypes. The commenters also cited several opinions from district courts and one appellate court as indicating that discrimination on the basis of gender identity, gender transition, sex stereotypes, or transgender status are, similarly, unlawful types of sex discrimination.[109] Other commenters provided cites to numerous other cases as including gender identity and sexual orientation as characteristics protected by sex discrimination law.[110]

Conversely, several commenters stated that *Bostock* does not support § 92.101(a)(2) as written. Some commenters stated that *Bostock* defined sex to include only ''biological distinctions between male and female'' and used the term ''transgender status''

[101] *See, e.g.,* Charlotte Patterson et al., Nat'l Acads. of Sci., Eng'g, & Med., *Understanding the Well-Being of LGBTQI+ Populations* (2020), *https://doi.org/10.17226/25877*; Lambda Legal, *When Health Care Isn't Caring: Lambda Legal's Survey of Discrimination Against LGBT People and People with HIV* (2010), *www.lambdalegal.org/health-care-report*; Cornell Univ., *What Does the Scholarly Research Say about the Effects of Discrimination on the Health of LGBT People?* (2019), *https://whatweknow.inequality.cornell.edu/topics/lgbt-equality/what-does-scholarly-research-say-about-the-effects-of-discrimination-on-the-health-of-lgbt-people/.*

[102] *See, e.g.,* Sharita Gruberg et al., Ctr. for Am. Progress, *The State of the LGBTQ Community in 2020* (2020), *https://www.americanprogress.org/issues/lgbtq-rights/reports/2020/10/06/491052/state-lgbtq-community-2020/*; Sandy E. James et al., Nat'l Ctr. for Transgender Equality, *The Report of the 2015 U.S. Transgender Survey,* p. 97 (2016), *https://transequality.org/sites/default/files/docs/usts/USTS-Full-Report-Dec17.pdf. See also* Caroline Medina et al., Ctr. For Am. Progress, *Discrimination and Barriers to Well-Being: The State of the LGBTQI+ Community in 2022* (2023), *https://www.americanprogress.org/article/discrimination-and-barriers-to-well-being-the-state-of-the-lgbtqi-community-in-2022/.*

[103] *See* Nat'l Council on Disability, *Organ Transplant Discrimination Against People with Disabilities* (2019), *https://www.ncd.gov/assets/uploads/reports/2019/ncd_organ_transplant_508.pdf.*

[104] *See* U.S. Renal Data System, *2021 Annual Report: End Stage Renal Disease* ch. 1 (2021) (Figure 1.8); Hannah Wesselman et al., *Social Determinants of Health and Race Disparities in Kidney Transplant,* 16 Clin. J. Am. Soc'y Nephrol. 262, 262 (2021).

[105] *See* Garyphallia Poulakou, Oscar Len & Murat Akova, *Immigrants as Donors and Transplant Recipients: Specific Considerations,* 45 Int. Care Med. 401 (2019), *https://pubmed.ncbi.nlm.nih.gov/30701293/.*

[106] *See, e.g.,* U.S. Dep't Health & Hum. Servs., Off. for Civil Rts., *OCR Resolves Disability Complaint of Individual Who Was Denied the Opportunity for Health Transplant List Placement* (Feb. 12, 2019), *https://www.hhs.gov/about/news/2019/02/12/ocr-resolves-disability-complaint-individual-who-was-denied-opportunity-heart-transplant-list.html.*

[107] E.O. 13988, 86 FR 7023 (Jan. 25, 2021). U.S. Dep't of Justice, Title IX Legal Manual, *https://www.justice.gov/crt/title-ix. See, e.g., Grimm* v. *Gloucester Cnty. Sch. Bd.,* 972 F.3d 586, 616–17 (4th Cir. 2020), *as amended* (Aug. 28, 2020), *reh'g en banc denied,* 976 F. 3d 399 (4th Cir. 2020), cert. denied, No. 20–1163 (June 28, 2021); *B.P.J.* v. *W. Va. State Bd. of Educ.,* No. 2:21–CV–00316, 2021 WL 3081883, at *7 (S.D.W. Va. July 21, 2021); *Koenke* v. *Saint Joseph's Univ.,* No. CV 19–4731, 2021 WL 75778, at *2 (E.D. Pa. Jan. 8, 2021); *Doe* v. *Univ. of Scranton,* No. 3:19–CV–01486, 2020 WL 5993766, at *11 n.61 (M.D. Pa. Oct. 9, 2020).

[108] *See, e.g., Doe* v. *Snyder,* 28 F.4th 103, 113–14 (9th Cir. 2022); *Emeldi* v. *Univ. of Or.,* 698 F.3d 715, 725 (9th Cir. 2012); *Franklin* v. *Gwinnett Cnty. Pub. Sch.,* 503 U.S. 60, 75 (1992); *Grimm* v. *Gloucester Cnty. Sch. Bd.,* 972 F.3d 586, 616 (4th Cir. 2020).

[109] *See Kadel* v. *Folwell,* 620 F. Supp. 3d 339, 379 (M.D.N.C. 2022); *Fain* v. *Crouch,* 618 F .Supp. 3d 313, 326–27 (S.D.W. Va. 2022); *Fletcher* v. *Alaska,* 443 F. Supp. 3d 1024, 1027, 1030 (D. Alaska 2020); *Flack* v. *Wisconsin Dep't of Health Servs.,* 395 F. Supp. 3d 1001, 1019–22 (W.D. Wis. 2019); *Boyden* v. *Conlin,* 341 F. Supp. 3d 979, 1002–03 (W.D. Wis. 2018); *Cf. Brandt by & through Brandt* v. *Rutledge,* 2022 WL 3652745, at *2 (8th Cir. Aug. 25, 2022).

[110] *See,* among others cited, *Grimm* v. *Gloucester Cnty. Sch. Bd.,* 972 F.3d 586, 593, 616, 619 (4th Cir. 2020), *reh'g en banc denied,* 976 F.3d 399 (4th Cir. 2020); *Whitaker* v. *Kenosha Unified Sch. Dist. No. 1 Bd. of Educ.,* 858 F.3d 1034, 1049–50 (7th Cir. 2017); *Fain* v. *Crouch,* No. 3:20–0740, 2022 U.S. Dist. LEXIS 137084, at *35–36 (S.D. W. Va. Aug. 2, 2022); *Scott* v. *St. Louis Univ. Hosp.,* No. 4:21–cv–01270–AGF, 2022 U.S. Dist. LEXIS 74691, at *18 (E.D. Mo. Apr. 25, 2022); *C.P.* v. *Blue Cross Blue Shield of Ill.,* 536 F. Supp. 3d 791, 793 (W.D. Wash. 2021); *Flack* v. *Wis. Dep't of Health Servs.,* 395 F. Supp. 3d 1001, 1014–15 (W.D. Wis. 2019); *Boyden* v. *Conlin,* 341 F. Supp. 3d 979, 997, 1002–03 (W.D. Wis. 2018); *Tovar* v. *Essentia Health,* 342 F. Supp. 3d 947, 953 (D. Minn. 2018); *Prescott* v. *Rady Children's Hosp.-San Diego,* 265 F. Supp. 3d 1090, 1098–1100 (S.D. Cal. 2017); *Adams* v. *Sch. Bd. of St. Johns Cnty.,* 968 F.3d 1286, 1305 (11th Cir. 2020); *Zarda* v. *Altitude Express, Inc.,* 883 F.3d 100, 112–13 (2nd Cir. 2018); *Franchina* v. *Providence,* 881 F.3d 32, 53–54 (1st Cir. 2018); *Hively* v. *Ivy Tech,* 853 F.3d 339, 340–41 (7th Cir. 2017).

rather than ''gender identity.'' A commenter argued that title VII should be treated as distinct from title IX because title IX uses the term ''on the basis of sex''—language the commenter described as requiring more than ''but for causation''—while title VII uses ''because of . . . sex.'' Other commenters discussed title IX to support arguments that discrimination on the basis of sex does not include discrimination on the basis of sexual orientation or gender identity, and that title IX only protects people on the basis of ''biological sex.''

Some commenters cited to various cases in opposition to the inclusion of gender identity and sexual orientation in proposed § 92.101(a)(2), including *State of Tennessee* v. *Department of Education,* 615 F. Supp. 3d 807 (E.D. Tenn. 2022), to support the belief that agencies cannot rely on the reasoning in *Bostock* to interpret what constitutes sex discrimination under title IX. Another commenter stated that E.O. 13988 improperly expands the application of *Bostock* and cited *Franciscan Alliance* v. *Burwell,* 227 F. Supp. 3d 660 (N.D. Tex. 2016) in support. Some commenters stated that RFRA's religious protections may supersede the sex discrimination protections described in *Bostock,* and one commenter cited *Hosanna-Tabor Evangelical Lutheran Church and School* v. *EEOC,* 565 U.S. 171 (2012), for the proposition that that First Amendment protections may supersede employment discrimination laws. Another commenter stated that OCR's interpretation of what is prohibited sex discrimination is contrary to law, citing to *Franciscan Alliance, Inc.* v. *Becerra* [111] and *Christian Employers Alliance* v. *EEOC.*[112]

Response: Case law offers strong support for the position that sex discrimination under section 1557 includes discrimination on the basis of gender identity and sexual orientation. As previously noted, a body of developing case law explains how to identify unlawful sex discrimination. As part of its prohibition on sex discrimination, this rule prohibits discrimination against individuals who do not conform with stereotypical notions of how an individual is expected to present as male or female, regardless of gender identity. This is consistent with longstanding case law; more than 30 years ago, a plurality of the Supreme Court held in *Price Waterhouse* that discrimination based on sex stereotypes was a prohibited form of sex discrimination. We have included a number of examples throughout the preamble discussion to help covered entities better understand their obligations. OCR is also committed to providing technical assistance to support compliance with this final rule and may consider additional guidance that may assist covered entities with their obligations.

As noted in the Proposed Rule, the inclusion of ''sexual orientation'' and ''gender identity'' in § 92.101(a)(2) is consistent with the Supreme Court's reasoning in *Bostock.* 87 FR 47858. Title IX and section 1557 prohibit discrimination ''on the basis of sex.'' [113] And the *Bostock* Court used the phrase ''because of sex'' and ''on the basis of sex'' interchangeably.[114] Because the statutory prohibitions against sex discrimination in title VII and title IX are similar, the Supreme Court and other Federal courts look to interpretations of title VII to inform title IX.[115] Thus, *Bostock's* discussion of the text of title VII informs the OCR's analysis of title IX and section 1557. Given the similarity in nondiscrimination language between title VII and title IX, many Federal courts that have addressed the issue have interpreted section 1557 and title IX consistent with *Bostock's* reasoning.[116] Since *Bostock,* three Federal courts of appeals have held that the plain language of title IX's prohibition on sex discrimination must be read similarly to title VII's prohibition.[117] OCR agrees with the reasoning in these cases.[118] Additionally, there is a significant amount of case law, pre-and post-*Bostock* that affirms that sex discrimination includes discrimination based on gender identity.[119]

We disagree with commenters' assertion that the Court's use of the term ''transgender status'' in *Bostock,* rather than ''gender identity,'' results in any meaningful distinction regarding protections afforded to transgender individuals or other individuals experiencing discrimination on the basis of their gender identity. The Court's choice of language reflects that it was addressing the gender identity of the plaintiff before it, who was transgender, and does not preclude the case's application to other gender identities. Indeed, even the dissent stated that ''there is no apparent difference between discrimination because of transgender status and discrimination because of gender identity.'' 590 U.S. at 686, n.6 (Alito, J. joined by Thomas, J., dissenting).

Additional citations by those opposing the language in § 92.101(a)(2) are either not applicable, already discussed in the Proposed Rule, or outdated. To begin, this rule does not

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[111] 553 F. Supp. 3d 361 (N.D. Tex. 2021), *amended,* No. 7:16–cv–00108–O, 2021 WL 6774686 (N.D. Tex. Oct. 1, 2021), *appeal docketed,* No. 21–11174 (5th Cir. Nov. 26, 2021); *see also Franciscan All., Inc.* v. *Becerra,* 47 F.4th 368 (5th Cir. 2022).

[112] *Christian Emp'rs All.* v. *EEOC,* No. 21–cv–00195, 2022 WL 1573689 (D.N.D. May 16, 2022).

[113] 20 U.S.C. 1681(a); 42 U.S.C. 18116.

[114] *See, e.g.,* 590 U.S. 653, 662, 681.

[115] *See, e.g., Franklin* v. *Gwinnett Cnty. Pub. Sch.,* 503 U.S. 60, 75 (1992); *Jennings* v. *Univ. of N.C.,* 482 F.3d 686, 695 (4th Cir. 2007); *Gossett* v. *Okla. ex rel. Bd. Of Regents for Langston Univ.,* 245 F.3d 1172, 1176 (10th Cir. 2001).

[116] *See, e.g., Doe* v. *Snyder,* 28 F.4th 103, 113–14 (9th Cir. 2022); *Grimm* v. *Gloucester Cnty. Sch. Bd.,* 972 F.3d 586, 616 (4th Cir. 2020); *but cf. Adams* v. *Sch. Bd. of St. Johns Cnty,* 57 F.4th 791, 811–15 (11th Cir. 2022) (en banc)).

[117] *See A.C. by M.C.* v. *Metro. Sch. Dist. Of Martinsville,* 75 F.4th 760, 769 (7th Cir. 2023); *Grabowski* v. *Ariz. Bd. Of Regents,* 69 F.4th 1110, 1116–17 (9th Cir. 2023); *Doe* v. *Snyder,* 28 F.4th 103, 113–14 (9th Cir. 2022); *Grimm* v. *Gloucester Cnty. Sch. Bd.,* 972 F.3d 586, 616 (4th Cir. 2020), *as amended* (Aug. 28, 2020), *cert. denied,* 141 S. Ct. 2878 (Mem) (2020).

[118] OCR acknowledges that at least one court has held that it would be a misapplication of *Bostock* to interpret the definition of ''sex discrimination'' under section 1557 and title IX to include gender identity and sexual orientation. In *Neese* v. *Becerra,* 640 F. Supp. 3d 668, the U.S. District Court for the Northern District of Texas held that the Department misapplied *Bostock* when it issued a public notice, 86 FR 27984 (May 25, 2021), stating that it would interpret section 1557 and title IX's prohibition on sex discrimination to include discrimination on the basis of sexual orientation and gender identity. The Department appealed that decision to the U.S. Court of Appeals for the Fifth Circuit and oral argument was held on January 8, 2024. The Department is not applying the challenged interpretation to members of the *Neese* class pending the appeal.

[119] *See, e.g., Whitaker By Whitaker* v. *Kenosha Unified Sch. Dist. No. 1 Bd. Of Educ.,* 858 F.3d 1034 (7th Cir. 2017) (title IX); *Smith* v. *City of Salem, Ohio,* 378 F.3d 566 (6th Cir. 2004) (title VII); *Rosa* v. *Park W. Bank & Trust Co.,* 214 F.3d 213 (1st Cir. 2000) (Equal Credit Opportunity Act); *Schroer* v. *Billington,* 577 F. Supp. 2d 293 (D.D.C. 2008) (title VII); *Boyden v. Conlin,* 341 F. Supp. 3d 979 (W.D. Wis. 2018) (section 1557 and title VII); *Flack* v. *Wis. Dep't. of Health Servs.,* 395 F. Supp 3d 1001, 1014 (W.D. Wis. 2019) (section 1557 and Equal Protection Clause); *Prescott* v. *Rady Children's Hosp. San Diego,* 265 F. Supp. 3d 1090, 1098–100 (S.D. Cal. 2017) (section 1557); *Tovar* v. *Essential Health,* 342 F. Supp. 3d 947, 957 (D. Minn. 2018) (section 1557). *See also Doe* v. *Snyder,* 28 F.4th 103, 113–14 (9th Cir. 2022); *Grimm* v. *Gloucester Cnty. Sch. Bd.,* 972 F.3d 586, 616 (4th Cir. 2020), *as amended* (Aug. 28, 2020), cert. denied, 141 S. Ct. 2878 (Mem) (2020); *Kadel* v. *Folwell,* No. 1:19–cv–00272, 2022 WL 2106270, at *28–*29 (M.D.N.C. June 10, 2022); *Scott* v. *St. Louis Univ. Hosp.,* No. 4:21–cv-01270–AGF, 2022 WL 1211092, at *6 (E.D. Mo. Apr. 25, 2022); *C.P. by & through Pritchard* v. *Blue Cross Blue Shield of Ill.,* No. 3:20–cv–06145–RJB, 2021 WL 1758896, at *4 (W.D. Wash. May 4, 2021); *Koenke* v. *Saint Joseph''s Univ.,* No. CV 19–4731, 2021 WL 75778, at *2 (E.D. Pa. Jan. 8, 2021); *Doe* v. *Univ. of Scranton,* No. 3:19–cv–01486, 2020 WL 5993766, at *11 n.61 (M.D. Pa. Oct. 9, 2020); *Maxon* v. *Seminary,* No. 2:19–cv–9969, 2020 WL 6305460 (C.D. Cal. Oct. 7, 2020); *B.P.J.* v. *W. Va. State Bd. Of Educ.,* No. 2:21–cv–00316, 2021 WL 3081883, at *7 (S.D.W. Va. July 21, 2021); *Clark Cnty. Sch. Dist. V. Bryan,* 478 P.3d 344, 354 (Nev. 2020).

rely on E.O. 13988 for its authority, so criticisms of that order do not undermine the final rule. *State of Tennessee* is inapposite. There, the court held that the plaintiffs had demonstrated a reasonable likelihood of success on the claim that two other Federal agencies violated the Administrative Procedure Act by foregoing notice-and-comment procedures.[120] That is not at issue here, as this is notice-and-comment rulemaking and not the issuance of informational documents. *Hosanna-Tabor* involved First Amendment limitations on the application of employment discrimination laws—specifically the ''ministerial exception'' that precludes application of employment discrimination laws to ''claims concerning the employment relationship between a religious institution and its ministers.'' 565 U.S. at 188. As discussed throughout the Proposed Rule, beginning at 87 FR 47826, OCR is aware of and discusses both *Franciscan Alliance* v. *Becerra* and *Christian Employers Alliance* v. *EEOC,* and the Department is not prohibited from finalizing this rule by either decision. 87 FR 47826. Additionally, the final rule adopts new procedures for recipients wishing to invoke Federal religious freedom and conscience protections. For more on those procedures, see § 92.302.

Finally, OCR disagrees with the commenters who cited *Franciscan Alliance* v. *Burwell,* 227 F. Supp. 3d 660 (N.D. Tex. 2016), in support of the view that section 1557 and title IX's prohibition on sex discrimination does not include discrimination on the basis of sexual orientation and gender identity. The legal landscape in this area has changed since that decision issued and the publication of the Proposed Rule. The *Franciscan Alliance* v. *Burwell* court concluded that the 2016 Rule's definition of ''sex'' as including ''gender identity'' was contrary to section 1557 because ''Title IX and Congress' incorporation of it in [section 1557 of] the ACA unambiguously adopted the binary definition of sex.'' *Id.* at 689. Four years later, the Supreme Court held that the prohibition on discrimination ''because of . . . sex'' under title VII covers discrimination on the basis of gender identity and sexual orientation, even assuming that ''sex'' refers ''only to biological distinctions between male and female.'' *Bostock,* 590 U.S. at 655. The *Bostock* Court held that the statute's prohibition on employment discrimination ''because of sex'' encompasses discrimination on the basis of sexual orientation and gender identity. *Id.* at 670–71.

Comment: Several commenters generally asserted that sex is an immutable, biological binary. Some commenters relayed that their religious beliefs include that sex is an immutable binary. A commenter stated that sex has a biological component that impacts medical care.

A commenter argued that if the rule does not recognize that sex is a biological binary, there will be increased confusion in the provision of medical services. Another commenter expressed concern that the rule would diminish the quality of health care received by some patients because some health conditions, such as symptoms of heart attacks, are based on ''biological sex characteristics.'' A commenter said that a prohibition of discrimination on the basis of gender identity would validate the recognition of gender identity and increase gender dysphoria.

Response: OCR recognizes that sex has biological components and knowledge of an individual's biological attributes is an essential component of providing high quality health care for all patients. For example, in the Proposed Rule, we discussed the various health disparities experienced by women, which require that providers have adequate knowledge of biology and anatomy to effectively address. 87 FR 47833–34.

OCR disagrees with commenters suggesting that nondiscrimination protections on the basis of gender identity will either cause confusion in the medical profession or lead to diminished quality of care. Health care providers are highly trained in issues of biology, anatomy, and physiology. This rule requires that individuals be treated without discrimination on the basis of sex. There is no evidence that demonstrates that compliance with civil rights protections, including on the basis of sex, has caused any confusion in the medical field. On the contrary, evidence suggests that when patients are protected on the basis of sex in health care programs, quality of care improves because patients at risk of discrimination are more likely to seek and receive high quality care. For example, research shows that individuals who are experiencing gender dysphoria—defined by the American Psychiatric Association to include ''clinically significant distress or impairment related to gender incongruence''—have a clinically significant decrease in distress if they have access to medically necessary care.[121]

Moreover, section 1557 prohibits discrimination on certain prohibited bases, and does not interfere with individualized clinical judgment about the appropriate course of care for a patient. OCR has a general practice of deferring to a clinician's judgment about whether a particular service is medically appropriate for an individual, or whether the clinician has the appropriate expertise to provide care. There is no part of section 1557 that compels clinicians to provide a service that they do not believe is medically appropriate for a patient or that they are not qualified to provide.

With respect to commenters' concerns about potential conflicts between the final rule and individuals' or organizations' sincerely held religious beliefs, we refer commenters to the discussion of this topic at § 92.302.

Comment: Some commenters stated that because OCR relied on *Bostock,* it is bound by the definition of ''sex'' in *Bostock* and that definition should be included in the final rule. These commenters opined that the term ''sex characteristics'' as used by OCR is sometimes contrary to a binary understanding of the term ''sex,'' and accordingly ''sex characteristics'' either must be avoided in the regulations or used in a manner not to contradict the term ''sex'' being binary.

Response: OCR has determined it is not necessary to define ''sex'' in this rule, as we have addressed a non-exhaustive list of what constitutes discrimination on the basis of sex at § 92.101(a)(2). The Supreme Court did not define the term ''sex'' in *Bostock,* but rather noted that nothing in their approach to the cases considered turned on the debate over whether ''sex'' was limited to ''biological distinctions between male and female,'' and the Court therefore proceeded on the assumption that ''sex'' carried that meaning. 590 U.S. at. 655.

OCR declines to remove reference to ''sex characteristics'' (including intersex traits) from § 92.101(a)(2). Discrimination on the basis of sex characteristics, including intersex variations, is a prohibited form of sex discrimination because discrimination based on anatomical or physiological sex characteristics is inherently sex-based. *See* 87 FR 47858.

Comment: Numerous commenters supported the explicit inclusion of

[120] *Tennessee* v. *U.S. Dep't of Educ.,* 615 F. Supp. 3d 807 (E.D. Tenn. 2022); *appeal docketed,* No. 22–5807 (6th Cir. Sept. 13, 2022) (oral argument held April 26, 2023).

[121] Jack Turban, M.D., M.H.S., *What is Gender Dysphoria?,* Am. Psychiatric Assoc., *https://www.psychiatry.org/patients-families/gender-dysphoria/what-is-gender-dysphoria* (Aug. 2022).

discrimination based on sex characteristics, including intersex traits, stating that discrimination based on intersex traits is inherently sex-based. Several commenters supported this proposal, citing barriers to appropriate care and coverage resulting from discrimination suffered by intersex patients.[122] These commenters cited a report in which more than half of intersex respondents reported that a provider refused to see them because of their sex characteristics or intersex variation and that almost two-thirds reported having concerns that if they disclosed their intersex status to a provider, they could be denied quality medical care.[123] A few commenters recommended that § 92.101(a)(2) include concrete examples of sex discrimination, specifically on the basis of intersex traits.

Response: Discrimination based on sex characteristics is a prohibited form of sex discrimination because discrimination based on anatomical or physiological sex characteristics is inherently sex-based. 87 FR 47858. It follows that discrimination on the basis of intersex traits is prohibited sex discrimination because the individual is being discriminated against based on their sex characteristics.

Comment: Numerous commenters generally supported the inclusion of pregnancy or related conditions as protected bases of sex discrimination at § 92.101(a)(2) and recommended that OCR include examples of pregnancy-related discrimination. Commenters recommended including protection for pregnancy-related conditions as a standalone provision to emphasize the importance of these protections. Commenters stated that protection against discrimination on the basis of pregnancy or related conditions would protect many patients. Commenters also pointed out that as drafted, the Proposed Rule does not consistently define sex discrimination to include pregnancy-related conditions because other sections just state ''pregnancy'' as opposed to ''pregnancy or related conditions.'' The commenters urged OCR to be consistent throughout the rule.

Response: The inclusion of ''pregnancy or related conditions'' is consistent with the longstanding interpretation of the ''ground'' of discrimination prohibited under title IX because pregnancy-based discrimination has long been understood as a form of sex-based discrimination under title IX. For many years preceding the enactment of the ACA, the Department (along with other agencies) determined that discrimination based on pregnancy or related conditions is discrimination based on sex.[124] Discrimination on the basis of pregnancy or related conditions may include, but is not limited to, instances of individuals who experience discrimination throughout pregnancy, labor and delivery, or the postpartum period. OCR agrees that the explicit inclusion of pregnancy or related conditions in the rule text is important for protecting many patients from discrimination.

As discussed in the Proposed Rule, OCR considered inclusion of a provision to specifically address discrimination on the basis of ''pregnancy or related conditions.'' 87 FR 47878. We received comments stating that a separate section was not appropriate. Those comments recommended that this issue be addressed under either § 92.101 (Discrimination prohibited) or § 92.206 (Equal program access on the basis of sex). Accordingly, we maintain the inclusion of ''pregnancy or related conditions'' here under § 92.101(a)(2). For a further discussion of ''pregnancy or related conditions,'' please refer to the preamble discussion at § 92.208 (Prohibition on sex discrimination related to marital, parental, or family status).

Comment: A commenter stated that protections from pregnancy-based discrimination should include an informed consent requirement for abortion and childbirth, because the commenter asserted that consent for a Cesarean delivery is often obtained through coercion.

Response: As noted in the Proposed Rule, 87 FR 47868, informed consent to any medical treatment is both a legal and ethical standard, regardless of the type of care, and serves as a basis for shared decision making.[125] OCR declines to make any changes in response to this comment.

Comment: Numerous commenters recommended that, in light of the Supreme Court's decision in *Dobbs* v. *Jackson Women's Health Organization,* 142 S. Ct. 2228 (2022), and increased restrictions on reproductive health, OCR should provide that ''pregnancy or related conditions'' includes termination of pregnancy in the final rule. A group of commenters opined that the definition of ''pregnancy or related conditions'' should expressly exclude an abortion.

Several commenters stated that OCR should clarify that this provision protects patients from discrimination on the basis of actual or perceived prior abortions. Several commenters stated that, as a result of abortion bans that have gone into effect post-*Dobbs,* women have been denied critical care, such as cancer treatment, because of abortion-related concerns. A commenter wrote that abortion is often necessary to save patients' lives, especially from complications like ectopic pregnancy or premature rupture of membrane.

Response: OCR appreciates commenters' concerns and recognizes that the Supreme Court decision in *Dobbs* changed the legal landscape as to abortion access. While we agree that protections afforded for pregnancy or related conditions include termination of pregnancy, OCR declines to revise the language at § 92.101(a)(2) to include or exclude specific examples and will interpret section 1557's protections on the basis of sex consistent with applicable case law addressing discrimination on the basis of sex, including pregnancy or related conditions.

OCR has concluded as a matter of statutory interpretation that section 1557 does not require the Department to incorporate the language of title IX's abortion neutrality provision, *see* preamble discussion at § 92.208 (Prohibition on sex discrimination related to marital, parental, or family status). At the same time, OCR emphasizes that a covered provider's decision not to provide abortions does not itself constitute discrimination in violation of section 1557. Also, a covered provider's willingness or refusal to provide, pay for, cover, or refer for abortion or to provide or participate in training to provide abortion also is not discrimination under section 1557. Section 1557 prohibits discrimination on the basis of race, color, national origin, sex, age, or disability in covered health programs or activities. A covered provider that generally offered abortion care could violate that prohibition if, for example, it refused to provide an abortion to a particular patient because of that patient's race or disability. But a covered provider does not engage in

[122] Lambda Legal & interACT Advocates, *Providing Ethical and Compassionate Health Care to Intersex Patients: Intersex-Affirming Hospital Policies* (2018), *https://legacy.lambdalegal.org/sites/default/files/publications/downloads/resource_20180731_hospital-policies-intersex.pdf.*

[123] *See* Caroline Medina & Lindsay Mahowald, Ctr. for Am. Progress, *Advancing Health Care Nondiscrimination Protections for LGBTQI+ Communities* (2022), *https://www.americanprogress.org/article/advancing-health-care-nondiscrimination-protections-for-lgbtqi-communities.*

[124] *See* 45 CFR 86.21(c)(2), (3); 86.40(b)(1), (4), and (5); 86.51(b)(6); 86.57(b)(d) (title IX regulation).

[125] Am. Med. Ass'n, *Informed Consent, https://www.ama-assn.org/delivering-care/ethics/informed-consent.*

discrimination prohibited by section 1557 if it declines to provide abortions based on religious or conscience objections to performing the procedure, based on a professional or business judgment about the scope of the services it wishes to offer, or for any other nondiscriminatory reason.

It bears emphasis that nothing in the ACA, including section 1557, has ''any effect on Federal laws regarding—(i) conscience protection; (ii) willingness or refusal to provide abortion; and (iii) discrimination on the basis of the willingness or refusal to provide, pay for, cover, or refer for abortion or to provide or participate in training to provide abortion.'' 42 U.S.C. 18023(c)(2)(A). In addition, nothing in the ACA, including section 1557, preempts or has any effect on State laws regarding ''the prohibition of (or requirement of) coverage, funding, or procedural requirements on abortions'' as provided in section 1303 of the ACA, 42 U.S.C. 18023(c)(1).

Against this legal landscape, OCR will evaluate specific claims of discrimination on prohibited bases on a case-by-case basis, and we decline to revise the language at § 92.101(a)(2). We note also that, as commenters suggested, this provision protects patients from discrimination on the basis of actual or perceived prior abortions. For example, a recipient's denial of unrelated medical care that the provider generally provides to other patients to an individual based solely on the fact they had a prior abortion would constitute prohibited discrimination within the meaning of section 1557. Moreover, both the 2016 and 2020 Rules recognized that discrimination on the basis of pregnancy termination can be a form of sex discrimination.

Comment: Conversely, a commenter argued that OCR should not interpret ''pregnancy or related conditions'' to include ''termination of pregnancy'' because of a concern that it will force health care providers to participate in abortions and requested that OCR provide further clarification as to what types of conduct would be prohibited discrimination under the rule. Another commenter stated the Proposed Rule wrongly treats abortion as a right protected from sex discrimination and that title IX contains an abortion neutrality provision that the rule would contravene.

Response: As discussed above, a covered provider's decision not to provide abortions does not itself constitute discrimination in violation of section 1557. A covered provider does not engage in discrimination prohibited by section 1557 if it declines to provide abortions based on religious or conscience objections to performing the procedure, based on a professional or business judgment about the scope of the services it wishes to offer, or for any other nondiscriminatory reason. A covered entity that chooses to provide abortion care but refuses to provide an abortion for a particular individual on the basis of a protected ground—such as race—would violate section 1557. For discussion regarding the title IX abortion neutrality provision, please see § 92.208.

Comment: Several commenters requested that OCR clarify that § 92.101(a)(2) prohibits discrimination against individuals when they are seeking or accessing fertility care, maternity care, and other reproductive health care specifically. A commenter recommended that OCR clarify that pregnancy-related care applies throughout pregnancy, childbirth, and the postpartum period.

Response: Section 1557 protects individuals against prohibited discrimination in all covered health programs and activities regardless of the type of care they are seeking or accessing, including fertility care, maternity care, and other reproductive health care. Similarly, section 1557 protects individuals seeking or accessing health programs and activities provided for or during preconception, pregnancy, childbirth, and postpartum recovery. Ensuring that section 1557's protections apply throughout the continuum of care is especially critical for Black women and other people of color, who face worse health outcomes and experience higher rates of discrimination throughout pregnancy and the postpartum period.[126]

Comment: Many commenters raised concerns about barriers to reproductive health care faced by LGBTQI+ patients. A commenter strongly urged more explicit inclusion of ''fertility'' as a form of impermissible sex-based discrimination—so that § 92.101(a)(2)(ii) prohibits discrimination on the basis of ''pregnancy, fertility, or related conditions''—as infertility is a serious issue that impacts many LGBTQI+ populations. Commenters stated that LGBTQI+ people continue to face barriers to fertility treatment, such as in vitro fertilization (IVF), and that coverage of fertility treatments often limit or exclude LGBTQI+ patients.

Response: OCR acknowledges the unique challenges faced by LGBTQI+ individuals seeking fertility treatment. Individuals are protected from discrimination regardless of the type of health care they seek, and we have concluded it is unnecessary to provide provisions for each specific form of health care available. Whether discrimination on the basis of sexual orientation or gender identity occurred in the provision or coverage of assistive reproductive technology—such as IVF—is necessarily fact specific. However, if a covered entity elects to provide or cover fertility services but categorically denies them to same-sex couples, it may violate section 1557's prohibition on sex discrimination.

Comment: Numerous commenters generally supported inclusion of sexual orientation as a protected basis for sex discrimination, and said that its inclusion would improve health care for LGBTQI+ individuals. Many commenters stated that LGBTQI+ individuals face discriminatory challenges to accessing health care and that the rule would alleviate these issues. Many commenters wrote that LGBTQI+ individuals often anticipate that they will experience discrimination in health care and thus often may not seek out care.

Response: It is well documented that LGBTQI+ individuals face discrimination when accessing or attempting to access health care and health insurance. Section 1557 is a critical tool in combating such discrimination and addressing the resulting health disparities and other negative impacts.

Comment: Numerous commenters generally supported the inclusion of discrimination on the basis of gender identity as a prohibited form of sex discrimination. Other commenters recommended including ''transgender or nonbinary status,'' ''nonbinary and gender-nonconforming,'' and ''including status as transgender, nonbinary, gender nonconforming, two-spirit, or other gender.''

Response: OCR recognizes that individuals use various terminology to describe their gender identity. For this reason, we decline to provide a definition of ''gender identity'' or ''transgender status'' in the regulation. We reiterate here that OCR will investigate discrimination against an individual based on having a gender identity that is different from their sex assigned at birth as discrimination on the basis of gender identity, regardless of whether the individual identifies with or uses the term ''transgender'' or another identity.

OCR is aware that the *Bostock* majority uses the term ''transgender

[126] Saraswathi Vedam et al., *The Giving Voice to Mothers Study: Inequity and Mistreatment During Pregnancy and Childbirth in the United States,* 16 Reprod. Health 1 (2019), *https://doi.org/10.1186/s12978-019-0729-2.*

status'' exclusively. But *Bostock* reasoned that when a person discriminates ''against transgender persons, the employer unavoidably discriminates against persons with one sex identified at birth and another today'' such that ''[a]ny way you slice it, the employer intentionally refuses to hire applicants in part because of the affected individuals' sex, even if it never learns any applicant's sex.'' *See Bostock,* 590 U.S. at 669. This therefore includes discrimination against a person because they are transgender, or because they identify in some other way that is inconsistent with their sex assigned at birth, *e.g.,* because they are gender nonconforming. Such discrimination is also based on requiring persons to conform to stereotypical norms about sex and gender, which can also serve as the basis for impermissible sex discrimination. *See, e.g., Whitaker,* 858 F.3d at 1048–49 (*citing Price Waterhouse,* 490 U.S. at 251). Therefore, the prohibition against discrimination based on gender identity, rather than just transgender status, more fully protects individuals from prohibited sex discrimination. Indeed, the *Bostock* dissent stated that, as defined by the American Psychological Association, ''there is no apparent difference between discrimination because of transgender status and discrimination because of gender identity.'' 590 U.S. at 686, n.6 (Alito, J. joined by Thomas, J., dissenting).

Comment: Several commenters supported OCR's general goal at § 92.101(b) of explicitly incorporating the prohibitions on discrimination found in title VI, section 504, title IX, and the Age Act and thought this approach is prudent, given that some health care entities may not be readily familiar with the specific regulatory standards and obligations that apply to them under civil rights laws. A few commenters noted that incorporating section 504 regulations pertaining to accessibility could create conflicting obligations and specifically objected to incorporating 45 CFR 84.23(c), which applies an outdated standard (the Uniform Federal Accessibility Standards) to new facility constructions. These commenters recommended including additional language in § 92.101(b)(1)(i) that expressly states ''(except for § 84.23(c)).''

Response: We appreciate commenters' concerns regarding inclusion of § 84.23(c). Because the rule has a separate subsection with respect to ''Accessibility for buildings and facilities,'' commenters should refer to this preamble's discussion of § 92.203.

Comment: Some commenters requested that OCR restore the 2016 Rule clarification that any age distinctions exempt from the Age Act are also exempt from section 1557 enforcement.

Response: OCR appreciates commenters' request for clarity regarding the Age Act's permitted age distinctions. This rule adopts by reference the Age Act implementing regulation provisions at 45 CFR part 91 (subpart B), which explicitly recognize that some age distinctions may be necessary to the normal operation of a program or activity or to the achievement of any statutory objective. *See* 45 CFR 91.13 (adopting statutorily permissive age distinctions found at 42 U.S.C. 6103(b)(1)).

Comment: A commenter stated that OCR should exercise its authority to enforce disparate impact claims in order to address systemic discrimination in health care.[127] Another commenter supported the approach taken by OCR in the Proposed Rule to not include the site location provision from the 2016 Rule, stating they believed section 1557's context, structure, and text make evident that Congress did not intend to import multiple, piecemeal legal standards and burdens of proof derived from different statutory contexts into the doctrinal patchwork; and that section 1557 provides the full range of enforcement mechanisms and remedies available to any person pursuing a discrimination claim under section 1557, regardless of their protected characteristic.

Response: After reviewing comments, OCR declines to include provisions similar to former 45 CFR 92.101(b)(3)(ii) and (iii), which are not included in the 2020 Rule. OCR will preserve the longstanding treatment of discrimination in the referenced statutes' implementing regulations consistent with relevant case law.

Summary of Regulatory Changes

For the reasons set forth above and considering the comments received, we are finalizing the provision as proposed in § 92.101, with modifications. We added ''or any combination thereof'' after disability and deleted the ''or'' before disability in § 92.101(a)(1).

Subpart C—Specific Applications to Health Programs and Activities

Because of section 1557's specific application to health programs and activities, subpart C provides additional detail regarding nondiscrimination requirements in these settings. The provisions in this subpart are responsive to the nature and importance of health care, health insurance coverage, and other health-related coverage, and related health programs and activities as those health-related issues impact individuals and communities protected by section 1557's prohibition of discrimination. These provisions are intended to provide clear instruction to covered entities and are informed by OCR's experience in both enforcement and in providing technical assistance as well as outreach to interested parties.

Meaningful Access for Individuals With Limited English Proficiency (§ 92.201)

In proposed § 92.201, we proposed provisions to effectuate section 1557's prohibition on national origin discrimination as it is applied to individuals with LEP in covered health programs and activities. In § 92.201(a), we proposed that covered entities ''must take reasonable steps to provide meaningful access to each limited English proficient individual eligible to be served or likely to be directly affected by its health programs and activities.''

In § 92.201(b), we proposed that language assistance services required under § 92.201(a) must be provided free of charge, be accurate and timely, and protect the privacy and independent decision-making ability of an individual with LEP.

In § 92.201(c), we proposed specific requirements for interpreter and translation services. Section 92.201(c)(1) proposed that when interpreter services are required under this part, a covered entity must offer a qualified interpreter. Section 92.201(c)(2) proposed that when translation services are required under this part, a covered entity must use a qualified translator.

In § 92.201(c)(3), we proposed regulatory language requiring a covered entity that uses machine translation to have translated materials reviewed by a qualified human translator when the underlying text is critical to the rights, benefits, or meaningful access of an individual with LEP; when accuracy is essential; or when the source documents or materials contain complex, non-literal, or technical language. We sought

[127] Ruqaiijah Yearby et al., *Structural Racism in Historical and Modern US Health Care Policy,* 41 Health Affairs 187 (2022), *https://www.healthaffairs.org/doi/10.1377/hlthaff.2021.01466*; Joe Feagin & Zinobia Bennefield. *Systemic Racism and U.S. Health Care,* 103 Soc. Sci. & Med. 7 (2014), *https://doi.org/10.1016/j.socscimed.2013.09.006*; Cara A. Fauci, *Racism and Health Care in America: Legal Responses to Racial Disparities in the Allocation of Kidneys,* 21 Boston Coll. Third World J. 35 (2001); Amitabh Chandra et al., *Challenges to Reducing Discrimination and Health Inequity through Existing Civil Rights Laws,* 36 Health Affairs 1041 (2017), *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5654529/.*

cannot state every modification that could result in a fundamental alteration because determining whether a modification is a fundamental alteration is a fact-specific process.

Summary of Regulatory Changes

For the reasons set forth above and considering the comments received, we are finalizing the provisions as proposed in § 92.205, without modification.

Equal Program Access on the Basis of Sex (§ 92.206)

OCR proposed a section clarifying covered entities' obligation to ensure equal access to their health programs and activities without discrimination on the basis of sex.

In proposed § 92.206(a), we described a covered entity's general obligation to provide individuals equal access to the covered entity's health programs or activities without discrimination on the basis of sex.

In proposed § 92.206(b)(1) through (4), we clarified certain types of discriminatory actions that would be prohibited for a covered entity in its provision of access to health programs or activities.

In § 92.206(b)(1), we proposed prohibiting a covered entity from denying or limiting health services, including those that are offered exclusively to individuals of one sex, to an individual based on the individual's sex assigned at birth, gender identity, or gender otherwise recorded.

In § 92.206(b)(2), we proposed prohibiting covered entities from denying or limiting a health care professional's ability to provide health services on the basis of a patient's sex assigned at birth, gender identity, or gender otherwise recorded.

In § 92.206(b)(3), we proposed prohibiting a covered entity from applying any policy or practice of treating individuals differently or separating them on the basis of sex in a manner that subjects any individual to more than *de minimis* harm.

In § 92.206(b)(4), we proposed prohibiting a covered entity from denying or limiting health services sought for the purpose of gender-affirming care that the covered entity would provide to a person for other purposes if the denial or limitation is based on a patient's sex assigned at birth, gender identity, or gender otherwise recorded.

In § 92.206(c), we proposed that nothing in this section requires the provision of any health service where the covered entity has a legitimate, nondiscriminatory reason for denying or limiting that service, including where the covered entity reasonably determines that such health service is not clinically appropriate for that particular individual.

In § 92.206(d), we proposed that the enumeration of specific forms of discrimination in paragraph (b) does not limit the general applicability of the prohibition in paragraph (a).

The comments and our responses regarding § 92.206 are set forth below.

Comment: Numerous commenters supported OCR's proposal to specifically address equal access on the basis of sex in the final rule. A supporter of the provision argued that patients who trust their provider not to discriminate against them will share better information, enabling better treatment. Some commenters specifically requested this section be strengthened by including specific examples of what constitutes discrimination based on sex characteristics.

Response: OCR agrees that open communication between a provider and their patient is a bedrock of the provision of quality care, and that cannot happen where the patient experiences or expects that they will face discrimination by the provider. In addition, we note that the question of whether prohibited discrimination has occurred is often context specific and fact intensive, so it is difficult to provide succinct examples of scenarios that would constitute prohibited discrimination in each and every instance.

Comment: Commenters urged OCR to include specific language related to reproductive health care and fertility treatments in §§ 92.206 and 92.207. A few commenters urged OCR to specify the full range of reproductive health care protected from discrimination under section 1557, including protections against discrimination based on reproductive health decisions. A few commenters said the final rule should make clear that section 1557 prohibits discrimination related to maternity care, such as failing to provide accessible medical equipment or transfer assistance, leaving wheelchair users unable to access care. Another commenter opined that the final rule should make clear that section 1557 prohibits discrimination relating to treating pregnancy emergencies and complications, including termination of pregnancy, miscarriage management, and other pregnancy outcomes.

Response: Matters related to reproductive health care, fertility, pregnancy, family status, and maternity care are addressed in § 92.208, and OCR refers commenters to that section. Covered entities must ensure accessibility of their health programs and activities for individuals with disabilities, which includes accessible equipment and transfer assistance.

Comment: Some commenters argued that it would be more appropriate to address the impacts of the *Dobbs* decision and protections against discrimination on the basis of obtaining an abortion in § 92.206 rather than in § 92.208 (Prohibition on sex discrimination related to marital, parental, or family status), because addressing abortion in the section on marital, parental, or family discrimination could convey that denying abortion care is only discriminatory in those contexts.

Conversely, many commenters expressed opposition to the inclusion of termination of pregnancy within the scope of equal program access on the basis of sex, primarily stating that the rule would force health care professionals to perform abortions or deem their refusal to do so discrimination.

Response: OCR appreciates commenters' feedback regarding the addition of pregnancy or related conditions in § 92.206 rather than in § 92.208. Based on a review of the totality of the comments, additional language has not been added to § 92.206, and we discuss this issue further in § 92.208. Further, the ACA itself provides that ''[n]othing in this Act shall be construed to have any effect on Federal laws regarding—(i) conscience protection; (ii) willingness or refusal to provide abortion; and (iii) discrimination on the basis of the willingness or refusal to provide, pay for, cover, or refer for abortion or to provide or participate in training to provide abortion.'' 42 U.S.C. 18023(c)(2)(A). OCR will comply with this provision. For further discussion regarding a health care professional's decision not to provide an abortion, including due to a sincerely held religious belief or conscience objection to performing the procedure, *see* §§ 92.208 and 92.302.

Comment: Many commenters recommended that in addition to the specific forms of discrimination based on gender identity, it is important to include specific forms of reproductive health and pregnancy-related care discrimination in § 92.206(b). Many commenters recommended incorporating a provision or provisions under § 92.206(b) to clarify that covered entities are prohibited from denying or limiting services—or denying or limiting a health professional's ability to provide services—based on a patient's

pregnancy or related conditions, including termination of pregnancy, contraceptive use, miscarriage management, assisted reproduction, fertility care, and pregnancy-related services. One of these commenters recommended that the language of this provision not be limited to reproductive or sexual ''health *care* decisions,'' as covered entities also discriminate based on reproductive and sexual health histories such as past experiences with sexual violence, which exist beyond the realm of services and that including ''care'' here could limit how covered entities understand this form of discrimination. Some commenters also stated that failure to codify some of the most prevalent forms of sex discrimination will directly undermine efforts to implement proposed §§ 92.101 and 92.206.

Response: OCR appreciates the recommendations regarding discrimination based on pregnancy or related conditions, including the request to provide additional examples, and directs commenters to the discussion at § 92.208. The rule does not include language related to discrimination based on health *care* decisions. The rule is not so limited—it prohibits discrimination in health programs and activities generally. This includes discrimination on the basis of sex in the context of health decisions or histories related to reproductive and sexual health.

Comment: Many commenters supported § 92.206 as important to ensure access to necessary health services that might otherwise be denied to people due to discrimination on the basis of sexual orientation or gender identity, with many providing specific examples of discrimination faced by LGBTQI$_+$ individuals. Some commenters recommended specifically addressing protections for LGBTQI$_+$ people seeking fertility treatments. A commenter recommended that OCR consider adding a subsection to § 92.206 or § 92.208 to discuss the prohibition of discrimination on the basis of sexual orientation and gender identity in access to fertility services, and provided examples of the numerous barriers that LGBTQI$_+$ individuals and same-sex couples face in accessing this type of reproductive health care.

Response: Section 1557 and this rule prohibit discrimination on the basis of sex, including sex characteristics, sexual orientation, and gender identity, in health care access. Depending on the specific facts at issue, barriers described may rise to the level of discrimination and would be evaluated under this rule's general prohibition of discrimination under § 92.101(a)(1), to make a case-by-case determination as to whether prohibited discrimination has occurred. In general, OCR anticipates that if a covered entity elects to provide or cover fertility services, but categorically denies them to same-sex couples or to individuals on the basis of sexual orientation or gender identity, such a denial of care or coverage may violate section 1557's prohibition on sex discrimination. We decline to add such specific language to the regulatory text as proposed.

Comment: Commenters recommended that OCR should add language to § 92.206(b) affirming that section 1557 prohibits covered entities from denying, limiting access to, or otherwise placing special caps, costs, or additional procedural requirements on medications or treatments needed specifically by people with disabilities, irrespective of whether those medications or treatments can also be used to end or complicate pregnancies or fertility.

Response: We address special caps, costs, or additional procedural requirements related to health insurance coverage and other health-related coverage in § 92.207, and direct commenters to that section. A discussion of medications and treatments related to pregnancy and fertility care is in § 92.208.

Comment: Many commenters recommended including ''transgender status'' in § 92.206(b)(1), (2), and (4) because there have been instances in which those seeking to permit discrimination against transgender people have justified it by pressing distinctions between transgender status and gender identity.

Response: As noted in the discussion for § 92.101(a)(2), the term ''gender identity'' necessarily encompasses transgender status and the two terms are often used interchangeably.[157] We decline to enumerate the full range of identities protected under the term ''gender identity.''

Comment: Multiple commenters expressed support for the rule's prohibition on denying or limiting care on the basis of a patient's assigned sex at birth, gender identity, or gender otherwise recorded at § 92.206(b)(2). A commenter expressed support for the rule's prohibition on covered entities denying or limiting a clinician's ability to provide clinically appropriate care when the failure to do so would constitute discrimination.

Another commenter supported this provision, arguing that it is necessary to ensure that specialists and providers who see LGBTQI+ patients every day do not experience retaliation for providing care. Pointing to State legislative efforts seeking to restrict or ban providers from offering safe and effective treatment to LGBTQI$_+$ patients, the commenter argued that such protections are particularly important to alleviate providers' fears that they may be subject to retaliation or loss of licensure for providing gender-affirming care. Another commenter similarly argued that covered entities sometimes discriminate against transgender patients by prohibiting their providers from providing certain services.

Response: As noted in the Proposed Rule, 87 FR 47866, this provision recognizes that prohibited discrimination may take the form of restrictions on individual providers, such as attending physicians, that have the effect of discriminating against patients. Where a covered entity imposes such a restriction based on a patient's gender identity or sex assigned at birth, the restriction may constitute prohibited discrimination in violation of this rule, even if the form that the restriction takes is a limitation on the ability of providers to prescribe or provide care.

Regarding providers' fears that they may be subject to retaliation by their employer or loss of licensure, this rule does not apply to employment practices, as discussed in § 92.2(b), but employees of covered entities remain protected against retaliation as provided in §§ 92.303 and 92.304. Not all State licensure boards receive Federal financial assistance from the Department; upon receipt of a complaint against a licensure board, OCR would need to first determine whether we have jurisdiction before commencing an investigation.

Also, we note that a health care provider's decision not to provide any service due to a sincerely held religious belief or conscience objection is discussed further in §§ 92.208 and 92.302.

Comment: Many commenters suggested that § 92.206(b)(2) would be clearer if the following phrase was deleted because it is redundant: ''if such denial or limitation has the effect of excluding individuals from participation in, denying them the benefits of, or otherwise subjecting them to discrimination on the basis of sex under a covered health program or activity.''

Response: OCR appreciates the suggestion and has considered it, but we

[157] *See, e.g., Bostock* v. *Clayton Cnty., Georgia,* 590 U.S. 644, 658–59 (2020); *Doe* v. *Mass. Dep't of Correction,* No. CV 17–12255–RGS, 2018 WL 2994403 (D. Mass. June 14, 2018); *Whitaker* v. *Kenosha Unified Sch. Dist. No. 1 Bd. of Educ.,* 858 F.3d 1034 (7th Cir. 2017).

will maintain the proposed language, as the phrase provides additional explanation of what would constitute discrimination. As we noted in the Proposed Rule, 87 FR 47866, this is modeled on the provision in the title VI regulations that notes that certain discriminatory employment practices may be prohibited to the extent that they result in discrimination against program participants, even though the primary objective of title VI is not to regulate employment practices. *See* 45 CFR 80.3(c)(3). Likewise, the phrase commenters propose deleting here clarifies that these restrictions on providers are prohibited only insofar as they result in discrimination against individuals on the basis of sex in a covered health program or activity. This phrase is necessary to establish a violation because a discriminatory act under this rule is one in which the individual is excluded from, denied the benefits of, or otherwise subjected to discrimination under a health program or activity on the basis of sex.

Comment: A few commenters stated that it appears that § 92.206(b)(2) is directly aimed at the United States Conference of Catholic Bishops' Ethical and Religious Directives for Catholic Health Care Services.[158] These commenters recommended that OCR disavow this provision and affirm support for the value of religiously affiliated health care and the right of faith-based hospitals to operate in accordance with their convictions.

Response: As stated throughout this preamble, OCR values the vital role that faith-based hospitals and other health care providers and systems play in our nation's health care system. With respect to concerns about potential conflicts between provisions of the final rule and individuals' or organizations' sincerely held religious beliefs, we refer commenters to the discussion at § 92.302. The aim of § 92.206(b)(2) is to address discrimination that has a secondary effect on the ability of individuals to participate meaningfully in and/or to receive health care from a covered health program in a nondiscriminatory manner. OCR did not, nor did it intend to, single out any religious teachings and will respect all guarantees of Federal religious freedom and conscience laws.

Comment: Commenters highlighted that transgender and nonbinary people face unique discrimination in inpatient settings that are separated by sex, particularly those that have only male and female facilities available. These commenters noted that this results in nonbinary people not having access to facilities consistent with their gender identity.

A few commenters raised concerns about the application of § 92.206(b)(3) to arrangements and practices involving patients who share intimate space with, or require intimate personal assistance from, other individuals. The commenters argued that the requirement to treat individuals consistent with their gender identity may raise concerns for privacy.

Response: OCR appreciates the commenters' feedback. As specified in the preamble discussion for § 92.101, this final rule protects all people regardless of gender identity, including transgender and nonbinary people. Nothing in this rule prohibits a covered entity from operating sex separated programs and facilities, so long as it does not subject anyone, including transgender and nonbinary individuals, to more than *de minimis* harm on the basis of sex. When a nonbinary individual seeks participation in a single-sex health program or activity or a health program or activity that maintains sex separate facilities, the covered entity should work with that individual to determine where they will best be served and where they can benefit the most from the health program or activity without experiencing trauma, distress, or threats to their safety due to an incorrect placement. A covered entity must not deny a nonbinary individual access to a health program or facility on the basis that the program or facility separates patients based on sex or offers separate male and female programs or facilities.

Courts have held that all individuals' safety and privacy can be protected without also excluding transgender individuals from accessing sex-separate facilities and activities consistent with their gender identity.[159] Nothing in the rule prevents covered entities from implementing policies or procedures to preserve any patient's privacy—consistent with the requirements of this rule and any other applicable laws. Providers have a range of tools at their disposal to accommodate individuals' privacy concerns and patient interests in a nondiscriminatory manner. For example, a provider generally may accommodate a patient's preferences about roommate assignments. A covered entity will be in violation of this rule if they refuse to admit a transgender person for care or refuse to place them in facilities consistent with their gender identity, because doing so would result in more than *de minimis* harm. We also note that no application of this rule shall be required insofar as it would violate Federal religious freedom and conscience laws. Recipients may rely on those protections directly, *see* § 92.3(c), or they may seek an assurance of a religious freedom or conscience exemption, *see* § 92.302(b).

Comment: A commenter opposed the rule on the grounds that it would violate the U.S. Constitution's Equal Protection Clause standard for sex discrimination claims, which the commenter asserted allows men and women to be treated differently based on inherent differences in biology when such differences are real and not based on stereotypes. The commenter argued that proposed § 92.206(b)(3) would inappropriately prohibit providers from using any sex-based distinction unless they can prove it does not cause more than *de minimis* harm. This commenter alleged that the true purpose of such a provision is not equal treatment for all patients but special treatment for transgender individuals, particularly with respect to the use of sex-separate facilities. This commenter also argued that the provision would contradict the Voluntary Resolution Agreement the Department entered into with Michigan State University (MSU) under section 1557, which requires the presence of a chaperone—the sex of whom should be determined by the wishes and comfort of the patient—for all sensitive examinations.[160]

Response: Not all differential treatment on the basis of sex constitutes unlawful discrimination under section 1557, and the final rule does not prohibit all differential treatment.[161] If a

[158] U.S. Conference of Catholic Bishops, *Ethical and Religious Directives for Catholic Health Care Services* (6th ed. 2018), *https://www.usccb.org/resources/ethical-religious-directives-catholic-health-service-sixth-edition-2016-06_0.pdf.*

[159] *Grimm* v. *Gloucester Cnty. Sch. Bd.,* 972 F.3d 586, 613–15 (4th Cir. 2020); *see also Cruzan* v. *Special Sch. Dist. # 1,* 294 F.3d 981, 984 (8th Cir. 2002) (per curiam) (holding that transgender woman's mere presence in a sex-separate space did not constitute actionable sexual harassment of her female co-workers); *Whitaker* v. *Kenosha Unified Sch. Dist. No. 1 Bd. of Educ.,* 858 F.3d 1034, 1052–53 (7th Cir. 2017).

[160] *See* Voluntary Resolution Agreement between U.S. Dep't of Health & Hum. Servs., Off. for Civil Rights & The Bd. of Trs. of Mich. State Univ., dba Mich. State Univ. & MSU HealthTeam & MSU Health Care, Inc. (2019), *https://www.hhs.gov/sites/default/files/vra-between-msu-and-ocr.pdf.*

[161] Several courts have held that discrimination against transgender people constitutes sex discrimination under the Equal Protection Clause. *See, e.g., Hecox* v. *Little,* Nos. 20–35813, 20–35815, 2023 WL 5283127, at *12 (9th Cir. Aug. 17, 2023); *Brandt* v. *Rutledge,* 551 F. Supp. 3d 882, 889 (E.D. Ark. 2021), *aff'd sub nom. Brandt ex rel. Brandt* v. *Rutledge,* 47 F.4th 661, 670 (8th Cir. 2022); *Grimm* v. *Gloucester Cnty. Sch. Bd.,* 972 F.3d 586, 608 (4th Cir. 2020); *Whitaker by Whitaker* v. *Kenosha Unified Sch. Dist. No. 1 Bd. of Educ.,* 858 F.3d 1034,

Continued

sex-based distinction has only a *de minimis* impact, it is not prohibited discrimination.[162] But treating individuals differently on the basis of sex constitutes sex discrimination where it imposes a more-than-*de minimis* level of harm. Under the rule, providers may use sex-based distinctions to administer individualized care, provided those distinctions do not cause more than *de minimis* harm.

We disagree with the proposition that purpose of § 92.206(b)(3) is special treatment for transgender individuals, particularly with respect to the use of sex-specific facilities. The purpose of this section is to prevent unlawful discrimination on the basis of sex. The prevention of discrimination on the basis of gender identity is an important government objective that is substantially achieved by this rule.

Further, the Voluntary Resolution Agreement entered into with MSU, provides that a patient may request a chaperone to be present at any time and that the patient's ''wishes and comfort should determine the sex of the chaperone.'' [163] It further specifies that MSU ''shall accommodate, to the extent practicable, the Patient's request for a same-sex chaperone.'' [164] The final rule does not prohibit patients from requesting or receiving a chaperone of the sex of their choosing.

Finally, OCR disagrees with the commenter that the rule violates the Equal Protection Clause. OCR's authority to promulgate this rule stems from a Federal non-discrimination statute, section 1557. This rule does not purport to interpret the Equal Protection Clause. Thus, even assuming the commenter is correct that the rule bans certain sex-based distinctions that would be permitted under the Equal Protection Clause, such a discrepancy would not mean the rule is unlawful. OCR may promulgate a rule that imposes different non-discrimination requirements on recipients of Federal funds than the non-discrimination requirements the Equal Protection Clause imposes on the government.[165]

Comment: A health research organization expressed support regarding § 92.206(b)(3)'s discussion of the impact on health research and clinical trials. The commenter commended OCR on its guidance on sex-specific health research. This commenter stated that the standard for limiting research outlined by OCR in the 2022 NPRM was reasonable and health researchers will typically be able to demonstrate the requisite justification for a sex-specific research project or clinical trial based on research protocols. However, the commenter requested OCR provide similar guidance for the final rule on whether health research protocols that target or exclude individuals with disabilities would be considered discriminatory.

Conversely, another organizational commenter disagreed with the statement on sex-specific clinical trials because the commenter believed it would pressure clinical researchers and organizations to disregard sex-based distinctions for fear of inviting a gender identity discrimination claim. The commenter claimed that the rule would contradict National Institutes of Health (NIH)'s expectation for clinical trials, which the commenter claimed required specifying the ''biological sex'' of subjects, by laying down an ''unscientific marker'' that sex-specific clinical trials can only be justified in limited circumstances.[166] The commenter further argued that this would represent a backward step for women's health, because the evaluation of diseases and treatments improved when researchers recognized that sex must be taken into account as a biological variable in medicine.

Response: OCR appreciates these comments regarding the application of this provision to sex-specific health research and clinical trials and the standard proposed for evaluating claims of discrimination in such health programs and activities. We agree that researchers should not have challenges showing necessary justifications for nondiscriminatory research distinctions grounded in a participant's reproductive, anatomical, and genetic characteristics.

We disagree with the proposition that OCR is disregarding sex-based distinctions in medicine. Health research and clinical trial protocols are not prohibited from specifying an individual's sex consistent with their reproductive, anatomical, and genetic characteristics, where those characteristics are relevant to the clinical trial. However, there are ways in which health research and protocols may result in discrimination, such as disallowing participation based on gender identity rather than on the basis of scientific requirement of the research.

Should the need arise, OCR will consider issuing guidance on the impacts of disability protections on research participation.

Comment: Several commenters supported the rule's prohibition on sex-specific health programs or activities that subject any individual to more than *de minimis* harm. One supportive commenter argued that this approach recognizes harm as the primary measure of discrimination and creates flexibility to identify new forms of harm, and another argued the standard of no more than *de minimis* harm is consistent with applicable case law, including *Bostock.* A commenter expressed appreciation for the Proposed Rule's detailed explanation of *de minimis* harm and the difference between clinical care for a patient.

Conversely, another commenter stated the Proposed Rule ''cherry picks'' a title IX court decision to justify a standard of ''more than *de minimis* harm'' as the basis for ''adjudicating gender identity,'' arguing that title IX has never required sex to be recognized as anything but ''objectively, biologically based.'' Similarly, another commenter argued the rule applies beyond denial or limitations on health services. The commenter argued that the rule would prohibit health care professionals, medical facilities, and insurance companies from using any sex-based distinction unless they can prove it does not cause more than *de minimis* harm, and that if a provider asks the wrong question or asks an appropriate question in the wrong manner then the provider will likely face a claim of discrimination on the basis of gender identity.

Response: OCR appreciates the range of comments provided on the proposed language regarding *de minimis* harm, and after careful review, OCR is finalizing the language as proposed. The rule does not prohibit all sex-based distinctions in health programs or activities, nor does it broadly prohibit any policy or practice of treating

1048 (7th Cir. 2017), *abrogated on other grounds as recognized by Ill. Republican Party* v. *Pritzker,* 973 F.3d 760, 762 (7th Cir. 2020); *Glenn* v. *Brumby,* 663 F.3d 1312, 1316 (11th Cir. 2011); *Smith* v. *City of Salem,* 378 F.3d 566, 572, 577 (6th Cir. 2004); *but see L. W. by & through Williams* v. *Skrmetti,* 83 F.4th 460 (6th Cir. 2023).

[162] *See, e.g., Oncale* v. *Sundowner Offshore Servs., Inc.,* 523 U.S. 75, 81 (1998) (title VII does not reach non-harmful ''differences in the ways men and women routinely interact with'' each other); *see also Burlington N. & Santa Fe Ry. Co.* v. *White,* 548 U.S. 53, 59–60 (2006) (''No one doubts that the term 'discriminate against' refers to distinctions or differences in treatment that injure protected individuals.'').

[163] MSU Agreement at IV.D.1.v.

[164] MSU Agreement at IV.D.1.vi.

[165] *Cf. Fitzgerald* v. *Barnstable Sch. Comm.,* 555 U.S. 246, 257 (2009) (recognizing that the liability standards under title IX and the Equal Protection Clause ''may not be wholly congruent'').

[166] The commenter does not provide a citation when making this statement; however earlier in their comment, the commenter cites a Notice from the National Institutes of Health (NIH): U.S. Dep't of Health & Hum. Servs., Nat'l Inst. of Health, *Consideration of Sex as a Biological Variable in NIH-funded Research,* NOT–OD–15–102 (June 9, 2015), *https://grants.nih.gov/grants/guide/notice-files/not-od-15-102.html.*

individuals differently based on sex. As noted in the Proposed Rule, although intentional differential treatment on the basis of sex would generally be considered prohibited discrimination, separation by sex or differential treatment on the basis of sex is permissible under section 1557 where it does not cause more than *de minimis* harm. 87 FR 47866. This distinction generally allows for sex-specific clinical trials when sex is relevant to the trial, for example, while still prohibiting differential treatment that causes harm.

Providers often need to make inquiries about a patient's sex-related medical history, health status, or physical traits related to sex in the course of providing care and this rule does not prohibit or inhibit that. 87 FR 47867–68. Such inquiries are not per se discriminatory, even where they touch on intimate or sensitive matters. For example, it is not discriminatory for a provider treating a patient presenting with symptoms consistent with an ectopic pregnancy to inquire about the possibility that the patient could be pregnant, regardless of that patient's gender identity. Similarly, when providing appropriate care to a patient, asking medically relevant questions about a patient's anatomy or medical history in a way that causes inadvertent distress—on its own—would not violate section 1557. However, it is important to note that if such questions are not relevant to assessing the patient's condition, or the patient has answered the questions and makes clear that further questions are unwelcome, the inquiries may rise to the level of harassment on the basis of sex. For example, if the conduct is so severe or pervasive that it denies a patient access to medical care, it would no longer be permissible. OCR will evaluate these types of harassment claims on a case-by-case basis to determine whether the alleged harassment was ''sufficiently severe, pervasive, and objectively offensive,'' to meet the standards for discriminatory harassment.[167]

In response to commenters that questioned the legal basis for our *de minimis* standard, we discussed in the 2022 NPRM, 87 FR 47866, n. 412, that sex-based distinctions that have only *de minimis* impact are not the type of discrimination that Congress envisioned.[168]

Comment: A commenter recommended that, based on existing racial disparities in maternal health and overall poor maternal health outcomes in the United States, § 92.206(b)(3) be amended to specify that harm exceeding the threshold of *de minimis* harm with respect to pregnancy and maternal health can include policies or practices that subject people to rough handling, harsh language, undertreatment of pain or pregnancy-related conditions, or other discriminatory mistreatment during childbirth or the prenatal or postpartum periods.

Response: OCR recognizes that there is ample research demonstrating the significant racial disparities in maternal health outcomes.[169] Section 92.206(b)(3) specifically addresses different treatment on the basis of sex, such as through sex-separate health programs and activities. Depending on the specific facts at issue, the treatment described by the commenter may rise to the level of discrimination and would be evaluated under this rule's general prohibition of discrimination under § 92.101.

Comment: An organizational commenter strongly supported the additional guidance provided by proposed §§ 92.206 and 92.207 and noted that the forms of discrimination highlighted in proposed §§ 92.206(b)(3) and (4) and 92.207(b)(3) through (5), in particular, affect many intersex people.

Response: OCR appreciates the commenter's feedback regarding the discrimination addressed in §§ 92.206(b)(3) and (4) and 92.207(b)(3) through (5) affecting intersex people as well. This final rule makes explicit in regulatory text that sex discrimination includes discrimination based on sex characteristics, including intersex traits, as reflected in § 92.101(a)(2).

Comment: Many commenters expressed support for the proposed provisions related to gender-affirming care at § 92.206(b)(4). These commenters stated that such care can be critical to the well-being of transgender and nonbinary people, and that accessing such care can reduce the risk of negative physical and mental health outcomes associated with gender dysphoria. Commenters discussed the negative impact of widespread health care discrimination against transgender people, stating that transgender people of color and transgender people with disabilities are at particularly high risk of discrimination and associated harms.

Response: OCR appreciates these comments and agrees that the nondiscrimination protections are important to transgender and nonbinary people's ability to access clinically appropriate care, especially those who may face elevated risk of harm due to discrimination on multiple protected bases.

In determining whether a covered entity violated section 1557 by denying or limiting a health service sought for the purpose of gender-affirming care, OCR will continue to consider evidence that the covered entity would provide that same service for other purposes. Evidence that OCR may consider to establish that the type of care is ordinarily provided could include, among other things, statements by the provider, information showing that the provider has provided similar care in the past, or documentation regarding the provider's scope of practice.

Where there is other evidence that the covered entity has subjected the individual to differential treatment on the basis of sex apart from the denial of care itself, OCR may investigate and make a case-by-case determination as to whether prohibited discrimination has occurred.

Comment: A few commenters stated that OCR is explicitly asserting that it has authority under section 1557 to regulate the practice of medicine according to its own determination of what is appropriate and non-discriminatory care, along with authority to definitively determine what is the current standard of medical care. Some commenters requested OCR amend the provision to specify that care standards cannot facially discriminate or otherwise result in discrimination based on a protected characteristic, such that covered entities cannot mask discrimination behind clinical policies or criteria.

Response: Section 1557 prohibits discrimination on certain prohibited bases, and does not (and cannot) require a specific standard of care or course of treatment for any individual or otherwise interfere with individualized clinical judgment about the appropriate course of care for a patient. OCR has a general practice of deferring to a clinician's judgment about whether a particular service is medically appropriate for an individual, or

[167] *Cf. Davis by Next Friend LaShonda D.* v. *Monroe Cnty. Bd. of Educ.,* 526 U.S. 629, 650 (1999) (Under title IX, discriminatory harassment must be ''severe, pervasive, and objectively offensive'').

[168] *See also Elborough* v. *Evansville Cmty. Sch. Dist.,* 636 F. Supp. 2d 812, 820–21 (W.D. Wis. 2009) (noting that Title IX does not ''authorize[ ]lawsuits for damages in all cases of differential treatment, no matter how isolated or minimal. The maxim that 'the law doesn't concern itself with trifles' applies to civil rights cases as it does to any other case.'').

[169] Donna L. Hoyert, U.S. Dep't of Health & Hum. Servs., Ctrs. for Disease Control & Prevention, *Maternal Mortality Rates in the United States* (Feb. 2022), *https://www.cdc.gov/nchs/data/hestat/maternal-mortality/2020/E-stat-Maternal-Mortality-Rates-2022.pdf*; Marian F. MacDorman et al., *Racial and Ethnic Disparities in Maternal Mortality in the United States Using Enhanced Vital Records, 2016–2017,* 111 a.m. J. Pub. Health 1673, 1671 (2021), *https://ajph.aphapublications.org/doi/10.2105/AJPH.2021.306375*.

whether the clinician has the appropriate expertise to provide care. There is no part of section 1557 that compels clinicians to provide a service that they do not believe is medically appropriate for a patient or that they are not qualified to provide.

Section 92.206(c) is consistent with the general principle in nondiscrimination law that entities facing allegations of discrimination have the opportunity to articulate a legitimate, nondiscriminatory basis for their challenged action or practice but that such a basis may not be a pretext for discrimination.

Comment: Some commenters expressed concern that OCR is setting standards of care for gender-affirming care in this rule, and that is outside the scope of OCR's authority. Many commenters weighed in with their views on the state of medical evidence relating to gender-affirming care and submitted citations to research studies and other data. Some comments characterized the evidence as lacking or mixed, and highlighted their concerns relating to gender-affirming care for minors. Others stated that there is robust evidence, including from major medical associations, supporting the provision of gender-affirming care, including that such medically necessary care benefits the health and well-being of transgender patients.

Response: This final rule prohibits discrimination on the basis of sex, consistent with Federal law. As such, nothing in this rule impedes covered entities from taking nondiscriminatory actions based on current medical standards and evidence, such as making decisions about the timing or type of protocols appropriate for care. The rule does not (and cannot) require a specific standard of care or course of treatment for any individual, minor or adult. Section 1557 prohibits discrimination on certain prohibited bases, and does not interfere with individualized clinical judgment about the appropriate course of care for a patient. OCR has a general practice of deferring to a clinician's judgment about whether a particular service is medically appropriate for an individual, or whether the clinician has the appropriate expertise to provide care.

Comment: A number of commenters had concerns or questions about the scope of how OCR would define gender-affirming care. Some commenters requested a definition or an enumeration of what types of procedures would fall within this term. Others raised concerns about the impact of such care and the benefits of such care.

Response: As with the 2016 Rule, 81 FR 31435, OCR declines to provide a regulatory definition for gender-affirming care. However, when we used the term ''gender-affirming care'' in both §§ 92.206 and 92.207, we are generally referring to care designed to treat gender dysphoria that may include, but is not necessarily limited to, counseling, hormone therapy, surgery, and other related services. 87 FR 47834 n.139. As noted elsewhere, the rule does not impose a categorical requirement that covered entities must provide gender-affirming care. Further, while we acknowledge comments in support of and opposed to gender affirming care and its subsequent impacts on individuals, we are not making any additional edits to the rule in response.

Comment: Some commenters opposing the rule raised First Amendment concerns and questioned the scope of what would be required of providers in terms of expressing support of transgender people who wish to access gender-affirming care, using the name and pronouns requested by patients, and speaking about gender-affirming care.

Response: OCR takes seriously concerns about, and is fully committed to upholding, the First Amendment, and nothing in these regulations restricts conduct protected by the First Amendment.[170] Whether discrimination is unlawful or considered harassment is necessarily fact-specific. This final rule does not purport to identify all of the circumstances that could constitute unlawful harassment. It is unlikely that an isolated incident with no other indications of animus or ill treatment would meet the standards for discriminatory harassment. Conversely, OCR notes that conduct, including verbal harassment, that is so severe or pervasive that it creates a hostile environment on the basis of sex is a form of sex discrimination.

Comment: A few commenters argued that providing gender-affirming care poses high malpractice lawsuit risks to providers, and therefore OCR should not categorically require providers to provide such services.

Response: As discussed elsewhere in this preamble, this final rule prohibits discrimination in the provision of health programs and activities and does not require provision of any specific services, including gender-affirming care. Section 1557 prohibits discrimination on certain prohibited bases, and does not interfere with individualized clinical judgment about the appropriate course of care for a patient. OCR has a general practice of deferring to a clinician's judgment about whether a particular service is medically appropriate for an individual, or whether the clinician has the appropriate expertise to provide care.

Comment: One commenter expressed concern that the rule would result in decreased access to health care, as providers may choose to leave Federal health care programs based on a belief that they will be required to provide gender-affirming care, especially if there is no avenue for providers with religious or conscience objections to certain types of care to request exemptions.

Response: Section 1557 requires that health care providers who receive Federal financial assistance must provide nondiscriminatory care. However, providers do not have an affirmative obligation to offer any health care, including gender-affirming care, that they do not think is clinically appropriate or if religious freedom and conscience protections apply. OCR believes that the majority of providers already provide nondiscriminatory care to their patients and will continue to do so. This commenter presented no evidence that a significant exodus of providers is likely, and we are not aware of any data to support a significant concern on this front. Providers with religious freedom or conscience concerns, however, may rely upon §§ 92.3 and 92.302.

Comment: A few commenters expressed support for nondiscrimination protections that prohibited discriminating against an individual because of their gender identity but opposed interpreting such protections to protect access to gender-affirming care.

Response: OCR appreciates these commenters' support for the rule's nondiscrimination protections on the basis of gender identity. We respectfully disagree, however, that such protections have no implications for the provision of gender-affirming care. A fact-specific analysis is necessary to determine whether prohibited discrimination has occurred, but the rejection of a practice closely linked with a protected status may, in conjunction with other evidence, lead to a finding of discrimination. This rule does not require or mandate the provision of any particular medical service. Section 1557 prohibits discrimination on certain prohibited bases, and does not interfere

[170] *See, e.g., W. Va. State Bd. of Educ.* v. *Barnette,* 319 U.S. 624, 642 (1943) (''We think the action of the local authorities in compelling the flag salute and pledge transcends constitutional limitations on their power and invades the sphere of intellect and spirit which it is the purpose of the First Amendment to our Constitution to reserve from all official control.'').

with individualized clinical judgment about the appropriate course of care for a patient. OCR has a general practice of deferring to a clinician's judgment about whether a particular service is medically appropriate for an individual, or whether the clinician has the appropriate expertise to provide care.

Comment: An organizational commenter supported reference to the multi-factor test found in *Arlington Heights* v. *Metro. Housing Dev. Corp.,* 429 U.S. 252 (1977), and the burden-shifting framework of *McDonnell Douglas Corp.* v. *Green,* 411 U.S. 792 (1973), among a non-exhaustive list of tools that OCR may utilize for investigating discrimination claims. The commenter asserted that sex discrimination claims are hard to prove, and that together these approaches are appropriate for their adjudication by allowing people to rely on different types of circumstantial evidence to collectively demonstrate a discriminatory act by a covered entity and by placing the onus on the covered entity to provide a legitimate, nondiscriminatory reason for its actions. Similarly, another commenter encouraged OCR to clearly state in the final rule that the familiar but-for causation test applies to establishing a violation of section 1557; that the use of the phrase ''legitimate, nondiscriminatory reason'' in these sections should not be construed in any way to limit the method of proof for any section 1557 claim to the *McDonnell Douglas* burden-shifting framework; and that this method cannot be used to defend an express sex-based classification that causes injury. Another commenter recommended that OCR clarify in the preamble to the final rule that the *McDonnell Douglas* burden-shifting framework and legitimate non-discriminatory reason framework apply to circumstantial evidence cases but not where there is direct evidence of discrimination.

Response: OCR agrees that different methods of proof drawn from civil rights case law should be used in analyzing claims of discrimination under this section including, but not limited to, the *Arlington Heights* multi-factor test and the *McDonnell Douglas* burden-shifting framework. For cases where the alleged discrimination is not based on a facially discriminatory policy, we are clarifying that the phrase ''legitimate, nondiscriminatory reason'' in these sections is taken from, but should not be construed to limit, the method of proof to the *McDonnell Douglas* burden-shifting framework. As we noted in the Proposed Rule, *Arlington Heights* provides a method of proof that uses a number of different types of evidence—*e.g.,* direct, circumstantial, statistical, and anecdotal—that, taken collectively, can demonstrate that the covered entity acted because of a protected basis; the *McDonnell Douglas* burden-shifting framework is an inferential method of proof most commonly applied in cases alleging discrimination in individual instances where a plaintiff alleges that a defendant treated similarly situated individuals differently because of a protected basis. 87 FR 47865. Under the *Arlington Heights* framework, *McDonnell Douglas* evidence identifying similarly situated comparators can also be considered but is not required.[171]

Comment: Many commenters supported the rule's clarification that while providers may exercise clinical judgment when determining if a particular service is appropriate for an individual patient, they may not refuse gender-affirming care based on a belief that such care is never clinically appropriate. A great number of individuals and organizations provided comment on the types of rationales that might constitute a legitimate, nondiscriminatory basis for a provider declining to provide gender-affirming care. Some commenters opined that it should not be considered discriminatory to deny care when a provider categorically objects to gender-affirming care. Other commenters appreciated the clarification that a provider's personal belief that gender-affirming care is never appropriate is not a legitimate, nondiscriminatory basis for denying such care. The majority of commenters opined that the rule provides adequate protection for providers exercising nondiscriminatory clinical judgment about the appropriateness of particular care for a specific patient, though some commenters disagreed.

Response: OCR appreciates commenters' views on proposed § 92.206(c). In light of comments received, we are modifying the language in this provision to provide additional specificity regarding how OCR will evaluate a covered entity's proffered legitimate, nondiscriminatory reason for denying care. We also add a reference to § 92.302 to make clear that this provision does not limit a recipient's ability to seek assurance of an exemption based on religious freedom or conscience laws. Also, we note that while many commenters specifically discuss providers' personal beliefs, these changes clarify that the rule applies to covered entities rather than specific individuals.

To provide additional specificity, we are striking the second sentence of § 92.206(c), which previously read, ''[h]owever, a provider's belief that gender transition or other gender-affirming care can never be beneficial for such individuals (or its compliance with a State or local law that reflects a similar judgment) is not a sufficient basis for a judgment that a health service is not clinically appropriate,'' in its entirety and replacing it with: ''A covered entity's determination must not be based on unlawful animus or bias, or constitute a pretext for discrimination. Nothing in this section is intended to preclude a covered entity from availing itself of protections described in §§ 92.3 and 92.302.'' Our reasons for this change are as follows:

First, many commenters strongly urged OCR to consider that providers may have a nondiscriminatory reason to not provide some aspects of or all gender-affirming care. OCR understands that a provider may have a legitimate nondiscriminatory reason not to provide a health service, which the newly revised § 92.206(c) makes clear. While this section has application in the gender-affirming care context, the revised language is also intended to make clear that it is not limited to that context. When OCR investigates claims of discrimination based on the denial of care, OCR will consider the covered entity's rationale for such denial, any supporting information the covered entity offers for its position, and any evidence of unlawful animus, bias, or other discriminatory factors in the case.

Second, and as discussed, section 1557 prohibits discrimination on certain prohibited bases, and does not interfere with individualized clinical judgment about the appropriate course of care for a patient. OCR has a general practice of deferring to a clinician's judgment about whether a particular service is medically appropriate for an individual, or whether the clinician has the appropriate expertise to provide care. There is no part of section 1557 that compels clinicians to provide a service that they do not believe is medically appropriate for a particular patient or that they are not qualified to provide.

Since the rule does not (and cannot) set a standard of care for gender-affirming care, the focus of any investigation will not be to generally

[171] *Pac. Shores Props., LLC* v. *Newport Beach,* 730 F.3d 1142, 1158–59 (9th Cir. 2013) (noting that a plaintiff need not rely on the *McDonnell-Douglas* approach to intentional discrimination but may instead produce other circumstantial evidence of intentional discrimination using *Arlington Heights,* as *McDonnell Douglas* ''is not a straightjacket requiring the plaintiff to demonstrate that such similarly situated entities exist'').

review a covered entity's clinical judgment but rather to determine whether the assertion of that judgment reflects unlawful animus or bias, or is a pretext for discrimination. Similarly, outside of the gender-affirming care context, OCR may find an invocation of clinical appropriateness to be pretextual if, for example, the evidence demonstrates that the covered entity asserted that pain medication was not clinically appropriate for a patient because of the belief that women exaggerate pain symptoms and inaccurately relay information about their symptoms.

Third, because many commenters expressed concern about the relationship between § 92.206(c) and religious or moral beliefs concerning gender-affirming care, we added an explicit reference in § 92.206(c) to § 92.302. The new language clarifies that § 92.206(c) does not preclude the process set forth in § 92.302 where a recipient's objection to gender-affirming care may be protected under religious freedom and conscience laws.

Comment: Many commenters also cited religious or moral objections to gender-affirming care, urging that these should be considered a legitimate, nondiscriminatory reason to decline to provide such care.

Response: OCR understands that recipients may have religious or conscience objections to the provision of certain types of care. Such an objection can serve as a legitimate, nondiscriminatory reason where it is neither pretextual nor discriminatory. If a provider typically declines to provide a particular health service to any individual based on a religious belief, regardless of individual's sex assigned at birth or gender identity, the provider likely meets § 92.206(c)'s standard for a ''legitimate, nondiscriminatory reason.'' And where a provider's religious belief causes the provider to treat individuals differently based on sex assigned at birth or gender identity, the provider may rely on the protections afforded by religious freedom and conscience laws or choose to seek assurance of those protections by making use of § 92.302(b)'s assurance of religious freedom and conscience exemption process, a feature that both the 2016 and 2020 Rules lacked. As discussed in more detail below, OCR is making several modifications to § 92.302 to strengthen and clarify this process.

Comment: Many commenters supported the inclusion of § 92.206(c) but recommended that OCR strengthen the language pertaining to providers complying with a State or local law as a justification for denying gender-affirming care, abortions, or other reproductive health care to clarify that as a Federal civil rights law, the rule preempts any such State or local law restricting access to such care. Some commenters suggested including language in the preamble to make clear that the majority of States' policies that restrict transgender and nonbinary people's access to health care would be barred. Another commenter expressed support for explicit preemption language, because otherwise providers would be forced to attempt to comply with State and local laws, while also trying not to run afoul of OCR's case-by-case judgment concerning what conduct may be considered discriminatory. Some commenters expressed concern that the rule could deem physicians' conduct discriminatory when declining to provide services because of State or local laws restricting those services, leaving them in an untenable position. Other commenters criticized the rule because they believe it preempts State laws restricting abortion and gender-affirming care and seeks to preempt State laws on religious freedom and conscience. A commenter expressed confusion as to how the rule would preempt State law as opposed to simply disallowing Federal funds from entities that do not comply.

Response: OCR understands providers' concerns that the provision's reference regarding compliance with State or local law would place them in a difficult position with regard to the conflicting demands of this rule's nondiscrimination requirements and various State and local laws restricting access to abortion or gender-affirming care. While we have removed the language from § 92.206(c) that many commenters supported, section 1557's nondiscrimination requirements nevertheless generally preempt conflicting State law for the reasons stated earlier in this preamble. That said, in exercising and determining its enforcement priorities, OCR will consider the specific factual record of each complaint on a case-by-case basis. This may include, among other things, consideration of whether any covered entity that is taking discriminatory actions under the rule is doing so because it believes in good faith it is obligated to do so by State or local law, whether that covered entity demonstrated a willingness to refer or provide accurate information about gender-affirming care, or is otherwise engaging in good faith efforts to ensure patients are receiving medically necessary care.

Comment: Several commenters expressed support for § 92.206(d)'s clarification that the enumeration of specific forms of prohibited discrimination in § 92.206(b) does not limit the general prohibition against discrimination in § 92.206(a), while recommending that additional preamble language be added to the final rule citing additional examples of discrimination and to provide confirmation that OCR's investigations will not be limited by the enumerated examples in § 92.206(b).

Response: We emphasize that § 92.206(b) is not an exhaustive list of all scenarios that would constitute of sex discrimination under the rule. We have provided additional examples of sex discrimination in this preamble, and OCR's investigations will not be limited by the enumerated forms of discrimination addressed in § 92.206(b) or elsewhere.

Comment: One commenter stated that OCR ignored *Burwell* v. *Hobby Lobby,* 573 U.S. 682 (2014), in the Proposed Rule and that the Proposed Rule is comparable to the Department's actions in that case, in which the Court found that the government's compelling interest in protecting women's health could be accomplished in a less restrictive manner.

Response: OCR has considered *Hobby Lobby* and will be mindful of it when carrying out enforcement of the final rule. For a further discussion of views regarding application of Federal conscience or religious freedom laws, refer to § 92.302.

Summary of Regulatory Changes

For the reasons set forth above and considering the comments received, we are finalizing the provision as proposed in § 92.206, with modifications. We have revised § 92.206(b)(1) to state: ''Deny or limit health services, including those that have been typically or exclusively provided to, or associated with, individuals of one sex . . . .'' We are revising § 92.206(c) to remove the sentence that reads: ''However, a provider's belief that gender transition or other gender-affirming care can never be beneficial for such individuals (or its compliance with a state or local law that reflects a similar judgment) is not a sufficient basis for a judgment that a health service is not clinically appropriate.'' To the end of § 92.206(c) we are adding sentences that read: ''A covered entity's determination must not be based on unlawful animus or bias, or constitute a pretext for discrimination. Nothing in this section is intended to preclude a covered entity from availing itself of protections described in §§ 92.3 and 92.302.''

Nondiscrimination in Health Insurance Coverage and Other Health-Related Coverage (§ 92.207)

In § 92.207, OCR proposed to prohibit discrimination on the basis of race, color, national origin, sex, age, or disability in the provision or administration of health insurance coverage and other health-related coverage. This proposed section would apply to all covered entities that provide or administer health insurance coverage or other health-related coverage that receive Federal financial assistance, and the Department in the administration of its health-related coverage programs.

In § 92.207(a), OCR proposed a general nondiscrimination requirement, and § 92.207(b) proposed specific examples of prohibited actions.

In § 92.207(b)(1), OCR specified that covered entities are prohibited from denying, cancelling, limiting, or refusing to issue or renew health insurance coverage or other health-related coverage, or denying or limiting coverage of a claim, or imposing additional cost sharing or other limitations or restrictions on coverage, on the basis of race, color, national origin, sex, age, or disability.

In § 92.207(b)(2), OCR proposed prohibiting marketing practices or benefit designs that discriminate on the basis of race, color, national origin, sex, age, or disability.

In § 92.207(b)(3), OCR proposed that it is prohibited discrimination to deny or limit coverage, deny or limit coverage of a claim, or impose additional cost sharing or other limitations or restrictions on coverage to an individual based upon the individual's sex at birth, gender identity, or gender otherwise recorded. We invited comment on this provision, including whether it sufficiently addresses the challenges transgender and gender nonconforming individuals are experiencing when seeking access to medically necessary care due to a discordance between their sex assigned at birth and their sex as recorded by their issuer.

In § 92.207(b)(4), OCR proposed to prohibit a covered entity from having or implementing a categorical coverage exclusion or limitation for all health services related to gender transition or other gender-affirming care.[172]

In § 92.207(b)(5), OCR proposed to ensure that a covered entity does not impose discriminatory limits on coverage for specific health services related to gender transition or other gender-affirming care, which would generally be the case if such limits are not applied when those same health services are not related to gender transition or other gender-affirming care.

In § 92.207(b)(6), OCR proposed an integration provision that prohibits covered entities from having or implementing a benefit design that does not provide or administer health insurance coverage or other health-related coverage in the most integrated setting appropriate to the needs of qualified individuals with disabilities.

OCR sought comment on the scope and nature of the benefit design features that result in unjustified segregation or institutionalization of qualified individuals with disabilities or place such individuals at serious risk of institutionalization or segregation. We were interested in feedback on the application of the integration requirement to a wide variety of health services and were particularly interested in comments on the application of the integration requirement to coverage of post-acute services, mental health services, and other services commonly provided by non-State payers (*i.e.,* health insurance issuers, self-insured group health plans, and other payers). OCR was also interested in feedback on the application of the integration requirement to the Medicaid program and its statutory framework at title XIX of the Social Security Act. Specifically, we requested input on how State Medicaid agencies are able to achieve compliance with the integration requirement through benefit design, such as through reimbursement, service scope, and service authorization that do not incentivize institutional services over community services. In addition, OCR requested input on the amount of time needed to reach compliance with needed benefit design modifications.

In § 92.207(c), OCR stated that nothing in this section requires the coverage of any health service where the covered entity has a legitimate, nondiscriminatory reason for determining that such health service fails to meet applicable coverage requirements, such as medical necessity requirements, in an individual case.

Finally, in § 92.207(d), OCR made clear that the enumeration of specific forms of discrimination in § 92.207(b) does not limit the general applicability of the prohibition in § 92.207(a).

OCR generally invited comment on how section 1557 might apply to: provider networks; how provider networks are developed, including factors that are considered in the creation of the network and steps taken to ensure that an adequate number of providers and facilities that treat a variety of health conditions are included in the network; the ways in which provider networks limit or deny access to care for individuals on the basis of race, color, national origin, sex, age, or disability; and the extent to which the lack of availability of accessible medical diagnostic equipment in a provider network limits or denies access to care for individuals with disabilities. We also sought comment on the extent, scope and nature of value assessment methods that discriminate on the basis of race, color, national origin, sex, age, or disability. We were interested in feedback on the civil rights implications of value assessment across a wide variety of contexts, including utilization management, formulary design, price negotiations, alternative payment models and other relevant applications. Finally, OCR invited comment on all aspects of this section. In particular, we sought comment on the anticipated impact of the proposed application to excepted benefits and short-term, limited duration insurance (STLDI) when such products are offered by a covered entity; how the Proposed Rule's nondiscrimination requirements would impact the industry that offers excepted benefits and STLDI and the consumers who rely upon those products; the prevalence of excepted benefits and STLDI offered by covered entities and the standard industry practices under which such plans are designed and administered; and excepted benefits and STLDI plans' scope of coverage, types of exclusions and limitations, underwriting practices, premium setting, and actuarial or business justifications for industry practices (as applicable), that may raise concerns about discrimination under section 1557.

The comments and our responses regarding § 92.207 are set forth below.

For ease of reference, OCR may simply refer to ''health insurance issuers'' or ''issuers'' throughout the preamble, but other covered entities may also be subject to the section under

[172] As noted in the discussion of § 92.206 above, this preamble uses the terms ''gender transition'' and ''gender affirmation'' interchangeably in discussing the range of care that transgender individuals (including those who identify using other terms, for example, nonbinary or gender nonconforming) may seek to treat gender dysphoria and support gender transition or affirmation. Because insurance coverage provisions and medical-necessity determinations more often use the term gender transition, within these provisions, the term gender affirmation encompasses gender transition, that is the terminology used in the text of the regulation. The use of the term ''gender transition'' in the regulation, however, is not intended to convey a narrower meaning than the term ''gender affirmation.''

discussion. In addition, for purposes of this preamble only, OCR uses the term ''health plan'' or ''plan'' interchangeably to refer generally to health insurance coverage and other health-related coverage that is subject to this rule. As used in this preamble, ''health plan'' or ''plan'' may include health insurance coverage or other health-related coverage offered in the group and individual markets, group health plan coverage, Medicare Advantage plans, Medicare Part D plans, and Medicaid programs that are subject to this rule. OCR does not intend ''health plan'' or ''plan'' to be regulatory terms in this regulation or to replace any existing or proposed term in Federal law.

OCR notes that a variety of entities may be considered covered entities subject to § 92.207, including but not limited to health insurance issuers, group health plans, Medicare Advantage Organizations, Medicare Part D plan sponsors, Medicaid managed care plans, pharmacy benefit managers, third party administrators (as part of a covered entity's operations when it meets the criteria in paragraph (2) of the definition of ''health program or activity'' under § 92.4), and the Department.

Comment: Commenters strongly supported the inclusion of an explicit provision related to prohibited discrimination in health insurance coverage and other health-related coverage, noting that it will help provide clarity for covered entities. Many commenters stated that it is clear from the statutory text of the ACA that Congress intended for section 1557 to apply to health insurance. Commenters stated that the 2020 Rule's rescission of similar protections created confusion, was contrary to the intent and purpose of the ACA, and increased the burden on States to monitor and enforce nondiscrimination laws. Commenters noted that ensuring covered entities provide health insurance coverage and other health-related coverage in a nondiscriminatory manner will reduce adverse health outcomes and address some of the barriers vulnerable communities face in accessing health insurance coverage and other health-related coverage. Commenters from the health insurance industry were generally supportive of reinstating the section with some suggested modifications. This includes one commenter noting that, as an employer, they appreciated the Proposed Rule's clarification prohibiting categorical exclusions, noting that the 2016 Rule's similar prohibition had allowed them to negotiate a nondiscriminatory plan to cover their employees.

One organizational commenter opposed to the inclusion of § 92.207 argued that health insurance issuers could face substantial costs, including compliance costs and claims costs, as a result of having to alter their coverages and business practices, which would result in higher premiums. This commenter also argued OCR is engaging in expansive and detailed regulation of numerous issuer business decisions in an arbitrary and capricious manner that could result in issuers facing heightened business risks and increased liability exposure.

Response: OCR agrees that section 1557 applies broadly, including to prohibit discrimination by covered entities that provide or administer health insurance coverage and other health-related coverage. As discussed throughout this preamble, particularly under the discussion of the definition of ''health program or activity'' under § 92.4, the ACA is clearly intended to apply to health insurance coverage and other health-related coverage and prohibit the discriminatory practices therein.

OCR disagrees that § 92.207 imposes expansive regulation of health insurance issuers and their business decisions in an arbitrary and capricious manner. The plain text of section 1557 applies to health insurance coverage and other health-related coverage; OCR is implementing Congressional intent to prohibit discrimination in health insurance coverage and other health-related coverage in § 92.207. In addition to section 1557, health insurance issuers are required to comply with myriad State and Federal laws regulating the practice of health insurance coverage and other health-related coverage. These laws include other Federal laws that regulate health insurance coverage and other health-related coverage practices, including nondiscrimination requirements.[173] Compliance with legal requirements, such as section 1557, is a standard business practice as a health insurance issuer. Further, health insurance issuers were subject to former § 92.207's requirements[174] from either July 18, 2016, or January 1, 2017 (if plan design changes were required as a result of the 2016 Rule), through August 18, 2020, the effective date of the 2020 Rule.

Comment: Some commenters supported § 92.207(b)(1), related to coverage denials and limitations. Some commenters asked OCR to state that cost sharing must not be used by covered entities in a discriminatory manner. Commenters acknowledged that cost sharing can be an effective tool, but they also expressed concern that insurance companies and pharmacy benefit managers are increasingly employing high cost sharing that disproportionately affects people with disabilities, chronic conditions, and other significant health needs. Commenters cited several studies that show patients who are uncertain about their ability to afford their out-of-pocket care expenses delay or forgo care or fall out of compliance with recommended follow-up steps.[175] Commenters noted that such gaps in care can have deadly consequences for individuals with certain conditions, such as people living with HIV/AIDS.

Commenters also provided examples of concerns related to cost sharing and patient financial assistance. A few commenters raised concerns about treatment of patient financial assistance, accumulator adjustment programs, copay maximizers, and alternative funding programs. Other commenters raised concerns about issuers designating drugs as ''non-essential-health-benefits'' to avoid certain

[173] *See, e.g.,* 42 CFR 422.100(f)(2) and (3), 422.110 (Medicare Advantage), 423.104(d)(2)(iii), 423.2262(a)(1)(iv) (Part D), 438.3(d) and (f) (Medicaid managed care), and 600.405(d) (Basic Health Program); 45 CFR 147.104(e) (group and individual health insurance markets), 156.125(a) and (b) (EHB), 156.200(e), and 156.225(b) (qualified health plans).

[174] Issuers were subject to those requirements except for provisions either enjoined or vacated through lawsuits. *See, e.g., Franciscan Alliance* v. *Burwell,* 227 F. Supp. 3d 660 (N.D. Tex. 2016).

[175] *See, e.g.,* Joel F. Farley, *Medicaid Prescription Cost Containment and Schizophrenia,* 48 Med. Care 5, 440–47 (2010), *https://pubmed.ncbi.nlm.nih.gov/20351586/*; Teresa B. Gibson & Ronald J. Ozminkowski, *The Effects of Prescription Drug Cost Sharing: A Review of the Evidence,* 11 a.m.. J. Managed Care 11, 730–40 (2005), *https://pubmed.ncbi.nlm.nih.gov/16268755/*; Daniel M. Hartung et al., *Impact of a Medicaid Copayment Policy on Prescription Drug and Health Services Utilization in a Fee-for-Service Medicaid Population,* 46 Med. Care 6, 565–72 (2008), *https://pubmed.ncbi.nlm.nih.gov/18520310/*; Nantana Kaisaeng et al., *Out-of-Pocket Costs and Oral Cancer Medication Discontinuation in the Elderly,* 20 J. Managed Care Pharmacy 7, 669–75 (2014), *https://pubmed.ncbi.nlm.nih.gov/24967520/*; Deliana Kostova & Jared Fox, *Chronic Health Outcomes and Prescription Drug Copayments in Medicaid,* 55 Med. Care 5, 520–27 (2017), *https://pubmed.ncbi.nlm.nih.gov/28234755/*; Sujha Subramanian, *Impact of Medicaid Copayments on Patients With Cancer,* 49 Med. Care 9, 842–47 (2011), *https://pubmed.ncbi.nlm.nih.gov/21577164/* ; Samantha Artiga et al., *The Effects of Premium and Cost-Sharing on Low-Income Populations: Updated Review of Research Findings,* Kaiser Family Found., pp.1–5 (2017), *https://www.kff.org/medicaid/issue-brief/the-effects-of-premiums-and-cost-sharing-on-low-income-populations-updated-review-of-research-findings/*; David B. Ridley & Kirsten J. Axelsen, *Impact of Medicaid Preferred Drug Lists on Therapeutic Adherence,* 24 Pharmacoeconomics Suppl. 3, 65–78 (2006), *http://www.ncbi.nlm.nih.gov/pubmed/17266389.*

essential health benefits (EHB) requirements.[176]

One organizational commenter expressed concerns about § 92.207(b)(1) and argued that this provision would impose new nondiscrimination tests on issuer business decisions that result in the denial or limitation of payment for a claim, on variations in cost sharing under the terms of a health plan, or on the imposition of other limitations or restrictions on coverage. The commenter argued this would result in expansive and detailed regulation of numerous issuer business decisions in an arbitrary and capricious manner.

Response: OCR appreciates commenters' concerns regarding cost sharing, which is explicitly addressed in § 92.207(b)(1). Covered entities are prohibited from ''impos[ing] additional cost sharing or other limitations or restrictions on coverage, on the basis of race, color, national origin, sex, age, or disability.'' We disagree with the commenter's concerns that this provision arbitrarily or capriciously imposes new nondiscrimination tests on issuer business decisions. Covered entities subject to this rule are prohibited from engaging in unlawful discrimination in their health programs or activities, including in health insurance coverage or other health-related coverage. Cost sharing is standard industry practice that is a feature of an issuer's health insurance coverage or other health-related coverage. Nothing in this rule dictates the business decisions an issuer should make in establishing its coverage limitations, including with regard to cost sharing. To the extent an issuer imposes cost sharing in its coverage, it cannot do so in a discriminatory manner. Comments related to violations of EHB requirements are outside the scope of this regulation.[177]

Comment: Commenters generally supported the prohibition on discriminatory marketing practices in § 92.207(b)(2). Commenters discussed that covered entities might use marketing practices to dissuade enrollment by individuals with high-cost conditions. For example, commenters noted that plans present inaccurate or confusing information about formularies and hide or fail to provide information about certain drugs. Several commenters referenced a 2022 study by the AIDS Institute that found 57.9 percent of the 299 Exchange plan documents reviewed did not list PrEP (pre-exposure prophylaxis to prevent HIV infection) as a free preventive service, though health insurance issuers were required to include such coverage for all plans offered through the Exchanges in 2022.[178] Commenters asked OCR to provide an example of discriminatory marketing practices in regulatory text. They further requested that OCR coordinate the study of marketing practices with other regulatory agencies.

Response: OCR concurs with the importance of ensuring that an issuer's marketing practices are not designed or implemented in a way that discriminates against individuals with a specific disability or on any other basis prohibited under section 1557. Inaccuracies or omissions in plan marketing materials may impede an individual's ability to determine what treatments and services are covered. While certain inaccuracies or omissions in marketing materials may not be prohibited discrimination under this section, inaccuracies or omissions that were intended to or resulted in discouraging individuals from enrolling in health insurance coverage and other health-related coverage or steering individuals away from enrolling in health insurance coverage and other health-related coverage on the basis of disability or other prohibited basis would raise concerns of prohibited discrimination. The determination of whether a particular marketing practice is prohibited under this section requires a case-by-case analysis dependent on the facts of the challenged marketing practice. Accordingly, OCR declines to specify particular examples in the regulation, though we included an example in the Proposed Rule, stating that covered entities that avoid advertising in areas populated by a majority of people of color to reduce the enrollment of people of color in their health insurance coverage could violate § 92.207. 87 FR 47869–70. We note that covered entities may be subject to other Departmental and Federal regulations governing marketing practices.[179] While OCR declines to coordinate a study of marketing practices, we continue to coordinate with other regulatory agencies on health insurance-related matters.

We note that individuals with LEP or disabilities may face challenges in accessing a covered entity's marketing materials. This final rule addresses such concerns in multiple ways, including by requiring covered entities to provide a Notice of Nondiscrimination under § 92.10; a Notice of Availability under § 92.11 (including in member handbooks at § 92.11(c)(5)(x)); taking reasonable steps to provide meaningful access to individuals with LEP under § 92.201; and taking appropriate steps to ensure effective communication for individuals with disabilities under § 92.202.

Comment: Numerous commenters supported the prohibition on discriminatory health plan benefit designs in § 92.207(b)(2). Commenters stated that covered entities employ many features of benefit design and delivery to deny coverage or discourage people with significant or high-cost health needs from enrolling in their plans. These include exclusions, cost sharing, formularies, visit limits, provider networks, service areas, benefit substitutions, prior authorization, and other utilization management that the commenters allege are arbitrary and not clinically based or appropriate.

Some commenters requested that OCR define the term ''benefit design'' or include specific examples of benefit design features in the regulatory text of § 92.207(b)(2). While some commenters expressed concern that failing to define benefit design in the regulation would result in a lack of clarity as to what the rule prohibits, other commenters supported OCR's proposed approach to avoid defining the term in a prescriptive manner.

One organizational commenter opposed § 92.207(b)(2) as imposing nondiscrimination tests on insurance benefit design, which the commenter argued would result in expansive and detailed regulation of a number of issuer business decisions in an arbitrary and capricious manner.

Response: Benefit design features may result in a discriminatory denial of access to medically necessary care, particularly for individuals with disabilities who have significant health needs. To address this concern, covered entities are explicitly prohibited from having or implementing benefit designs

[176] *See* section 1302 of the ACA, codified at 42 U.S.C. 18022.

[177] *See* 42 U.S.C. 18022, 300gg–6(a); 45 CFR 156.100 through 165.155.

[178] Letter from The AIDS Institute to Dr. Ellen Montz, Deputy Admin'r & Dir. (June 9, 2022), *https://www.theaidsinstitute.org/letters/marketplace-insurance-plan-prep-compliance*. In general, under section 2713 of the PHS Act and its implementing regulations, plans and issuers must provide coverage, without cost sharing, for recommended preventive services for plan years (in the individual market, policy years) that begin on or after the date that is 1 year after the date the recommendation or guideline is issued. 26 CFR 54.9815–2713(b); 29 CFR 2590.715–2713(b); 45 CFR 147.130(b).

[179] *See, e.g.,* 45 CFR 147.104(e) (health insurance issuers offering coverage in the individual and group markets) and 156.225(b) (qualified health plans); 42 CFR 423.2263 (Medicare Part D marketing requirements).

that discriminate on any protected basis as set forth under § 92.207(b)(2).

We decline to define ''benefit design'' or specify types of benefit design features in the regulatory text. Section 92.207(b)(2) sufficiently notifies covered entities that discriminatory benefit designs are prohibited under this rule. In addition, we seek to avoid being overly prescriptive or unintentionally inconsistent with other Departmental regulations that may define benefit design.[180] While OCR declines to provide examples of specific benefit design features in the regulatory text, for purposes of applying section 1557 and this final rule, examples of benefit design features include, but are not limited to, coverage, exclusions, and limitations of benefits; prescription drug formularies; cost sharing (including copays, coinsurance, and deductibles); utilization management techniques (such as step therapy and prior authorization); medical management standards (including medical necessity standards); provider network design; and reimbursement rates to providers and standards for provider admission to participate in a network.

OCR disagrees with the organizational commenter's concern that this provision arbitrarily or capriciously imposes new nondiscrimination tests on issuer business decisions. This section does not dictate what business decisions an issuer must make in establishing its benefit design and does not specify any particular design feature must be included. OCR acknowledges that issuers have discretion in designing their plans; however, they must do so in a nondiscriminatory manner as discussed throughout this section.

Comment: Commenters requested that OCR provide a non-exhaustive list of presumptively discriminatory benefit design examples. Some commenters also suggested that OCR incorporate the presumptively discriminatory benefit design examples provided in CMS' EHB regulations [181] or otherwise rely on other nondiscrimination provisions in CMS regulations implementing the ACA. Commenters stated that allowing plan discretion on every benefit other than gender dysphoria undercuts the regulation. Many commenters stated that OCR should recognize that most benefit design elements are inherently discriminatory as they apply disproportionately to individuals with disabilities and chronic conditions. Commenters expressed concerns that without presumptively discriminatory benefit design examples, issuers will adopt designs that exclude or make lifesaving treatments unaffordable for individuals in protected categories. Commenters noted that such designs include cost-sharing requirements, restrictive medical necessity standards, narrow networks, drug formularies, adverse tiering, benefit substitution, utilization managements, exclusions, visit limits, quantity limits, waiting periods, service areas, and coercive wellness programs.

Response: OCR declines to provide specific examples of presumptively discriminatory benefit designs in the rule due to the fact-intensive analysis needed to determine whether a particular benefit design feature is discriminatory under this section. We also decline to give examples of presumptively discriminatory benefit designs similar to those in EHB regulations applicable to non-grandfathered health insurance coverage in the individual and small group markets that CMS finalized in the preamble of its Notice of Benefit and Payment Parameters for 2023 final rule.[182] Essential health benefits are governed by CMS regulations and not by this final rule. While many of the practices cited by CMS would raise concerns of prohibited discrimination under this rule, OCR's determinations that a particular benefit design is discriminatory will be a fact-specific inquiry that OCR will conduct on a case-by-case basis. OCR's process for analyzing claims of discrimination in benefit design is discussed in more detail under the *Benefit Design Analysis* discussion later in this section. OCR will consider issuing guidance on discriminatory practices prohibited under this section in future guidance.

OCR disagrees that the prohibition against categorical exclusions or limitations of coverage for all health services related to gender transition or other gender-affirming care under § 92.207(b)(4) undercuts the regulation. Such explicit, categorical exclusions or limitations impermissibly single out an entire category of services based on an individual's transgender status and are presumptively discriminatory on the basis of sex as prohibited under this section. As discussed in detail under § 92.206, this rule includes specific provisions related to gender-affirming care given the widespread discriminatory denial of care for such services and its direct connection to an individual's transgender status.[183] As discussed in more detail below, covered entities may raise a defense under § 92.207(c) where they contend that they have a legitimate, nondiscriminatory basis for a coverage limitation that may otherwise appear to constitute discrimination. Recipients may also rely upon §§ 92.3 and 92.302(a) or request an assurance of exemption under § 92.302(b) based on their view that religious freedom or conscience protections apply.

We also decline to incorporate examples of presumptively discriminatory benefit designs similar to those in EHB regulations applicable to non-grandfathered health insurance coverage [184] in the individual and small group markets that CMS finalized in the preamble of its Notice of Benefit and Payment Parameters for 2023 final rule. Essential health benefits are governed by CMS regulations and are not addressed by this final rule. While many of the practices cited by CMS would raise concerns of prohibited

[180] Other Departmental and Federal regulations governing private health insurance and public health coverage refer to ''benefit design'' and ''marketing practices.'' *See, e.g.,* 45 CFR 147.104(e), 156.20, 156.125(a) (health insurance issuers offering coverage in the individual and group markets), 156.200(b)(3), 156.225(b) (qualified health plans), 156.110(d), and 156.111(b)(2)(v) (EHB benchmark plans); 42 CFR 422.100(f)(3) (Medicare Advantage), 423.2263 (Medicare Part D marketing requirements), 423.882, 423.894(d) (Medicare retiree prescription drug plans), 440.347(e) (Medicaid benchmark plans), and 600.405(d) (Basic Health Program); 29 CFR 2510.3–40(c)(1)(iv)(A) (multiple employer welfare arrangements under ERISA).

[181] *See* Patient Protection and Affordable Care Act; HHS Notice of Benefit & Payment Parameters for 2023, 87 FR 27208, 27301–02 (May 6, 2022).

[182] Patient Protection and Affordable Care Act; HHS Notice of Benefit & Payment Parameters for 2023, 87 FR 27208, 27301–05 (May 6, 2022) (providing the following examples of presumptively discriminatory benefit designs under CMS' EHB nondiscrimination regulations applicable to non-grandfathered health insurance coverage in the individual and small group markets: (1) limitation on hearing aid coverage based on age; (2) autism spectrum disorder coverage limitations based on age; (3) age limits for infertility treatment coverage when treatment is clinically effective for the age group; (4) limitation on foot care coverage based on diagnosis (whether diabetes or another underlying medical condition); and (5) access to prescription drugs for chronic health conditions (adverse tiering)). We note these regulations are enforced by CMS and are distinct from section 1557 and other civil rights laws enforced by OCR.

[183] *See, e.g., Bos. All. of Gay, Lesbian, Bisexual & Transgender Youth* v. *U.S. Dep't of Health & Hum. Servs.,* 557 F. Supp. 224, 239 (D. Mass. 2021) (''[p]laintiffs have shown a substantial risk that insurers will deny reimbursement for treatment they previously covered based on the elimination of the prohibition on categorical coverage exclusions. Out2Enroll's analysis indicates that ''the number of insurers using transgender-specific exclusions . . . more than doubled'' after HHS promulgated the 2020 Rule.'').

[184] In general, health coverage is considered grandfathered if it was in existence and has continuously provided coverage for someone (not necessarily the same person, but at all times at least one person) since March 23, 2010, provided the plan (or its sponsor) or the issuer has not taken certain actions resulting in the plan relinquishing grandfathered status, as more fully described at 26 CFR 54.9815–1251, 29 CFR 2590.715–1251, and 45 CFR 147.140.

discrimination under this rule, OCR's determinations that a particular benefit design is discriminatory will be a fact-specific inquiry that OCR will conduct on a case-by-case basis. OCR's process for analyzing claims of discrimination in benefit design is discussed in more detail under the *Benefit Design Analysis* discussion later in this section. OCR will consider issuing guidance on discriminatory practices prohibited under this section in future guidance.

Comment: Commenters asked OCR to include examples of discriminatory benefit design specifically related to prescription drug formularies. These commenters provided examples of practices they considered to be discriminatory, such as issuers placing most or all drugs used in the treatment of certain conditions into the highest cost sharing tier; excluding single tablet regimens even when they are the standard of care for a condition; requiring the use of specialty pharmacy programs that require mail delivery even when that adds unnecessary and burdensome administrative barriers and delays to obtaining drugs; and using quantity limits for an entire class of medications without scientific or clinical explanation. Commenters expressed concerns that discriminatory prescription drug formularies discourage enrollment among certain populations, including individuals with HIV, mental health needs, or other chronic conditions. Commenters noted that enrollees who need high-cost medications often must choose between plans that will provide adequate coverage of their medication or plans that cover their preferred providers. A commenter cited a study that showed that Black and Hispanic/Latino people are more likely to abandon medications at the pharmacy because of high cost.[185] Finally, some commenters recommended that OCR develop specific mechanisms to monitor prescription drug formulary practices and coverage of physician-administered ''medical benefit'' drugs to ensure that formularies are not used to discriminate against patients with specific disabilities.

Response: Benefit design practices related to prescription drugs have an enormous impact on individuals' access to medically necessary medication. Coverage of prescription drugs could pose concerns of prohibited discrimination and OCR would investigate such practices under the rule on a case-by-case basis. OCR declines to state that specific practices are per se discriminatory under the rule because each investigation is a fact-specific inquiry, based on nondiscrimination principles and relevant case law,[186] including consideration of the covered entity's reason for the design feature in question.

As discussed in the Proposed Rule, several benefit design practices related to drug formularies could be discriminatory under this section, including prescription drug formularies that place utilization management controls on most or all drugs that treat a particular condition regardless of their costs without placing similar utilization management controls on most or all drugs used to treat other conditions, and benefit designs that place utilization management controls on most or all services that treat a particular disease or condition but not others. 87 FR 47874. OCR notes that coverage of physician-administered ''medical benefit'' drugs would be considered part of a plan's benefit design and therefore subject to this rule.

While we identify some prescription drug practices above that may raise concerns under section 1557, this rule does not prohibit covered entities from engaging in nondiscriminatory practices related to prescription drug benefit design. For example, covered entities may utilize preferred drug lists, such as preferred drug lists under the Medicaid program under title XIX of the Social Security Act, as long as the coverage criteria does not constitute prohibited discrimination. In addition, as discussed in more detail below, covered entities are not prohibited from applying nondiscriminatory utilization management techniques in their drug formularies.

Comment: Many commenters expressed concerns about benefit designs that impose coverage limitations or exclusions related to health services that could result in discrimination on the basis of disability. For example, some commenters argued that plans should not be permitted to have blanket exclusions for services related to ASD or applied behavioral analysis (ABA) therapy, a therapeutic intervention sometimes recommended for autistic children.

Several commenters raised concerns about how frequently insurance benefit design practices inappropriately limit coverage of durable medical equipment. Commenters noted that issuers place unique annual coverage caps on items such as wheelchairs, ventilators, and hearing aids. A commenter noted an example of an individual with hearing loss that requires treatment other than cochlear implants being denied coverage of hearing aids and outpatient visits to an audiologist due to their issuer's blanket exclusion of programs or treatments for hearing loss other than cochlear implants. Another commenter noted that issuers limit coverage of multiple-use speech-generating devices, which are most useful and effective for autistic individuals, even when those devices are less expensive than single-use speech generating devices.

Other commenters expressed concerns that covered entities include clinically inappropriate limits on the coverage of habilitative and rehabilitative services and devices. Commenters noted that such limitations, including on the number of covered visits, discriminate against people with more significant disabilities who need extensive habilitation or rehabilitation in order to gain, regain, or maintain functioning. Commenters requested that OCR clarify that blanket limitations or exclusions of habilitative services for individuals with specific disabilities are prohibited discrimination under section 1557 when those same services are allowed for rehabilitation of nondisabled persons. Commenters noted that people with developmental disabilities are routinely denied coverage for habilitative services needed to gain skills or improve functioning while an identical service is covered for individuals who require it for rehabilitative care to restore functioning. For example, a commenter noted that coverage of ''speech therapy to restore speech'' results in excluding all children with developmental delays who need the therapy to *attain* speech. Commenters noted that habilitative services are important for children who are delayed in walking or talking or need to learn other muscular skills for the first time and for individuals with disabilities to be able to live as independently as possible.

Response: OCR appreciates the variety of concerns raised by commenters. A coverage limitation or exclusion that is based on a specific disability or condition (or other basis prohibited by section 1557, such as age, discussed below), would be investigated as

[185] PhRMA, *Patient Experience Survey: Barriers to Health Care Access in the Patient Experience,* pp. 10–11 (2021), *https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/P-R/PES-Report_100621_Final.pdf* (stating that utilization management disproportionately impacts people of color (Black Americans (56 percent) and Hispanic Americans (60 percent) versus white Americans (36 percent)) and that barriers imposed by utilization management can contribute to poor medication adherence or prescription abandonment).

[186] *See, e.g., Doe* v. *CVS Pharmacy, Inc.,* 982 F.3d 1204, 1212 (9th Cir. 2020); *Doe* v. *BlueCross BlueShield of Tenn.,* 926 F.3d 235, 241 (6th Cir. 2019).

potentially discriminatory under this rule. Blanket exclusions of all treatments related to a particular condition, such as ASD or hearing loss, would raise significant concerns of prohibited discrimination on the basis of disability such that OCR would expect the covered entity to provide a legitimate, nondiscriminatory reason for the exclusion. Non-categorical exclusions or limitations for certain treatments related to a specific disability or condition may also raise concerns under the rule. This rule, however, does not require covered entities to cover all services related to a specific disability or condition. Application of standard disability discrimination principles requires a specific analysis of each claimed exclusion. We therefore decline to expressly state that a particular coverage exclusion or limitation is per se discriminatory on the basis of disability under this rule. Determinations of whether a particular coverage exclusion or limitation is discriminatory will be evaluated on a case-by-case basis, in accordance with longstanding civil rights principles and relevant case law, as discussed throughout this section. When investigating a potentially discriminatory exclusion or limitation, OCR will consider whether the covered entity has a legitimate, nondiscriminatory reason for the challenged design feature. If OCR determines that the covered entity's reason is a legitimate, nondiscriminatory reason that is not a pretext for discrimination, OCR will conclude that the challenged exclusion or limitation is not prohibited under the rule.

Regarding durable medical treatment, the commenters' example of exclusions of coverage for programs or treatments for hearing loss other than cochlear implants has been the subject of at least two court cases where the courts have held that such exclusions do not state a claim for proxy disability discrimination under section 1557.[187]

We also note that health insurance issuers may be subject to other Departmental authorities that are relevant to issues raised by commenters.[188] For example, to the extent durable medical equipment is an EHB, like hearing aids are in some states, covered entities may also be subject to CMS' EHB nondiscrimination regulations at 45 CFR 156.125 applicable to non-grandfathered health insurance coverage in the individual and small group markets.[189] Further, CMS' EHB regulations require coverage of habilitative services and devices, and specify that plans may not impose limits on coverage of habilitative services and devices that are less favorable than limits imposed on coverage of rehabilitative services and devices.[190]

Comment: Many commenters raised concerns related to mental health services. Commenters asked OCR to require both public and private payers to remedy the current inadequacies and inequities in mental health service reimbursement rates and policies, explaining that reimbursement rates have been historically lower for mental health services than physical health services. Commenters also identified a range of specific mental health benefit design inequities, including the need for intermediate-care facility coverage for high-use patients with non-urgent care needs to mobile crisis response that is on par to that of physical emergency response. Commenters also requested that the rule align with the mental health parity protections in the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008 (MHPAEA).

Response: OCR acknowledges commenters' concerns regarding coverage for mental health services. Mental health services may be needed by people who may or may not be individuals with disabilities under this rule. OCR will examine complaints alleging less favorable treatment for mental health coverage as compared to physical health coverage on a case-by-case basis to determine if the coverage discriminates against people with disabilities. Reimbursement rates and policies are subject to § 92.207 as part of a plan's benefit design, and thus must be provided in a nondiscriminatory manner. We also discuss reimbursement rates in the context of the integration provision under § 92.207(b)(6).

We decline to incorporate or align this rule with MHPAEA, as section 1557 is a distinct Federal civil rights law. We note that coverage limitations found to violate section 1557 may also be prohibited under MHPAEA.[191]

Comment: Commenters expressed concerns about issuers discriminating against enrollees based on age through certain benefit designs. Commenters provided examples of practices they believed to be discriminatory, such as issuers requiring an ASD diagnosis by a certain age to access coverage for ASD-related health care; not covering hearing aids for adults when otherwise covered for children; and imposing limitations on wheelchair and mobility device replacement for children that fail to align with how quickly children outgrow such devices. One commenter asked that OCR require issuers to attest that their pediatric benefit packages are comprehensive and age-appropriate by demonstrating that physical and mental health benefits do not have age, visit, or coverage limits that are not based on medical necessity or that are based on adult metrics. Commenters noted that plans that limit coverage to specific conditions or a child's capacity to attain a certain functional status will unfairly prevent many children with special health care needs from accessing critically important services.

Response: Section 1557 prohibits discrimination on the basis of age, consistent with the Age Act and its implementing regulations. The Age Act allows age distinctions under certain circumstances, including distinctions

[187] *Schmitt* v. *Kaiser Found. Health Plan of Wash.,* 965 F.3d 945, 960 (9th Cir. 2020); *E.S.* v. *Regence BlueShield,* No. 2:17–cv–01609–RAJ, 2022 WL 279028, at *8–9 (W.D. Wash., Jan. 31, 2022).

[188] *See, e.g.,* Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008 (MHPAEA).

[189] *See* Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2023, 87 FR 27208, 27301–02 (May 6, 2022) (concluding that age limitations on hearing aid coverage are presumptively discriminatory under 45 CFR 156.125 when applied to EHB and there is no clinical basis for the age distinction). We note these regulations are enforced by CMS and are distinct from section 1557 and other civil rights laws enforced by OCR.

[190] 45 CFR 156.110(a)(7) and 156.115(a)(5)(ii).

[191] The Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008 (MHPAEA), Public Law 110–343; 42 U.S.C. 300gg–26 (HHS); 29 U.S.C. 1185a (Department of Labor); 26 U.S.C. 9812 (Department of Treasury), and implementing regulations at 45 CFR 146.136 and 45 CFR 147.160, 29 CFR 2590.712, and 26 CFR 54.9812–1, respectively; The Departments of the Treasury, Labor, and HHS also published proposed rules on August 3, 2023 (88 FR 51552), to amend existing regulations and establish new regulations for the nonquantitative treatment limitation comparative analyses required under MHPAEA, as amended by the Consolidated Appropriations Act, 2021. The proposed rules would amend the existing rules to prevent group health plans and health insurance issuers offering group or individual health insurance coverage that provides both medical and surgical benefits and mental health or substance use disorder benefits from using nonquantitative treatment limits to place greater limits on access to mental health and substance use disorder benefits as compared to medical/surgical benefits; *see also* U.S. Dep't of Labor, U.S. Dep't of Health & Hum. Servs., U.S. Dep't of the Treasury, 2022 MHPAEA Report To Congress: *Realizing Parity, Reducing Stigma, and Raising Awareness: Increasing Access to Mental Health and Substance Use Disorder Coverage* (2022), *https://www.dol.gov/sites/dolgov/files/EBSA/laws-and-regulations/laws/mental-health-parity/report-to-congress-2022-realizing-parity-reducing-stigma-and-raising-awareness.pdf*; U.S. Dep't of Labor, *Self-Compliance Tool for the Mental Health Parity and Addiction Equity Act (MHPAEA),* p. 38 (2020), *https://www.dol.gov/sites/dolgov/files/EBSA/laws-and-regulations/laws/mental-health-parity/self-compliance-tool.pdf.*

that reasonably take into account age as a factor necessary to the normal operation or the achievement of any statutory objective [192] of a program or activity; are based on age-related factors that bear a direct and substantial relationship to the normal operation of the program or activity or to the achievement of a statutory objective; provide special benefits to the elderly or children; or are contained in a rule or regulation issued by the Department.[193] As a result, not all age-related distinctions in State or Federal law, including Department regulations, are prohibited by section 1557.[194] As noted above, these permissible age distinctions form part of the ''ground'' of discrimination prohibited under the Age Act, because they identify distinctions that either are not forbidden age discrimination, 42 U.S.C. 6103(b)(1)(A) (''reasonably takes into account age as a factor necessary to the normal operation or the achievement of any statutory objective of such program or activity''), or are not age discrimination at all, *id.* section 6103(b)(1)(B) (''based upon reasonable factors other than age'').

When investigating a benefit design with an age distinction, OCR will first determine whether the distinction is permitted under the Age Act (and therefore section 1557). If it is not, OCR will then investigate the age distinction to determine whether it violates section 1557. As with other benefit design investigations, OCR's analysis will involve a fact-specific inquiry and will consider a covered entity's reason for the age distinction in its benefit design. The covered entity's justification must be a legitimate, nondiscriminatory reason, as discussed under § 92.207(c). For example, if an issuer is not able to provide a legitimate, nondiscriminatory reason to substantiate an age distinction in ASD coverage, such an age distinction would likely violate section 1557. We reiterate that this rule does not require a covered entity to provide coverage for all health services related to a particular disability or condition; rather, it requires covered entities to design their plan benefits in a nondiscriminatory manner. We note that covered entities may also be subject to relevant CMS EHB nondiscrimination regulations regarding presumptively discriminatory age distinctions.[195]

OCR does not agree that it is necessary to require a separate attestation related to pediatric benefit packages. As recipients of Federal financial assistance, issuers are required to submit an Assurance of Compliance with section 1557 under § 92.5, which attests that they will not discriminate on the basis of age, among other prohibited bases.

Comment: A commenter requested that OCR clarify the obligation of issuers and plan administrators to ensure that their staff, as well as the staff of any subsidiary entities with which they do business, receive explicit training on the relationship between benefit design choices and practices and activities that can amount to discrimination based on race, color, national origin, sex, age or disability.

Response: Covered entities are responsible for ensuring their staff, subrecipients, and subcontractors are compliant with section 1557. Section 92.9 requires covered entities to provide training to relevant employees on their section 1557 Policies and Procedures, and while we note that it is in a covered entity's best interest to ensure that relevant staff are adequately trained, we decline to specify additional training requirements at this time.

Comment: Commenters requested that the final rule expressly state that section 1557 prohibits proxy discrimination in benefit design, either in the preamble or regulation. Commenters expressed concern that absent express incorporation of proxy principles, covered actors may attempt to evade section 1557's nondiscrimination provisions. A commenter requested that the final rule incorporate established discrimination principles and noted that issuers continue to justify discriminatory plan designs by taking the position that health plans that target a particular medical service rather than a disability are neutral or uniform with respect to all enrollees. As an example, the commenter noted that plans restricting coverage of dialysis justify it as not being discriminatory against enrollees with end-stage renal disease. The commenter requested that the final rule declare that discriminatory plan designs that limit dialysis treatment are a form of prohibited disability discrimination under section 1557 due to the fact that dialysis services are a near perfect proxy for end-stage renal disease, according to the commenter.

Response: Proxy discrimination occurs when a policy or practice treats individuals differently on the basis of seemingly neutral criteria that are so closely associated with the disfavored group that discrimination on the basis of such criteria is, constructively, facial discrimination against the disfavored group.[196] Proxy discrimination is one of many basic civil rights theories available to OCR when investigating complaints under section 1557 and which courts have applied in cases alleging discrimination under section 1557.[197] Due to the fact-intensive nature of the analysis necessary, including determinations of whether a particular benefit design is discriminatory,[198] we decline to expressly include this theory of discrimination in the rule text. As we have noted above, all claims under this section will be evaluated on a case-by-case basis.

Comment: Some commenters noted that health insurance coverage and other health-related coverage may employ coverage limitations that are facially neutral and apply to all enrollees but have a disparate impact on a basis protected under section 1557. Specifically, commenters observed that these limitations and exclusions can have a particular discriminatory effect on individuals with disabilities who have chronic conditions and significant health needs.

Response: OCR utilizes all applicable causes of action when investigating potential discrimination under section 1557 consistent with relevant case law. For further discussion related to OCR's enforcement procedures, see § 92.301.

[192] 45 CFR 91.12(b) (Defining ''Statutory objective'' to mean ''any purpose of a program or activity expressly stated in any Federal statute, State statute, or local statute or ordinance adopted by an elected, general purpose legislative body.'').

[193] *See* 42 U.S.C. 6103(b); 45 CFR 91.12 through 91.14 and 91.17.

[194] *See, e.g.,* 42 U.S.C. 300gg; 45 CFR 147.102 (permitting premium rates charged by a health insurance issuer for health coverage offered in the individual or small group market to vary with respect to the particular plan of coverage by age, among other factors).

[195] *See, e.g.,* Patient Protection and Affordable Care Act; HHS Notice of Benefit & Payment Parameters for 2023, 87 FR 27208, 27301–02 (May 6, 2022) (providing examples of presumptively discriminatory benefit designs under CMS' EHB nondiscrimination regulations applicable to non-grandfathered health insurance coverage in the individual and small group markets that include limitations on hearing aid coverage based on age, autism spectrum disorder coverage limitations based on age, and age limits for infertility treatment coverage when treatment is clinically effective for the age group). These regulations are enforced by CMS and are distinct from section 1557 and other civil rights laws enforced by OCR.

[196] *Schmitt* v. *Kaiser Found. Health Plan of Wash.,* 965 F.3d 945, 958 (9th Cir. 2020) (citing *Davis* v. *Guam,* 932 F.3rd 822, 837 (9th Cir. 2019)).

[197] *See, e.g., Schmitt* v. *Kaiser Found. Health Plan of Wash.* No. 2:17–cv–01611–RSL, 2018 WL 4385858 (W.D. Wash. Sept. 14, 2018), *aff'd in part, rev'd in part and remanded,* 965 F.3d 945 (9th Cir. 2020); *E.S.* v. *Regence BlueShield,* No. 2:17–CV–01609–RAJ, 2022 WL 279028, at *1 (W.D. Wash. Jan. 31, 2022).

[198] *See, e.g., Schmitt* v. *Kaiser Found. Health Plan of Wash.,* No. 2:17–cv–01611–RSL, 2018 WL 4385858 (W.D. Wash. Sept. 14, 2018), *aff'd in part, rev'd in part and remanded,* 965 F.3d 945 (9th Cir. 2020); *E.S.* v. *Regence BlueShield,* No. 2:17–CV–01609–RAJ, 2022 WL 279028, at *1 (W.D. Wash. Jan. 31, 2022).

Comment: Commenters requested that the final rule make clear the language in § 92.207(b), which addresses sex-related health services, includes the full spectrum of reproductive health services and treatments and medications for people with disabilities that may prevent, complicate, or end fertility or pregnancies.

Response: OCR appreciates the unique challenges faced by people with disabilities seeking reproductive health care. Section 1557 prohibits discrimination on prohibited bases regardless of the type of care an individual is seeking or receive. Therefore, we do not believe it is necessary to provide specific provisions related to each form of care an individual may seek.

Comment: Commenters requested that the final rule expressly state that infertility diagnoses, treatment, and services, including assisted reproductive technology, if offered, must be covered without regard to sexual orientation, gender identity, sex characteristics (including intersex traits), or any other protected basis. Commenters raised several examples of benefit design or coverage related to assisted reproductive technology that they stated should be prohibited as discriminatory against individuals based on their relationship status and sexual orientation. As examples, commenters cited requiring enrollees to use their spouse's sperm to fertilize their eggs for in vitro fertilization and requiring that single enrollees or those in non-heterosexual relationships pay out of pocket for a predetermined number of failed intrauterine insemination cycles before providing coverage when heterosexual couples do not have to meet the same standard. Commenters stated that issuers justify these types of benefit design features on outdated definitions of infertility. A commenter argued that in vitro fertilization coverage should include screening for genetic abnormalities that are unique to enrollees' lineage as a matter of reproductive justice and religious freedom.

Response: OCR agrees that to the extent plans cover infertility diagnosis, treatment, and services, including assisted reproductive technology, they must do so on a nondiscriminatory basis, including for same-sex couples. Due to the fact-intensive nature of the analysis necessary, determinations of whether a particular benefit design is discriminatory under this section will be evaluated on a case-by-case basis.

Comment: Commenters recommended that OCR add a new paragraph to § 92.207(b) affirming that denying or limiting coverage of, or coverage of a claim for, health services because they may prevent, cause complications to, or end fertility or pregnancies is prohibited. Commenters asserted this language would address discrimination by a State program that otherwise provides coverage of contraceptives but excludes a specific contraceptive because of a medically inaccurate assertion that the contraception causes an abortion, or a provider network that only includes facilities that refuse to provide certain types of contraception. Commenters emphasized that individuals are currently being improperly denied access to medications or treatments for care unrelated to abortion because the medicine is also used for abortion care.

Response: Denying access to specific medication or health services that may potentially be used for medication abortion purposes but are prescribed for reasons unrelated to abortion care may constitute discrimination under section 1557.[199] OCR finds it unnecessary to add any additional regulatory language to prohibit such discrimination on the basis of disability and sex. As noted above, simultaneous discrimination on multiple prohibited bases is important to account for and is prohibited by section 1557.

Comment: A commenter asked OCR to provide confirmation that while nothing in the regulation would require a covered entity to cover abortions, to the extent plans do cover abortions, they must do so on a nondiscriminatory basis.

Response: As the commenter stated, nothing in this rule requires the provision of any particular medical care, including abortion. To the extent plans offer coverage for termination of pregnancies and related services, they must do so on a nondiscriminatory basis.

Comment: Commenters recommended that OCR revise the regulatory text of proposed § 92.207(b)(4) and (5) to address sex discrimination related to pregnancy or related conditions by adding discrimination related to abortion, fertility care, and contraception. Some commenters requested that OCR specifically add ''termination of pregnancy, contraception, fertility care, miscarriage management, pregnancy loss, maternity care, other reproductive and sexual health services, or any health services'' to the prohibitions on exclusions, limitations, and cost sharing related to gender transition or other gender-affirming care in § 92.207(b)(4) and (5).

Response: OCR declines this suggestion. Section 92.207(b)(4) and (5) are not intended to list all types of potentially prohibited exclusions. The general prohibition on discriminatory limitations under § 92.207(b)(1) would apply to any exclusion or limitation related to all types of care that resulted in discrimination on the basis of sex.

Comment: Some commenters stated that they oppose § 92.207 to the extent it violates religious freedom and conscience protections. Other commenters stated that they opposed § 92.207 because it prevents plans from excluding coverage of all gender affirming care.

Response: Section 92.207 does not violate such protections because providers may rely on the protections of Federal religious freedom and conscience laws or choose to seek assurance of those protections from OCR under this final rule. With respect to concerns about potential conflicts between provisions of the final rule and individuals' or organizations' conscience or religious freedom, please refer to the preamble discussion of § 92.302. Additionally, we are revising § 92.207(c) to specify that nothing in this section precludes a covered entity from availing itself of protections described in § 92.3 and § 92.302. This modification is consistent with the revised language in § 92.206(c). As noted elsewhere in this preamble, and in § 92.3(c), insofar as the application of any rule requirement would violate applicable Federal protections for religious freedom and conscience, such application shall not be required.

Comment: Many commenters expressed strong support for the provisions in § 92.207(b)(3) through (5), citing the extensive discrimination faced by transgender people in the health insurance coverage and other health-related coverage context. Several legal service providers described their experiences assisting clients facing various types of discrimination in their health plans, even where State law or the plan terms provided some protection for gender-affirming care. Some commenters noted these provisions also addressed forms of discrimination commonly faced by intersex people. Commenters noted that the physical, mental health, and financial costs of such discrimination could be high, with individuals forgoing necessary care, facing extreme financial

[199] *See* U.S. Dep't of Health & Hum. Servs., *Guidance to the Nation's Retail Pharmacies: Obligations Under Federal Civil Rights Laws to Ensure Nondiscriminatory Access to Health Care at Pharmacies* (Sept. 29, 2023), *https://www.hhs.gov/civil-rights/for-individuals/special-topics/reproductive-healthcare/pharmacies-guidance/index.html.*

burdens, and experiencing distress when denied access to necessary medical care.

Both supporters and opponents of the Proposed Rule raised many of the same issues discussed in § 92.206(b)(4) (prohibiting categorical coverage exclusions on gender transition or other gender-affirming care) and (c) (discussing legitimate, nondiscriminatory reasons for denying or limiting care) above. As with § 92.206, some commenters asked OCR to define gender-affirming care or provide more detail about what types of care must be covered.

Response: OCR agrees that transgender and intersex people have long faced discrimination in the health insurance coverage and other health-related coverage context. Many of OCR's responses to the comments in § 92.206(b)(4) (prohibiting categorical coverage exclusions on gender transition or other gender-affirming care) and (c) (discussing legitimate, nondiscriminatory reasons for denying or limiting care) above are applicable to the comments in this section as well. For example, for the reasons we discussed above, we will not provide a definition of ''gender-affirming care'' in the regulation text.

Comment: Commenters noted that even plans without categorical exclusions will exclude certain types of gender-affirming care as ''cosmetic.'' Commenters noted that categorizing procedures as cosmetic when needed for gender-affirming care is contrary to established standards of care for the treatment of gender dysphoria and urged OCR to explicitly prohibit such procedure-specific exclusions. Some commenters further noted that plans will often consider these procedures on a case-by-case basis when not related to gender transition but will not do so when the care is related to gender transition.

Many commenters recommended deleting the word ''all'' from § 92.207(b)(4) to make clear that the exclusion of *any* gender-affirming care from coverage is prohibited. Some commenters stated that this change would be more consistent with § 92.207(b)(5), which more generally prohibits discriminatory limits on gender-affirming care coverage.

Response: OCR appreciates commenters' feedback and concern about forms of discrimination beyond broad categorical coverage exclusions. While we understand that some gender-affirming care exclusions are limited to the specific type of care at issue, we decline to revise the language of § 92.207(b)(4). Section 92.207(b)(5)'s general prohibition on limitations or restrictions on coverage for gender transition or other gender-affirming care reaches the narrower exclusions or restrictions on gender-affirming care.

We also decline to state that any denial of gender-affirming care will necessarily be discriminatory regardless of context or rationale. We will instead consider claims of discrimination raising non-categorical denials on a case-by-case basis. Where OCR receives complaints about such exclusions or restrictions, we will investigate on a case-by-case basis whether they constitute prohibited discrimination under § 92.207(b)(5) or any other applicable provision of the rule. Since section 1557 only prohibits discrimination and does not prescribe any specific standard of care, such denials will violate the final rule only where they entail discrimination on the basis of sex. As stated throughout this section, covered entities will have the opportunity to provide a legitimate, nondiscriminatory reason for such exclusions or restrictions.

Comment: Some commenters proposed striking the phrase ''if such denial, limitation, or restriction results in discrimination on the basis of sex'' from § 92.207(b)(5), stating that the elimination would make this provision clearer. Commenters viewed this phrase as confusing and redundant, as they stated that limiting or restricting coverage for services related to gender-affirming care is necessarily discriminatory. Another commenter noted the intersectionality of discrimination and stated that this language may be limiting.

Response: For the reasons discussed above, we disagree that any restriction impacting gender-affirming care will necessarily constitute prohibited discrimination. For example, if an insurance plan places restrictions on coverage for gender-affirming surgeries that are no more stringent than the restrictions placed on any other type of surgical care, those restrictions will not violate the rule. As such, we decline to make the deletion proposed by these commenters.

OCR agrees that the rule prohibits discrimination in the provision or coverage of gender-affirming care whether it is on the basis of sex or on the basis of race, color, national origin, age, or disability. That said, allegations about such discrimination are best brought under § 92.207(b)(1), as § 92.207(b)(5) is aimed at the types of denials or limitations on coverage that are based on a person's gender identity and are thus a form of sex discrimination.

Comment: Commenters noted that even plans without categorical exclusions of gender-affirming care may adopt barriers to accessing such care, such as more stringent pre-approval processes. The commenters noted that these requirements could result in transgender people ultimately not receiving necessary care or having to invest significant time and resources to navigate the barriers. Some commenters additionally noted the high mental health toll on individuals facing discriminatory limitations on medically necessary care.

Response: OCR appreciates the commenter's feedback and concern about the forms of discrimination transgender people encounter in seeking coverage for gender-affirming care but declines to revise § 92.207(b)(3) as suggested. Section 92.207(b)(5) prohibits limitations or restrictions on coverage for gender transition or other gender-affirming care.

Comment: Many commenters supported the provisions limiting issuers' ability to deny care based on a person's sex assigned at birth, gender identity, or gender otherwise recorded, noting that transgender, nonbinary, and intersex people can all face such discriminatory denials. Other commenters objected to these provisions, expressing concern that this would compel issuers to pay for care that was not medically necessary or appropriate for a given individual.

Response: Section 92.207(c) makes clear that a nondiscriminatory determination that care is not medically necessary based on a patient's anatomy or medical need is permissible. For example, this final rule would not prohibit a covered entity from denying coverage for preventive health services for a transgender patient where such care is not medically necessary, such as a prostate exam for a transgender man who does not anatomically have a prostate. In contrast, the rule may prohibit a covered entity from denying coverage for medically necessary preventive care for a transgender patient.

Comment: One provider group urged OCR to work with the Office of the National Coordinator for Health Information Technology (ONC) and electronic health record vendors to ensure that there are options for separately identifying a patient's gender identity and anatomy to reduce the risk of improper denials.

Response: OCR appreciates the suggestion that discriminatory denials could be reduced if the records systems used by providers, issuers, and other covered entities provide better options

for recording gender identity and sex characteristics. While minimum standards for record systems are not within the scope of the rule, we are committed to working with ONC and other relevant stakeholders to explore solutions to this issue.

Comment: Commenters noted that transgender people often have difficulty getting their health coverage to update their records to reflect their correct name and gender. Commenters noted that gender marker mismatches in health insurance records can result in denial of coverage for clinically appropriate care, and one commenter urged OCR to make clear that claims processing procedures that automatically deny coverage for care based on a perceived mismatch of sex or gender is a form of impermissible sex discrimination.

Response: OCR appreciates commenters' concerns about coverage denials due to a sex mismatch in claims processing procedures, which can result in transgender patients being denied coverage for a medically necessary and clinically appropriate services. However, we decline to categorically state that sex mismatch denials are always discriminatory. Instead, OCR will consider and investigate complaints raising this issue on a case-by-case basis under § 92.207(b)(3). While we refrain from categorically stating that initial sex mismatch or coding denials are prohibited under this rule, we caution that denials resulting in an undue delay or denial of services, such as repeated denials, could result in a finding of prohibited discrimination. For more information on OCR's view of this issue, please see the 2016 Rule preamble's discussion on computer systems with gender coding resulting in gender mismatches at 81 FR 31436.

Comment: With respect to cases where coverage for comparable treatments is relevant to the discrimination analysis, some commenters urged OCR to clarify that the question of what is comparable can be construed broadly, rather than parsing minor differences in broadly similar types of care.

Response: OCR declines to identify a bright line of how similar care must be to be considered comparable when such considerations are relevant to a discrimination claim, as there are many factors that may be relevant to this analysis, and our approach is case by case.

Comment: Commenters who addressed the integration requirement in § 92.207(b)(6) overwhelmingly supported the newly proposed provision, which clarifies the prohibition on having or implementing benefit designs that do not provide or administer health insurance coverage or other health-related coverage in the most integrated setting appropriate to the needs of qualified individuals with disabilities. Several noted the particular importance of this provision and access to community integration in light of the COVID–19 pandemic and the higher infection risks associated with congregate settings. A few commenters noted the role that discrimination on multiple bases may play with regard to community integration, highlighting the overrepresentation of people of color in institutional settings, and the relationship between access to effective communication and community integration. Numerous comments included examples of current practices that may violate the integration provision.

Commenters agreed that this provision should apply to both benefit design and implementation of a benefit design, including: coverage, exclusions, and limitations of benefits; prescription drug formularies; cost sharing (including copays, coinsurance, and deductibles); utilization management practices; medical management standards (including medical necessity standards); provider network design; provider reimbursement; standards for provider admission to participate in a network; benefits and service administration contracted to third parties, such as pharmacy benefit managers; and quality measurement and incentive systems. Many commenters requested that OCR clarify that the convenience or potential cost-saving of administering treatments in institutional settings are not legitimate, nondiscriminatory reasons for not providing comparable benefits in less restrictive settings.

Commenters suggested that providing coverage to qualified individuals with disabilities in the most integrated setting appropriate should not be done in a way that unnecessarily increases costs for all enrollees or compromises individual health benefits.

Response: We appreciate support for the inclusion of this provision. OCR recognizes the importance of providing and administering health coverage in the most integrated setting appropriate to the needs of qualified individuals with disabilities; we also recognize that discrimination on multiple bases heightens barriers and are committed to addressing allegations of discrimination on all bases protected under section 1557. As discussed in the Proposed Rule, 87 FR 47873, this provision encompasses both the benefit design of the benefit being offered by a covered entity as well as the indirect mechanisms that affect the implementation of the benefit design within a covered entity's control, such as utilization management practices, provider reimbursement, contracting out to third-party contractors such as pharmacy benefit managers, and quality measurement and incentive systems. OCR is not prescriptive in the list of potential mechanisms that could result in prohibited discrimination through implementation of a benefit design because it is a case-by-case analysis depending on the facts of each situation.

With respect to concerns about unnecessarily increasing costs to comply with this provision, OCR notes that institutional care is generally more expensive than community-based care and that increased cost alone is not necessarily a fundamental alteration.[200] However, concerns related to cost can be raised through a fundamental alterations defense.[201]

Comment: Nearly all commenters who addressed this provision agreed with the 2022 NPRM preamble language stating that requiring prior authorization, step therapy, or other utilization management when individuals access treatment in the community but not in an institution, would constitute discrimination if the discrepancy results in unnecessary segregation or a serious risk of unnecessary segregation. Commenters noted that these practices place additional terms and conditions on the receipt of certain benefits in integrated settings that are not in place within segregated or institutional settings, and that they can often delay care and cause unnecessary institutionalization. For example, commenters asserted that people with physical and sensory disabilities, complex medical needs, and people with psychiatric and mental disabilities are often required to try less expensive and often unsuccessful medication (*i.e.,* step therapy) before being able to access effective treatments in the community. If utilization management techniques are only required for community-based treatment and not for institutional care, commenters argued this may push individuals urgently in need of care into institutional setting so they can access treatment more quickly. In contrast, one commenter suggested that it may be clinically appropriate to distinguish between institutional settings and home and community-based settings (HCBS) through the use of medical management

[200] *Fisher* v. *Okla. Health Care Auth.,* 335 F.3d 1175, 1183 (10th Cir. 2003).

[201] *Id.* at 1182.

tools like prior authorization and step therapy due to closer monitoring by medical professionals in institutional settings.

Response: OCR shares commenters' concerns about the potential discrimination associated with the serious risk of institutionalization. The integration mandates of the ADA and section 504 apply to people with disabilities who are at serious risk of segregation or institutionalization, not only to people with disabilities who are currently in institutions.[202] For example, an individual could show sufficient risk of institutionalization such that it would constitute a violation of this provision if a covered entity's failure to provide community services or its cut to such services will likely cause a decline in health, safety, or welfare that result in the serious risk of institutionalization or segregation.

As articulated in the Proposed Rule, 87 FR 47873, step therapy and other utilization management practices that impose different standards on members or beneficiaries in the community than in institutional settings are discriminatory if the discrepancy results in unnecessary segregation or a serious risk of unnecessary segregation. Section 1557's incorporation of section 504's integration provision through § 92.101(b)(1) makes clear that serious risk of institutionalization is covered under section 1557 as well, given that the vast majority of courts have found section 504 and title II of the ADA prohibits actions, omissions, policies, and practices that place individuals at serious risk of unjustified isolation. Indeed, nearly every court of appeals to address the issue has held that the integration mandate of the ADA and section 504 apply not only to people with disabilities who are currently in institutions, but also to people with disabilities who are at serious risk of segregation or institutionalization.[203] As noted in *Fisher* v. *Oklahoma,* the integration mandate's ''protections would be meaningless if plaintiffs were required to segregate themselves by entering an institution before they could challenge an allegedly discriminatory law or policy that threatens to force into segregated isolation.'' [204] Likewise, section 1557's integration mandate would ring hollow if individuals were required to show that they have already had to submit to institutionalization in order to assert their right to receive services in the most integrated setting appropriate to their needs.

Further, even if a serious risk of unnecessary institutionalization was not an actionable claim in and of itself, it would still be appropriate for courts to grant relief to those at serious risk in order to prevent the unnecessary institutionalization prohibited by law.[205] For these reasons, the rule's integration provision explicitly prohibits benefit design that results in a serious risk of institutionalization.

Plans continue to be able to limit services, use utilization review standards, and employ other limitations to manage costs as long as they are not discriminatory in doing so.

OCR has revised the regulation text to clarify that the integration requirement under section 1557 extends to practices that result in the serious risk of institutionalization or segregation. We recognize that the question of what constitutes ''serious risk'' is a fact-based inquiry, which is why the Federal courts to have considered the question have provided only general guidance on determining risk rather than an exhaustive test.[206]

Comment: Several commenters strongly disagreed with the 2022 NPRM preamble language that stated that a State Medicaid program would generally not be required to provide a new benefit because that would fundamentally alter the nature of the program. Commenters noted that a State Medicaid program or other covered entity may have to expand its HCBS waiver programs or modify eligibility for particular services where necessary to satisfy the integration provision, and that there are many situations in which a State program has been required to create a ''new'' community-based benefit, where that benefit was previously only available in institutional settings. For example, commenters stated that a covered entity that provides for residential treatment for certain substance use disorder conditions and does not provide coverage of such services in appropriate community-based settings may need to create a ''new benefit'' by offering an existing institutional benefit in the community.

Response: After considering these comments, we clarify here that while a State Medicaid program is not required to create ''new'' programs to assist people with disabilities, nor are states required to provide a particular standard of care or level of benefits, covered entities must nevertheless adhere to section 1557's disability nondiscrimination requirements—including the integration requirement—with regard to the services they in fact provide. When a covered entity chooses to provide a service, it must do so in a nondiscriminatory fashion by ensuring access to that service in the most integrated setting appropriate to the needs of the qualified individual.[207] States may be required to offer services in an integrated setting that they have only been offering in segregated settings; that is not offering a ''new service,'' but instead is ensuring the service is offered in integrated settings and not just in segregated settings.[208]

[202] *See, e.g., Waskul* v. *Washtenaw Cnty. Cmty. Mental Health,* 979 F.3d 426, 460–62, (6th Cir. 2020) (''Plaintiffs may thus state a claim by sufficiently alleging that they are at serious risk of institutionalization''); *Steimel* v. *Wernert,* 823 F.3d 902, 911–12 (7th Cir. 2016) (agreeing that the mandate applies to ''persons at serious risk of institutionalization or segregation''); *Davis* v. *Shah,* 821 F.3d 231, 262–64 (2d Cir. 2016) (''We thus hold that a plaintiff may state a valid claim . . . by demonstrating that the defendant's actions pose a serious risk of institutionalization for disabled persons.''); *Pashby* v. *Delia,* 709 F.3d 307, 322 (4th Cir. 2013) (individuals state claims under the ADA and the Rehabilitation Act when ''they face a risk of institutionalization''); *M.R.* v. *Dreyfus,* 663 F.3d 1100, 1117–18 (9th Cir. 2011), *amended by* 697 F.3d 706 (9th Cir. 2012) (plaintiff must ''show that the challenged state action creates a serious risk of institutionalization''); *Fisher* v. *Okla. Health Care Auth.,* 335 F.3d 1175, 1181–82 (10th Cir. 2003) (plaintiffs who ''stand imperiled with segregation'' because of state action may state a claim under the ADA's integration mandate); *but see U.S.* v. *Miss.,* No. 21–60772, 2023 WL 6138536, at *5–*9 (5th Cir. Sep. 20, 2023) (rejecting the United States' at-risk *Olmstead* claim).

[203] *See supra* footnote 202 (citing cases).

[204] 335 F.3d 1175, 1181 (10th Cir. 2003).

[205] *See, e.g., U.S.* v. *W.T. Grant Co.,* 345 U.S. 629, 633 (1953) (explaining that ''[t]he purpose of an injunction is to prevent future violations'' and that such relief is appropriate where there is a ''cognizable danger of recurrent violation.'').

[206] For example, in *Davis* v. *Shah,* 821 F.3d 231, 262–63 (2d Cir. 2016), the court quoted DOJ, noting that ''a plaintiff 'need not wait until the harm of institutionalization or segregation occurs or is imminent' '' to bring a claim under the ADA. A plaintiff establishes a ''sufficient risk of institutionalization to make out an *Olmstead* violation if a public entity's failure to provide community services . . . will likely cause a decline in health, safety, or welfare that would lead to the individual's eventual placement in an institution.'' *See also Waskul* v. *Washtenaw Cnty. Cmty. Mental Health,* 979 F.3d 426, 462 (6th Cir. 2020) (finding ''declines in health, safety, or welfare'' as to sufficient to show plaintiffs were at serious risk of institutionalization).

[207] *See Olmstead,* 527 U.S. 581, 603 (1999); *see also Radaszewski* v. *Maram,* 383 F.3d 599, 609 (7th Cir. 2004) (citing *Olmstead,* 527 U.S. at 603 n. 14, for the principle ''that States must adhere to the ADA's nondiscrimination requirement with regard to the services they in fact provide'') (''While 'a State is not obligated to create new services,' it 'may violate Title II when it refuses to provide an existing benefit to a disabled person that would enable that individual to live in a more community-integrated setting.'''').

[208] *See* U.S. Dep't of Justice, Civil Rts. Div., *Statement of the Dep't of Justice on Enforcement of the Integration Mandate of Title II of the Americans with Disabilities Act and Olmstead* v. *L.C.,* Question 8 (February 28, 2020), *https://www.ada.gov/olmstead/q&a_olmstead.htm* (stating that ''(p)ublic entities cannot avoid their obligations under the ADA and Olmstead by characterizing as a ''new

Continued

OCR clarifies that a program providing community-based services that are already available in institutional settings is not a new program for purposes of evaluating a fundamental alteration defense.[209] In addition, states may be required to offer services in an integrated setting that have only been offered in a segregated setting. Providing services beyond what a State currently covers under its Medicaid program may not be a fundamental alteration under § 92.205 (Requirement to make reasonable modifications), and existing nondiscrimination law, including section 504 and the ADA,[210] may require states to provide those services, under certain circumstances. In addition, to the extent that a benefit, including an optional benefit, is already provided in institutions as part of the State's program, the same or a substantially similar benefit must be offered in the community in a manner that does not incentivize institutional services over community services.

Comment: OCR received many comments in response to our request for comment on the application of the integration provision to State Medicaid programs. A number of comments related to Medicaid program designs required by title XIX of the Social Security Act. One commenter recommended that any action by a State Medicaid authority to reduce the existing scope of Medicaid-funded home and community-based long term services and supports, or to more strictly limit eligibility for them, that would have the effect of forcing people with disabilities who currently do, or could, live in their own homes and participate in unrestricted community activities into segregated, congregate, and/or institutional residential or day settings, or to cease their current level of community participation, on the basis of any general categorization of disability would be discriminatory under this provision.

Response: We appreciate the many comments highlighting potential issues related to community integration and State Medicaid programs. This rule does not impact the ability of states to target benefits under section 1915(c), section 1915(i), or section 1937 of the Social Security Act, consistent with Medicaid law. At the same time, the fact that a State chooses to use a Medicaid authority to target a particular disability population does not relieve a State of its obligations towards other populations. We will continue to work with our partners in CMS to ensure the robust provision of services in a nondiscriminatory manner to the maximum extent possible. We remind covered entities that obligations under the Medicaid statute are distinct from obligations under section 1557, and compliance with Medicaid requirements does not per se constitute compliance with section 1557.

Comment: A significant number of commenters raised concerns with ''use-in-the-home'' policies, where an insurance issuer will cover the provision of a benefit or service solely for use ''in the home.'' For example, commenters discussed that a covered entity might offer supplemental oxygen equipment for use in the home but decline to provide sufficient oxygen or equipment for an individual to access the broader community. Similarly, commenters noted that issuers might decline to cover medically necessary wheelchairs with functions that an individual needs to access the broader community outside their home. Commenters also provided examples of other kinds of medical diagnostic equipment, durable medical equipment, and home-use devices that are often not covered, but which would replace services provided in an institution and enable individuals to receive care in their home and community.

Commenters expressed concern that many State Medicaid programs, delegated managed care companies, and employer-sponsored private health plans have adopted the Medicare Mobility Assistive Equipment Coverage Policy [211] (a policy designed specifically to apply in the context of Medicare Part B) as their policy, despite what commenters see as the statutory differences between Medicare Part B and other authorities. Commenters contended that the unnecessary and unmandated adoption of such a policy in all programs unnecessarily restricts benefits to a low bar, denying people the ability to live in the most integrated setting possible.

Response: We appreciate the concerns raised by commenters. Each covered entity should review any legal authority governing the coverage they may provide to ensure that they are not interpreting it in a manner that results in discrimination. For example, Medicaid programs that impose homebound or ''in-the-home'' criteria that are not statutorily required under Federal law may be unnecessarily restricting services in the community in violation of civil rights laws. Where an in-the-home restriction is included in a statute, covered entities may not automatically deny coverage for any good or service that may also have use outside of the home, but must assess each claim to determine whether the denial will violate the most integrated setting requirement.

Comment: Many commenters expressed the need for § 92.207(b)(6), due to states increasingly turning to managed care plans to deliver Medicaid benefits. These commenters expressed concern that large issuers that administer a range of private employer plans and individual plans, as well as public Medicare and Medicaid plans, could employ uniform coverage policies across their plans that do not adequately support community integration. Commenters additionally noted that that Medicaid agencies should monitor whether Medicaid Managed Care Organizations (MCOs) are appropriately authorizing services in the community and that under current law states contracting with MCOs cannot escape liability when MCOs discriminate against people with disabilities.

Response: We appreciate the concerns raised by commenters. We recognize the increasing reliance on alternative payment models for the delivery or management of services to individuals with disabilities. The shift towards managed care in State Medicaid programs and other changes, such as quality incentives, quality assurance activities, and risk-sharing arrangements, requires addressing unnecessary segregation in these emerging models in this rule.

As we noted in the Proposed Rule, 87 FR 47873, covered entities designing contracts with MCOs, pharmacy benefit managers, or other third-party entities taking on financial risk for the delivery of health services should carefully scrutinize their capitation,

service'' services that they currently offer only in institutional settings.''); *see also Townsend* v. *Quasim,* 328 F.3d 511, 517 (9th Cir. 2003) (''Here, the precise issue is not whether the state must provide the long term care services sought by Mr. Townsend and the class members—the state is already providing these services—but in what location these services will be provided.'').

[209] *See Townsend,* 328 F.3d at 517 (''[c]haracterizing community-based provision of services as a new program of services not currently provided by the state fails to account for the fact that the state is already providing those very same services. If services were to constitute distinct programs based solely on the location in which they were provided, *Olmstead* and the integration regulation would be effectively gutted.'').

[210] While this final rule periodically references the ADA and section 504, the requirements under this rule are under section 1557, a separate legal authority. Accordingly, the integration requirements, like other requirements under this section 1557 rule, do not limit or impact the interpretation of integration requirements under the ADA and section 504.

[211] U.S. Dep't of Health & Hum. Servs., Ctrs. for Medicare & Medicaid Servs., *National Coverage Determination, Mobility Assistive Equipment (MAE)* (2005), *https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?NCDId=219.*

reimbursement, quality measurement, and incentive structures to ensure that they do not result in the unjustified segregation of individuals with disabilities or place individuals with disabilities at serious risk of institutionalization or segregation. When responsibility for services is shared across multiple entities, for example, under a managed care contract, both the State Medicaid agency and the contracted entity have obligations under this provision if they are both recipients of Federal financial assistance.

Comment: Many commenters discussed challenges related to mental health services, noting that the lack of available and funded community alternatives to institutional mental health care will continue to result in the institutionalization of individuals with serious mental illness, whether in hospitals, inpatient psychiatric facilities, prisons, or other secure facilities.

Many commenters voiced concern related to discharge planning, as people requiring intensive mental health services are often referred only to institutional or otherwise congregate care options, rather than comparably intensive services in community-based settings. Commenters recommended that OCR clarify that this can constitute a violation of the integration provision if it forces people with psychiatric disabilities to enter segregated settings in order to receive access to adequate services.

Other commenters discussed the disparity in access to community-based care for children who need mental health care.

Response: OCR appreciates the significant concerns related to the availability of community-based behavioral health services, particularly services to address youth mental health. With respect to discharge planning, a hospital or acute care provider that routinely discharges individuals with disabilities, including those with serious mental illness, to nursing homes, psychiatric residential treatment facilities, or other segregated care settings due to discharge planning procedures that do not assess for home-based support services or refer individuals to community-based providers may violate this provision. Covered entities are prohibited from implementing planning, service system design, and service implementation practices that result in the serious risk of institutionalization or segregation.

Comment: Several commenters provided insight into the relationship between community integration and reimbursement rates necessary to sustain a direct care workforce. Commenters explained that individuals receiving care in the community often fail to receive all of the hours of care for which they are approved due to a lack of provider capacity to fully staff the approved hours. Commenters noted that nurse's aides and other individuals who provide assistance in institutional settings are often paid at a higher rate than home health aides and other direct care professionals, resulting in an imbalanced direct care workforce. Commenters emphasized the importance of rate setting to incentivize HCBS.

Response: Reimbursement rates and network adequacy both constitute methods of program administration. As such, these are factors that OCR would consider as reimbursement practices or methods of administration related to this provision.

Comment: Commenters suggested additional guidance clarifying implementation of this provision, including incorporating DOJ's guidance on enforcement of the integration requirement under title II of the ADA describing how to provide the most integrated setting appropriate for an individual or group of individuals; [212] addressing the remedies available for violations of the integration provision; and explaining how OCR will undertake a fundamental alteration analysis. One commenter recommended incorporating the fundamental alteration defense into regulatory text. Commenters underscored the importance of setting a high bar for a fundamental alteration, noting that programs must alter an essential aspect of the health program or activity. Other commenters urged OCR to clarify how the fundamental alteration analysis applies to the integration provision, including whether and how OCR will incorporate DOJ guidance and case law related to the ADA's fundamental alteration defense for ADA title II entities. Commenters also requested clarification on whether covered entities will be required to establish an *Olmstead* integration plan [213] to raise the fundamental alteration defense, and if so, guidance related to that requirement.

Commenters also asked OCR to explain in future guidance how covered entities, including Medicaid programs, must coordinate community-based primary care and specialty mental health care and offer case management to avoid discrimination on the basis of disability and to avoid placing individuals with mental disabilities at serious risk of institutionalization.

Commenters further suggested guidance to covered entities explaining the specific HCBS that are essential to achieving compliance with the integration requirement, including as part of EHB. Commenters suggested that it would be discriminatory if EHB plans set higher reimbursement rates for a service or item for individuals in segregated settings rather than community-based settings; if rehabilitation services for physical conditions are covered, but not psychiatric rehabilitation services; and if a particular benefit (such as personal care services) is offered in greater amounts to individuals in segregated settings by virtue of the plan benefit design.

Finally, commenters encouraged OCR to develop joint guidance with DOJ on section 1557, section 504, and titles II, III, and IV of the ADA to ensure the rights of people with disabilities to access community integration in health care settings.

Response: We appreciate the comments requesting clarification through sub-regulatory guidance. We will consider future guidance after this rule has been finalized and are committed to our continued partnership with DOJ in developing shared guidance on civil rights requirements. The availability of the fundamental alteration defense is clear as drafted and so we decline to specifically incorporate this recommendation into regulation text. In this final rule, we clarify that a program is not required to provide coverage for a service in the most integrated setting appropriate to an individual's needs if it would fundamentally alter the program to do so.

Comment: Commenters, primarily representatives of the insurance industry, supported proposed § 92.207(c) that specified nothing in this section requires coverage of any health service where the covered entity has a legitimate, nondiscriminatory reason for determining that such health service fails to meet applicable coverage

[212] U.S. Dep't of Justice, Civil Rts. Div., *Statement of the Dep't of Justice on Enforcement of the Integration Mandate of Title II of the Americans with Disabilities Act and Olmstead* v. *L.C.* (June 22, 2011), *https://www.ada.gov/olmstead/q&a_olmstead.htm.*

[213] Under the ADA, an *Olmstead* plan is a public entity's plan for implementing its obligation to provide individuals with disabilities opportunities to live, work, and be served in integrated settings. U.S. Dep't of Justice, Civil Rts. Div., *Statement of the Dep't of Justice on Enforcement of the Integration Mandate of Title II of the Americans with Disabilities Act and Olmstead* v. *L.C.* (June 22, 2011), *https://www.ada.gov/olmstead/q&a_olmstead.htm.*

requirements, such as medical necessity requirements, in an individual case. Commenters appreciated that OCR acknowledged that a covered entity's legitimate, nondiscriminatory reason for its actions may serve as a defense under this section.

Some commenters requested clarification that use of the phrase ''legitimate, nondiscriminatory reason'' not be construed in any way to limit the method of proof for any section 1557 claim to the *McDonnell Douglas* burden-shifting framework; that this method cannot be used to defend an express sex classification that causes injury; that the familiar but-for causation test applies to establishing a violation of section 1557; and that the *McDonnell Douglas* burden-shifting framework and legitimate nondiscriminatory reason framework apply to circumstantial evidence cases but not where there is direct evidence of discrimination.

Response: OCR appreciates commenters' support of this provision. As discussed throughout this section and in the Proposed Rule, in instances where there is not a facially discriminatory policy and OCR is investigating whether a particular action or practice is discriminatory under this rule, covered entities have the opportunity to defend the challenged action or practice by providing a legitimate, nondiscriminatory reason for its actions that is not pretext for discrimination. OCR will then evaluate whether the reason given by the covered entity is a pretext for prohibited discrimination. When considering whether a proffered reason is pretextual, OCR will consider, among other things, whether a denial of a health service is based on medical necessity standards or other reasonable medical management techniques that are not discriminatory, as discussed in more detail below.

To provide additional clarity about OCR's analysis when evaluating whether a covered entity's legitimate, nondiscriminatory reason is pretextual, OCR is revising § 92.207(c) to state that a covered entity's denial or limitation of a health service must not be based on unlawful animus or bias, or constitute a pretext for discrimination. This modification is consistent with the revised language in § 92.206(c). Under either section, in instances where there is no evidence of a facially discriminatory policy, covered entities may assert a legitimate, nondiscriminatory basis for actions that could otherwise give rise to the inference of discrimination. Consistent with general principles of civil rights law, OCR will consider such asserted bases but may also investigate to determine whether such asserted bases are pretextual and whether there is evidence that the challenged action was taken because of unlawful animus, bias, or other discriminatory factors.

In evaluating claims of discrimination, OCR relies on general nondiscrimination principles and longstanding civil rights case law. Such principles include, but are not limited to, the multi-factor test articulated in *Arlington Heights* and the *McDonnell Douglas* burden-shifting framework, which were discussed in detail in the Proposed Rule at 87 FR 47865. *Arlington Heights* sets forth a method of proof that utilizes different types of evidence that collectively may demonstrate that a covered entity acted, at least in part, because of a protected basis. The *McDonnell Douglas* burden-shifting framework is an inferential method of proof used to show that a covered entity treated similarly situated individuals differently because of a protected basis. Under *McDonnell Douglas,* where non-facial evidence of discrimination exists, a covered entity must articulate a legitimate, nondiscriminatory reason for its actions. The entity's legitimate, nondiscriminatory reason may refute the evidence of discrimination, unless it can be established that this reason is a mere pretext for prohibited discrimination. In response to the commenters' concerns about how § 92.207(c) may be interpreted inconsistently with the principles set forth in *McDonnell Douglas* and other civil rights principles, please see our response to the same comments under § 92.206 in which we affirm commenters' interpretations are correct—*McDonnell Douglas'* burden-shifting framework and legitimate nondiscriminatory reason framework apply to circumstantial evidence cases but not in cases where there is direct evidence of discrimination based on a facially discriminatory policy.

Comment: Some commenters appreciated OCR clarifying that medical management techniques based on clinical evidence are permitted, including the use of reasonable medical necessity and utilization management techniques based on clinical standards and evidence-based guidelines, when applied in a neutral manner. Commenters noted that medical management tools provide an important role in promoting quality care and reducing health care costs.

Other commenters raised concerns about medical necessity criteria and other medical management tools, noting that such tools may limit access to needed services and treatment. Commenters noted that discriminatory decisions often occur under the guise of medical necessity determinations. Some commenters argued that medical management practices such as prior authorization, step therapy, and durational or quantity limits are inherently discriminatory and inconsistent with patient health and safety. Many commenters strongly supported OCR clarifying that excessive use or administration of benefit utilization management tools that target particular disabilities could violate section 1557. Commenters asked OCR to expressly note the limitation on the use of utilization management tools in the text of the regulation.

Commenters asked OCR for examples of excessive medical management and suggested the following examples: requiring step therapy for new enrollees who are already on a working course of treatment; transferring management of particular medicines to niche vendors that apply more extensive medical management through specialty carve-out programs; requiring the use of off-label medications within step therapy; and imposing categorical prior authorization and step therapy requirements on most or all drugs required to treat a particular disease. Commenters noted that issuers apply such medical management techniques to discourage individuals with high-cost needs from enrolling in their plans. A commenter cited evidence that plans have restricted access to lower-cost brand drugs and generics when demand for those drugs attracts patients who have overall high health costs.[214] Other commenters noted that information about treatment limitations can be difficult to find for enrollees and cited evidence of issuers building arbitrary coverage denials into their business plans.[215] Commenters cited a study that found that more than half of step therapy policies developed by commercial health plans were more

[214] Michael Geruso et al., *Screening in Contract Design: Evidence from the ACA Health Insurance Exchanges,* 11 a.m. Econ. J.: Econ. Pol. 2, 64–107 (2019), *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8130799/.*

[215] Karen Pollitz et al., *Claims Denials and Appeals in ACA Marketplace Plans in 2021,* Kaiser Family Found. (2022), *https://www.kff.org/private-insurance/issue-brief/claims-denials-and-appeals-in-aca-marketplace-plans/* (finding nearly 17 percent of in-network claims in non-group qualified health plans were denied in 2021; insurer denial rates varied widely around this average, ranging from 2 to 49 percent; about 14 percent were denied because the claim was for an excluded service, 8 percent were due to lack of preauthorization or referral, 2 percent were based on medical necessity, and 77 percent were classified as ''all other reasons'').

restrictive than recommended clinical guidelines.[216]

Some commenters requested that OCR revise the text of § 92.207(c) to state that, in addition to medical necessity requirements, covered entities may employ reasonable medical management techniques.

Response: OCR appreciates the variety of comments and recommendations put forth by commenters related to the rule's coverage of medical management techniques, including medical necessity standards and utilization management techniques.

OCR agrees that revising the regulatory text to reference reasonable medical management techniques would provide clarity and would be consistent with other provisions in the ACA and the Proposed Rule. Therefore, OCR is revising § 92.207(c) to state that applicable coverage requirements include reasonable medical management techniques, including medical necessity.

Further, as stated in the Proposed Rule, covered entities are not prohibited from employing reasonable medical management techniques as long as they are not discriminatory and are not otherwise prohibited under other applicable Federal and State law. 87 FR 47873–74. As just one example, covered entities participating in the Medicaid program under title XIX of the Social Security Act are not prohibited from implementing nondiscriminatory utilization management techniques, such as prior authorization.[217]

Under § 92.207(c), an issuer may assert a legitimate, nondiscriminatory reason for its denial or limitation of coverage of a health service that asserts the denial was based on medical necessity standards—or any other medical management technique. When assessing whether the challenged action was based on prohibited discrimination rather than on nondiscriminatory medical necessity standards, OCR will review a medical necessity determination only to make sure that it is a bona fide medical judgment, not conduct a review of the medical judgment underlying the medical necessity determination, but rather will assess whether the rationale for the denial was based on impermissible discriminatory considerations. In its review, OCR may require a covered entity to provide the following information: its medical necessity standards or guidelines; the clinical, evidence-based criteria or guidelines [218] relied upon to make the medical necessity determination; and the medical substantiation for the medical necessity determination. As discussed previously, OCR will evaluate a covered entity's assertion that its actions were based on legitimate, nondiscriminatory reasons to determine if it is pretextual. Medical necessity determinations that are not based upon general medical judgments or based on clinical, evidence-based criteria or guidelines may be considered evidence of pretext for discrimination.

Similarly, as noted in the Proposed Rule, 87 FR 47872, we affirm that covered entities are not prohibited from using other reasonable medical management techniques, such as utilization management tools, when applied in neutral, nondiscriminatory manner and not otherwise prohibited under other applicable Federal and State law. Utilization management techniques include prior authorization,[219] step therapy (or ''fail-first''),[220] and durational or quantity limits.[221]

OCR shares commenters' concerns about potentially discriminatory practices related to medical management techniques and the negative impacts of excessive utilization management. As such, when relying on medical necessity requirements and other medical management techniques to deny coverage for a health service, covered entities must ensure that such tools are developed and applied in a neutral, nondiscriminatory manner. OCR would have concerns about guidelines that establish more restrictive requirements for certain diseases or conditions without a nondiscriminatory justification. In addition, OCR expects that limitations within such guidelines should be applied consistently with clinical standards within each patient population disease state, condition level, and diagnostic category to ensure equal clinical treatment across protected bases. That is, all patients diagnosed with a particular disease state must receive the same treatment that is deemed clinically appropriate, regardless of their race, color, national origin, sex, age, or disability.

We affirm that excessive use or administration of utilization management practices that target a particular condition that could be considered a disability or other prohibited basis under section 1557 could be discriminatory under this rule. OCR declines to state in preamble or regulatory text that specific practices are per se discriminatory under section 1557. As discussed throughout this section, OCR must conduct a fact-specific inquiry into allegations of discriminatory actions and consider a covered entity's proffered reason for the challenged action.

Comment: OCR received a number of comments discussing costs as a legitimate, nondiscriminatory reason for benefit designs under § 92.207(c). Commenters supported the rule allowing clinical evidence to support a benefit design and requested that OCR allow covered entities to use extraordinary costs as justification for certain benefit designs. Commenters stated that covered entities use utilization management controls, such as drug tiering, as part of their benefit design to keep coverage affordable. Commenters noted concerns that high-cost drugs or other services could lead to health plans becoming insolvent if they are unable to apply utilization management controls where all treatments for a particular condition are high cost, particularly when they are expensive new drugs or gene therapies. Commenters argued that issuers and plans must retain some flexibility in their approach to covering and paying for high-cost drugs and services. Commenters expressed concern that § 92.207 would prohibit covered entities from having utilization management controls on all or most drugs or services

[216] Kelly L. Lenahan et al., *Variation in Use and Content of Prescription Drug Step Therapy Protocols, Within and Across Health Plans,* 40 Health Affairs 11, 1749–57 (2021), *https://www.healthaffairs.org/doi/abs/10.1377/hlthaff.2021.00822?journalCode=hlthaff* (finding that plans applied step therapy in 38.9 percent of drug coverage policies, with varying frequency across plans (20.6–57.5 percent); 34.0 percent were consistent with corresponding clinical guidelines, 55.6 percent were more stringent, and 6.1 percent were less stringent).

[217] *See, e.g.,* 42 U.S.C. 1396r–8(d).

[218] *See also* Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2023, 87 FR 27208, 27296–300 (May 6, 2022) (discussing newly promulgated 45 CFR 156.125(a), which states ''[a] non-discriminatory benefit design that provides [EHB] is one that is clinically-based'').

[219] Medicare defines ''prior authorization'' as ''the process through which a request for provisional affirmation of coverage is submitted to CMS or its contractors for review before the service is provided to the beneficiary and before the claim is submitted for processing.'' 42 CFR 419.81 (Medicare definition of ''prior authorization'' for hospital outpatient department services). *See also* Ctrs. for Medicare & Medicaid Servs., *Prior Authorization Process for Certain Hospital Outpatient Department (OPD) Services Frequently Asked Questions (FAQs),* Q1 (Dec. 27, 2021), *https://www.cms.gov/files/document/opd-frequently-asked-questions.pdf.*

[220] Medicare defines ''step therapy'' for the Medicare Advantage Program as a ''utilization management policy for coverage of drugs that begins medication for a medical condition with the most preferred or cost effective drug therapy and progresses to other drug therapies if medically necessary.'' 42 CFR 422.2.

[221] Durational or quantity limits place limits on the frequency or number of benefits to be provided, such as limiting therapy visits to once per week or limiting prescription drug coverage to a 30-day supply of a medication.

that treat a particular condition or disease, regardless of their cost, and asked OCR to affirm that placing all treatments for a certain disease or condition in one tier may not in fact be discriminatory by default, but rather an appropriate benefit design due to the high cost of those particular items or services.

Conversely, other commenters asked OCR to clarify that covered entities cannot justify benefit designs that disfavor coverage for medically necessary services based on cost savings. Commenters noted that as costs of medications and therapies have increased, covered entities have significantly increased the use of utilization management, including adding arbitrary prior authorization processes not based in clinical evidence for new cancer therapies. They added that rare disease patients face the additional challenge of having no or few treatment alternatives if a preferred medication or therapy is not covered.

Response: OCR reiterates that § 92.207 does not prohibit a covered entity from engaging in reasonable utilization management techniques applied in a neutral, nondiscriminatory manner and that are not otherwise prohibited under other applicable Federal and State law. As noted above, excessive use or administration of utilization management tools that target a particular condition that could be considered a disability or other prohibited basis could violate section 1557. Where there is an alleged discriminatory practice or action that is not based on a facially discriminatory policy, § 92.207(c) provides that the covered entity has the opportunity to provide a legitimate, nondiscriminatory reason for the practice. Covered entities are not restricted in what information they elect to provide to OCR as part of their justification for the challenged practice or action. OCR will carefully review a covered entity's proffered reason to ensure it is not pretext for discrimination.

OCR discussed previously that determinations on whether a particular benefit design feature is discriminatory, such as utilization management or drug tiering, will be made on a case-by-case basis. Accordingly, OCR declines to specify whether certain benefit design practices are per se discriminatory.

Comment: One organization raised concerns that OCR is asserting *de facto* authority over the relationship between health insurance and medical care, and that OCR is asserting that it has authority under section 1557 to regulate the practice of medicine and the structure of health insurance coverage according to its own determination of what is ''appropriate'' and ''nondiscriminatory,'' along with the authority to definitively determine what is, or is not, the current standard of medical care. The commenter further states that OCR may in the future assert and exercise similar claims of authority with respect to other medical practices, standards of care, or health insurance coverages.

Response: As previously discussed throughout this preamble, section 1557 was intended to prohibit discrimination in health insurance coverage and other health-related coverage, as the statute's plaint text makes apparent. Congress expressly granted the Secretary the authority to promulgate regulations to implement section 1557. 42 U.S.C. 18116(c). Therefore, OCR is acting within its statutory authority in promulgating this final rule to regulate health insurance coverage or other health-related coverage provided or administered by a recipient health insurance issuer or other covered entity. OCR disagrees with the commenter that this rule establishes a standard of medical care, or requires certain health insurance coverages. As specified in the preceding discussion, when assessing whether a challenged action was based on prohibited discrimination rather than on nondiscriminatory medical necessity standards, OCR will not conduct a general review of the medical judgment underlying the medical necessity determination, but rather will assess whether there is facial or other direct evidence of discriminatory intent or if a proffered rationale for the denial was pretext for discrimination. Further, this final rule does not require coverage of a particular health service; rather, it requires that the coverage being offered must be provided in a neutral and nondiscriminatory manner.

Comment: Commenters stated that issuers should provide transparent information on coverage details, utilization management practices, denial rates, and reasons for denials. Specifically, a commenter requested that this section be strengthened by implementing a requirement for health plans to disclose medical necessity determinations when care or coverage is denied based on medical necessity to individual enrollees. The commenter further suggested that OCR adopt the approach in the MHPAEA final rule, requiring disclosure of medical necessity criteria to potential beneficiaries or enrollees and the reasons behind denials of coverage or reimbursement. Commenters emphasized that disclosure would help providers and consumers to identify and challenge discriminatory denials of medically necessary care, which can be difficult to do when data regarding the coverage they need either does not exist or the issuer holds the data on details of coverage, denial rates, and reasons for denial.

Response: OCR agrees with commenters that transparency about medical management policies and coverage determinations and denials is useful information for the public, and we encourage issuers to disclose such information to all enrollees. OCR considered requiring issuers to affirmatively disclose certain plan information to the public, but we decline to do so at this time. We have determined that placing a transparency requirement on health insurance issuers covered under section 1557 would not be helpful on issuers if required in every situation, and because the scope and application of section 1557 is broader than, and imposes different requirements from, MHPAEA. We stress that OCR has the authority to request and receive information from a covered entity on the details of coverage, medical management policies, denial rates, and reasons for denials, among other things, when necessary to determine compliance with section 1557.[222] In addition, we note that appeals processes that subject individuals protected by section 1557 to excessive administrative burdens in accessing coverage benefits that other enrollees are not required to navigate when accessing coverage may be discriminatory under section 1557.

Comment: OCR received many comments on the use of value assessment methods in benefit design and pricing and coverage decisions, and their impacts on treatments for people with disabilities and older adults, particularly in access to prescription drugs and benefit design. Commenters suggested that some payers use these assessment methods to steer patients away from newer or more innovative treatments to less effective options. Commenters on this issue appreciated OCR's recognition in the Proposed Rule that these methods can have discriminatory impacts, though commenters did not provide uniform input about how to address these impacts.

Several commenters called for increased oversight of value assessment methods by OCR, and some called on OCR to ban the use of the quality-

[222] 45 CFR 92.303 (section 1557); 80.6 (title VI); 84.61 (section 504, incorporating title VI's § 80.6); 86.71 (title IX, incorporating title VI's § 80.6); 91.34 (Age Act).

adjusted life year (QALY) framework and similar methods. Commenters supporting a ban on the use of QALYs stated that these methods are inherently discriminatory because they assign a lesser numerical value to extending the lives of people with disabilities and older adults compared to people without disabilities or younger persons, especially when applied to benefit design or access to prescription drugs.[223]

Response: OCR recognizes that value assessment methods can be helpful tools in making decisions in various contexts within health care and are used widely. The use of value assessment methods that result in discrimination on the basis of race, color, national origin, age, disability and sex are prohibited under section 1557's general mandate of nondiscrimination. That is, where a value assessment uses methods that penalize patients or groups of patients on a ground protected by section 1557 and where such methods then result in limiting access to an aid, benefit, or service, they may violate section 1557. In response to commenters, we note that value assessment tools cannot be used to, to deny or afford an unequal opportunity to qualified individuals with disabilities or on the basis of age with respect to the eligibility or referral for, or provision or withdrawal of any aid, benefit, or service, including the terms or conditions under which they are made available. We further note that methods of value assessment are permissible so long as they do not discriminate in discounting the per-year value of life extension on the basis of age or disability under section 1557.

In addition, OCR has proposed a prohibition against the discriminatory use of value assessment methods in pending rulemaking under section 504. 88 FR 63409. Proposed § 84.57, which applies to recipients of Federal financial assistance from HHS, prohibits, directly or through contractual, licensing, or other arrangements, using any measure, assessment, or tool that discounts the value of life extension on the basis of disability to deny or afford an unequal opportunity to qualified individuals with disabilities with respect to the eligibility or referral for, or provision or withdrawal of any aid, benefit, or service, including the terms or conditions under which they are made available.

Given that many different measures exist for use in value assessment and may be applied in different ways, this discussion applies to evaluating any value assessment methodology rather than commenting on specific measures at this time. However, we appreciate the concerns raised by the commenters and will take them into account as OCR proceeds with future work on value assessment.

Comment: Many comments on value assessment also requested further development of new value assessment measures and the incorporation of input from patients with disabilities (and, per some commenters, their family members and providers) into value assessment schema. Commenters urged the Department to support the development and dissemination of these methodologies. Another commenter noted that cultural barriers existed in institutions that prevented the adoption of new metrics.

Response: OCR appreciates commenters' input and encourages and supports the development of such metrics and the incorporation of input from people with disabilities and other interested groups protected under section 1557, as reflected in research priorities elsewhere in the Department. Numerous research and grantmaking initiatives from the National Institutes of Health (NIH) and the National Institute on Disability, Independent Living, and Rehabilitation Research (NIDILRR) support this and similar efforts.[224] In addition, OCR notes that the National Council on Disability issued an updated policy brief released in November 2022.[225]

Benefit Design Analysis

The comments and our responses regarding benefit design are set forth below.

In the Proposed Rule, we discussed that OCR will apply basic nondiscrimination principles to the facts of the particular plan or coverage when analyzing allegations of discrimination under this section to determine if the challenged action is unlawful. We discussed that, consistent with general principles in civil rights law, covered entities will have the opportunity to articulate a legitimate, nondiscriminatory justification for an alleged discriminatory action or practice, and that OCR will scrutinize the justification to ensure it is not a pretext for discrimination.

Comment: Some commenters requested that OCR provide additional guidance explaining how it intends to investigate potential violations by health programs or activities engaged in providing or administering health insurance coverage or other health-related coverage and to ensure ongoing compliance with Federal law. Commenters urged OCR to establish clear, predictable standards that covered entities can rely upon when designing their plans and that will ensure OCR's ''case-by-case'' analysis does not result in only retroactive reviews of existing plans or lead to arbitrary results.

Another commenter noted that if OCR will not provide presumptively discriminatory benefit design examples, OCR should provide more information to educate covered entities about what OCR interprets to be best practices other than the information, corrective plans, and resolution agreements it stated it would publish on its website in the 2016 Rule. The commenter urged OCR to publicly publish deidentified information on each and every investigation that it pursues, including the specific actions purported to be discriminatory by a covered entity, the alleged basis of discrimination, and OCR's resolution of the complaint so that covered entities can educate themselves on best practices and actions that OCR may deem to be discriminatory.

Response: We appreciate the comments requesting further specificity regarding OCR's analysis when investigating potential violations under this section. We agree that providing clarity to covered entities promotes compliance and reduces prohibited discrimination. Each potentially discriminatory action involves unique

[223] These concerns were also highlighted in testimony at a recent Congressional hearing on proposed legislation to ban the use of QALYs in all Federal health programs. *See Lives Worth Living: Addressing the Fentanyl Crisis, Protecting Critical Lifelines, and Combatting Discrimination Against Those with Disabilities: Hearing on H.R. 467, H.R. 498, H.R. 501, and H.R. 485 Before the Subcomm. on Health of the H. Comm. on Energy & Com.,* 118th Cong. (2023) (statement of Kandi Pickard, President & CEO, Nat'l Down Syndrome Society), *https://d1dth6e84htgma.cloudfront.net/Witness_Testimony_Pickard_HE_02_01_2023_065c903370.pdf?updated_at=2023-01-30T21:38:38.787Z* (speaking on her support of Protecting Health Care for All Patients Act, H.R. 485, 118th Cong. (2023)).

[224] Funding Opportunity Announcement, U.S. Dep't of Health & Hum. Servs., Nat'l Insts. of Health, *NIH Faculty Institutional Recruitment for Sustainable Transformation (FIRST) Program: FIRST Cohort (U54 Clinical Trial Optional)* (December 8, 2020), *https://grants.nih.gov/grants/guide/rfa-files/RFA-RM-20-022.html*; U.S. Dep't of Health & Hum. Servs., Adm. for Cmty. Living, *Disability and Rehabilitation Research Projects (DRRP) Program, https://acl.gov/programs/research-and-development/disability-and-rehabilitation-research*; U.S. Dep't of Health & Hum. Servs., Nat'l Insts. of Health, *All of Us Research Program, https://allofus.nih.gov/*.

[225] Nat'l Council on Disability, *Alternatives to QALY-Based Cost-Effectiveness Analysis for Determining the Value of Prescription Drugs and Other Health Interventions* (2022), *https://www.ncd.gov/report/alternatives-to-qaly-based-cost-effectiveness-analysis-for-determining-the-value-of-prescription-drugs-and-other-health-interventions/*.

abortion coverage and services.[313] Each of these laws continues to apply and is not affected by this rule. Accordingly, it is not necessary to incorporate title IX's abortion neutrality provision.

OCR emphasizes that a covered provider's decision not to provide abortions or abortion coverage does not itself constitute discrimination in violation section 1557. As described above, section 1557 prohibits discrimination on the basis of race, color, national origin, sex, age, or disability in covered health programs or activities. As such there may be nondiscriminatory reasons for a provider not to offer abortion care or coverage. A covered entity does not engage in discrimination prohibited by section 1557 if it declines to provide abortions based on religious or conscience objections to performing the procedure, based on a professional or business judgment about the scope of the services it wishes to offer, or for any other nondiscriminatory reason.

Comment: Many commenters who supported OCR's proposal noted that section 1557 does not require incorporation of title IX's abortion neutrality provision because if Congress wanted to include such a provision, it would have done so either by explicitly referencing title IX's abortion neutrality provision or by including text matching 20 U.S.C. 1688. Commenters suggested that silence on the incorporation or importation of title IX's abortion neutrality provision is not an oversight on the part of Congress, but instead an intentional decision, as Congress legislates with knowledge of the basic rules of statutory construction.

Many commenters stated that the Congressional drafters of section 1557 did not pick and choose among the multiple title IX exceptions, including those specific to military training, admissions decisions, and membership practices of certain tax-exempt organizations, and that there is no justification for OCR to do so either. They maintained that the statute only references title IX for the prohibition of sex discrimination. Commenters also said there was no need to import title IX's abortion neutrality provision given the availability of existing Federal statutory protections for covered entities and individuals who object to the provision, payment, or referral of abortion services. Many commenters noted that OCR proposed a process in which a covered entity could seek an exemption based on conscience or religious conflicts. These commenters argued that, where permitted by relevant Federal laws, such analysis by OCR would also account for any potential harm to third parties.

Response: For the reasons we set forth above, OCR maintains that importing title IX's abortion neutrality provision in this rule is not legally required by the statute.

Comment: Other commenters who supported not importing the title IX abortion neutrality provision suggested that the final rule should include the Proposed Rule's discussion that EMTALA protects emergency care for pregnancy-related conditions, including termination of pregnancy. Some commenters expressed that the final rule should make clear that section 1557 incorporates section 1303(d) of the ACA, 42 U.S.C. 18023(d), which states that nothing in title I of the ACA relieves any health care provider from providing emergency services as required by EMTALA.

Response: OCR does not enforce EMTALA and directs commenters to the discussion of EMTALA under § 92.3. OCR notes that the 2022 NPRM's discussion of EMTALA does not alter any requirements under section 1557, EMTALA's existing obligations, or the Department's previous guidance regarding EMTALA. Nothing in this rule changes or otherwise affects any health care provider's obligations with respect to EMTALA, including with respect to the rights, remedies, procedures, or legal standards available to individuals and entities under section 1303(c) of the ACA.

Comment: Many commenters objected to OCR's proposal that it was not required to import title IX's abortion neutrality provision in this rule. These commenters argued that the provision must be included to explicitly address that section 1557 and its implementing regulations are abortion neutral. Some commenters maintained that the 2022 NPRM's request for comment on whether ''it could be beneficial to include a provision specifically prohibiting discrimination on the basis of pregnancy-related conditions as a form of sex-based discrimination,'' 87 FR 47879, constituted an ''abortion mandate'' that would discriminate against providers and covered entities who object to abortion. Some commenters stated that the inclusion of ''pregnancy or related conditions'' as a form of sex discrimination without importing title IX's abortion neutrality provision would strip providers of their ability to object to pregnancy terminations. Some commenters acknowledged that other Federal laws exist to protect religious freedom and conscience, but nevertheless expressed concerns that absent the provision's adoption of title IX's abortion neutrality provision, health care providers and entities with religious objections would be left without protections and would be forced to provide, cover, pay, or refer for abortion services.

Response: OCR appreciates commenters' concerns, but for the reasons stated above, we disagree. A covered entity does not engage in discrimination prohibited by section 1557 if it declines to provide, pay for, cover, or refer for abortions based on religious or conscience objections to performing the procedure. OCR also intends to enforce and comply with all applicable religious freedom and conscience protections, including section 1303 of the ACA, the Weldon, Church, and Coats-Snowe amendments, RFRA, and other applicable religious freedom and conscience laws. We have added a procedure for recipients whereby they may rely on such protections or seek assurance of those protections, if they wish. See § 92.302.

Comment: Other commenters who objected to the Department's position contended that, on the one hand, OCR was relying on title IX's regulations to prohibit discrimination on pregnancy-related conditions, while, on the other hand, ignoring title IX's statutory abortion neutrality provision and religious exception. These commenters argued that OCR is arbitrarily and capriciously picking and choosing which provisions of title IX to implement. They stated that, under title IX, declining to provide or pay for any service related to abortion is not treated as prohibited sex discrimination and therefore it cannot be that the same action, under section 1557, could constitute prohibited sex discrimination. Several commenters argued that the abortion neutrality provision, unlike title IX's exceptions, is a rule of construction that applies to all of title IX, including the statute's prohibition on sex discrimination, and thus OCR must incorporate the provision into any section 1557 implementing regulations.

Response: OCR appreciates commenters' concerns. As we explained above, however, section 1557 incorporates some, but not all, parts of title VI, title IX, the Age Act, and section 504. Specifically, section 1557 incorporates the ''ground'' of discrimination and the ''enforcement mechanisms'' under the referenced statutes, including title IX. Section 1557 is best read to incorporate existing interpretations of what constitutes sex discrimination under title IX, including regulatory interpretations and case law.

[313] *See* 42 U.S.C. 18023(b).

But section 1557 does not incorporate provisions of title IX or that statute's regulations that do not define or interpret what constitutes a ground of discrimination or an enforcement mechanism. Those provisions include the religious exception and the abortion neutrality provision. This reading gives meaning to every term in section 1557, while recognizing that although the statute incorporates parts of other civil rights statutes, each statute addresses distinct issues and contexts. Title IX's abortion neutrality provision is a rule of construction as to what acts can be required of recipients under title IX, but nothing in the provision states that it construes what constitutes a ground of prohibited discrimination. In section 1557, Congress was explicit in the limited incorporation of title IX when it listed only the ground to be prohibited by itle IX and the enforcement mechanisms that apply, and the title IX abortion neutrality provision is not an enforcement mechanism.

Comment: Many commenters stated that OCR's proposal to not import the title IX abortion neutrality provision is contrary to Congress's intent when it drafted section 1557 and explicitly adopted by reference the entire title IX scheme under 20 U.S.C. 1681 *et seq.* Commenters stated that enactment of title IX did not simply prohibit sex discrimination, because at least two categories of conduct are not, in Congress's view, what constitutes sex discrimination for purposes of title IX—religious decisions by an entity that conflict with the terms of title IX and the refusal to provide or pay for abortion. In their view, this means that OCR cannot prohibit discrimination based on termination of pregnancy or abortion as a form of sex discrimination.

Response: OCR appreciates commenters' concerns but disagrees that the manner in which Congress chose to cite title IX in section 1557 indicates an intent to limit what constitutes discrimination of the basis of sex for the reasons stated above. OCR specifically disagrees that the inclusion of ''*et seq.*'' indicates Congress's intent to incorporate the entire statute, thereby negating Congress's use of the terms ''ground prohibited'' and ''enforcement mechanisms'' when describing which portions of title IX shall be incorporated in section 1557. Moreover, as discussed in detail above (*see* Treatment of the Title IX Religious Exception), OCR's analysis considers the entire statute, including title IX's specific limitation to the context of educational programs and activities.

Comment: Commenters argued that title IX's adoption by reference supports Congress's longstanding position to legislate in a manner that remains neutral with respect to abortion. In support of this view, some commenters pointed to the Pregnancy Discrimination Act of 1978, where Congress prohibits discrimination on the basis of pregnancy, childbirth, or related medical conditions, but also explicitly included an exemption for health insurance benefits for abortion which, in their view, demonstrates Congress's intent to remain neutral on abortion.

Response: OCR will adhere to the specific terms Congress enacted in section 1557 as well as other applicable Federal laws, including section 1303 of the ACA, the Weldon, Church, and Coats-Snowe amendments, RFRA, and other applicable religious freedom and conscience laws.

Comment: Other commenters who objected to OCR's proposal not to import title IX's abortion neutrality provision in the rule expressed concern that OCR ignored section 1303 of the ACA, 42 U.S.C. 18023, which they opine requires abortion neutrality throughout the ACA. For example, commenters discuss that section 1303(a), which gives States the option to prohibit abortion coverage in health plans, would be rendered meaningless if the final rule requires such coverage by either prohibiting discrimination on the basis of pregnancy-related conditions or by failing to include a provision establishing section 1557's abortion neutrality. Commenters stated that section 1303 forecloses any construction of section 1557 that would require the provision or coverage of abortion.

Response: OCR appreciates commenters' concerns regarding section 1303's applicability to section 1557. Section 1303(a) provides that States and qualified health plans may, to the extent allowed by State law, opt to offer or prohibit abortion coverage; it does not require that section 1557 to import the language of title IX's abortion neutrality provision. Section 1303 primarily grants States flexibility to decide whether qualified health plans sold through their respective Exchanges can include coverage benefits for abortion services. *See* 42 U.S.C. 18023(a) (''State opt-out of abortion coverage''). And, unless otherwise prohibited by State law, participating issuers may elect to cover abortion services in qualified health plans. For qualified health plans that elect to offer as a coverage benefit abortion services for which Federal funding is prohibited, section 1303 establishes separate accounting requirements to ensure Federal funds are segregated and maintained separate from a policy holder's out-of-pocket funds, which may pay for abortion coverage. 42 U.S.C. 18023(b)(2)(B)–(C). OCR acknowledges that section 1303 allows qualified health plans the independence to choose whether to provide abortion coverage where consistent with State law, but it does not command that the final rule import title IX's abortion neutrality provision.

OCR reiterates, moreover, that a covered provider's decision not to provide abortions or abortion coverage does not itself constitute discrimination in violation of section 1557. A covered entity that generally offered abortion care could violate section 1557 if, for example, it refused to provide an abortion to a particular patient because of their race or disability. But a covered provider does not engage in discrimination prohibited by section 1557 if it declines to provide abortions based on religious or conscience objections to performing the procedure, based on a professional or business judgment about the scope of the services it wishes to offer, or for any other nondiscriminatory reason. Further, OCR maintains that importing title IX's abortion neutrality provision is not required given the recognition of the ACA provisions on abortion and the inclusion of those provisions in regulatory text.

Comment: Several commenters pointed to the Weldon and Church Amendments to assert that OCR does not have the authority to prohibit discrimination on the basis of pregnancy termination and requested that OCR include title IX's abortion neutrality provision to avoid any uncertainty on the issue. Other commenters urged OCR to include affirmative language in the final rule that section 1557 does not require the provision of, referral for, or coverage of abortion to eliminate any uncertainty maintained by many religious providers.

Response: OCR remains committed to upholding the Federal laws, including the abortion and conscience provisions of the ACA itself, the Church, Coats-Snowe, and Weldon Amendments; the generally applicable requirements of RFRA; and other applicable Federal laws that provide protection to covered entities. It is not necessary to include title IX's abortion neutrality provision in the final rule to provide certainty as to the safeguards in place to protect religious freedom and conscience. As discussed, a covered entity does not engage in discrimination prohibited by section 1557 if it declines to provide abortions based on religious or conscience objections to performing the procedure. Also, we refer again to the process described at § 92.302, whereby

Comment: Many other commenters expressed the view that this change in position by the Department reflects the evolution of how the Part B program operates today. Commenters explained that while Part B once served as contracts of insurance for those who qualified, today, individual providers directly bill and receive payment from the Federal Government itself.

Response: The Department acknowledges commenters' point that the current manner in which the Part B program is administered is a factor in our changed view on whether Part B funds meet the definition of ''Federal financial assistance''. As the commenters noted, a majority (⅔) of providers enrolled in Part B bill and are paid directly by the Medicare program. 87 FR 47889. However, this is not solely determinative regarding the change in interpretation. As noted in the 2022 NPRM, under *Grove City College* v. *Bell,* 465 U.S. 555, 569 (1984), Federal funds are Federal financial assistance regardless of whether they are provided directly by the Federal Government to an entity or are provided initially to beneficiaries (*i.e.,* program participants) for the specified purpose of assisting with payment for services.

Comment: Several commenters stated that this change in position will increase equity in access to quality health care for individuals with LEP, immigrants, and communities of color, as these groups are more likely to participate in Part B. Other commenters expressed the view that this interpretation allows the Department to align Part B providers' nondiscrimination obligations to Medicare Part A, which will result in better care for individuals with disabilities and will eliminate confusion for older adults who cannot determine whether their Part B provider receives any other type of Federal financial assistance. Other commenters stated that this will offer significant relief for older patients, individuals with disabilities, and LGBTQI+ adults by providing the same protections and rights regardless of the nature of the Medicare provider or the service they are receiving. These patients will no longer have to determine whether they are eligible for both Medicare and Medicaid, or whether they have Medicare or Medicaid, in order to assess what nondiscrimination protections they are afforded. A few commenters expressed the view that this will be particularly helpful for enrollees who rely on small specialty providers for care, such as medical equipment suppliers, that receive only Part B and no other form of Federal financial assistance. Several other commenters also explained that because many Medicare providers also serve people with other forms of health coverage, including private insurance, this change will increase access to quality health care for underserved communities who face disproportionate discrimination and barriers.

Response: The Department appreciates these comments and generally agrees that bringing all Medicare programs in line with other Federal financial assistance programs will bring about better health outcomes and increase equity in access to care. This position is also supported by the similarities across the Medicare programs and eliminates an inconsistency in the application of the definition of ''Federal financial assistance'' that the Department has determined is no longer justifiable.

Comment: A few commenters suggested that the Department should have a delayed date for when the revised interpretation regarding Part B payments as Federal financial assistance becomes effective. Some suggested at least 180 days and up to 365 days for newly covered providers to reach compliance for those practices that have not been subject to these requirements in the past. Several commenters stated that newly covered entities will need sufficient time to implement appropriate procedures, such as having a one-year applicability date or a safe-harbor compliance window of at least 6 months. However, one commenter expressed that the Department should impose the same implementation timeline for all covered entities, given that, in their view, very few entities will be providers who are not already Federal financial assistance recipients. This commenter explained that additional time is not necessary because OCR is also providing entities with technical assistance to reach compliance.

Response: The Department appreciates commenters' concerns and has amended the applicability date to give newly covered recipients sufficient time to come into compliance with civil rights obligations, as described below in the ''Summary of Changes.'' As this new designation of Part B applies to all Federal financial assistance-based civil rights statutes enforced by the Department, to the extent covered entities require assistance, OCR will provide adequate support.

Notice of Interpretation and Dates

A. *Notice of interpretation.*

The Department is finalizing its interpretation that Medicare Part B (''Part B'') funding meets the definition of ''Federal financial assistance'' for the purpose of title VI, title IX, section 504, the Age Act, and section 1557.

B. *Effective date.*

This interpretation is effective upon its publication in the **Federal Register**.

C. *Applicability date.*

The Department recognizes that that there are some recipients that do not receive any Federal financial assistance other than Part B funds and that these recipients be newly required to comply with section 1557 and other Federal civil rights laws enforced by OCR. The Department acknowledges that these recipients will require time to come into compliance as a result of this change in position. Therefore, while this revised interpretation is effective upon publication in the **Federal Register**, it will have a one-year delayed applicability date. Thus, compliance by entities whose Federal program participation has been limited to Part B must be in compliance with title VI, title IX, section 504, the Age Act, and section 1557 no later than May 6, 2025. An Assurance of Compliance, as required by 45 CFR 92.5, must be filed with the Department by entities whose Federal program participation has been limited to Medicare Part B no later than May 6, 2025. This can be completed via OCR's Assurance of Compliance portal at *https://ocrportal.hhs.gov/ocr/aoc/instruction.jsf*. Similarly, if such a recipient accepts a form of Federal financial assistance other than Part B prior to May 6, 2025, they will be required to complete an Assurance of Compliance at that time, consistent with section 1557 and the other Federal civil rights laws enforced by OCR.

IV. CMS Amendments

In the 2022 NPRM, the Department proposed clarifying CMS provisions that govern Medicaid and CHIP; PACE; health insurance issuers, including issuers providing EHB and issuers of qualified health plans (QHPs), and their officials, employees, agents, and representatives; States and the Exchanges carrying out Exchange requirements; and agents, brokers, or web-brokers that assist with or facilitate enrollment of qualified individuals, qualified employers, or qualified employees into Exchange coverage so that they again identify and recognize discrimination on the basis of sexual orientation and gender identity as prohibited forms of discrimination based on sex. The Department sought comments on CMS' proposal to explicitly mention only gender identity and sexual orientation in its amendments, while understanding that

discrimination on the basis of sex stereotypes, sex characteristics, and pregnancy or related conditions is also prohibited sex discrimination.

We are clarifying and emphasizing our intent that if any provision of this final rule is held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, or stayed pending further action, it shall be severable from this final rule, and from rules and regulations currently in effect, and not affect the remainder thereof or the application of the provision to other persons not similarly situated or to other, dissimilar circumstances. Through this rule, we adopt provisions that are intended to and will operate independently of each other, even if each serves the same general purpose or policy goal. Where a provision is necessarily dependent on another, the context generally makes that clear.

Comment: The majority of commenters on the proposed CMS amendments in the 2022 NPRM supported the proposal to explicitly identify and recognize discrimination on the basis of sexual orientation and gender identity as prohibited types of sex discrimination. However, many of the commenters noted that the language in the CMS amendments did not match the language explaining what constitutes sex discrimination in the proposed section 1557 implementing regulation (proposed 45 CFR 92.101(a)(2)). Commenters encouraged the agency to adopt the language in proposed § 92.101(a)(2). Specifically, those commenters suggested that the CMS amendments should revise the term ''sex'' to ''sex (including discrimination on the basis of sex characteristics, including intersex traits; pregnancy or related conditions; sexual orientation; gender identity; transgender status; and sex stereotypes)'' rather than ''sex (including sexual orientation and gender identity)'' as proposed for the various CMS regulations. Commenters argued that adopting the language from § 92.101(a)(2) in the CMS amendments would avoid confusion and ensure consistency of implementation and enforcement among the nondiscrimination protections in the CMS amendments and section 1557. In many contexts, CMS program regulations are more visible to some providers, patients, patient advocates, and other stakeholders than section 1557 requirements and are more readily translated into institutional policy, training, and patient awareness. Commenters asserted that the Department having a consistent description of sex discrimination would improve consistency across Department regulations, further the health and safety of program beneficiaries, and protect them from discrimination in health care. One commenter emphasized that a statement in the 2022 NPRM that CMS understands that discrimination on the basis of sex stereotypes, sex characteristics, and pregnancy or related conditions is prohibited sex discrimination, without the inclusion of such language in the regulatory text, provides inadequate notice to entities required to comply with the CMS amendments.

Response: The Department is finalizing the proposed amendments to the CMS regulations, with a revision to the description of sex discrimination to conform to the language in 45 CFR 92.101(a)(2). We appreciate that so many commenters made this suggestion and raised important issues concerning avoiding confusion, ensuring consistent implementation, and providing greater clarity for compliance and enforcement. In the Proposed Rule, CMS noted in the preamble that it understands that sex discrimination includes discrimination based on sex stereotypes, sex characteristics, including intersex traits, and pregnancy or related conditions, but limited the explicit mention in the regulatory text to gender identity and sexual orientation, sought comments. 87 FR 47891. The Department agrees with commenters that the amendments in the regulation should reflect CMS' intended interpretation of sex discrimination to avoid confusion for regulated entities and to better address the barriers to obtaining health care, including those faced by LGBTQI+ people, that CMS noted in the Proposed Rule. As there are entities that must comply with both CMS nondiscrimination provisions and section 1557, adopting identical language will ensure consistency across the policies and requirements applicable to entities subject to all of the provisions. As finalized, these CMS regulations provide that discrimination based on ''sex'' includes discrimination based on sex characteristics, including intersex traits; pregnancy or related conditions; sexual orientation; gender identity; and sex stereotypes. The list in the regulation text is not an exhaustive one that outlines all the ways (or the only ways) that discrimination can be based on sex but, rather, it only identifies examples; CMS interprets these regulations accordingly. However, nothing in this rule impedes regulated entities from taking nondiscriminatory actions based on current medical standards and evidence, such as individualized and nondiscriminatory decisions based on current medical standards and evidence about the timing or type of protocols appropriate for care. The rule does not (and cannot) require a specific standard of care or course of treatment for any individual, minor or adult.

Summaries of regulatory changes are outlined below, along with responses to comments. In the following sections, for brevity, all references to ''sex discrimination'' or ''discrimination on the basis of sex'' mean ''discrimination based on sex (including discrimination on the basis of sex characteristics, including intersex traits; pregnancy or related conditions; sexual orientation; gender identity, including transgender status; and sex stereotypes).''

A. Medicaid and Children's Health Insurance Program (CHIP)

In 42 CFR 438.3(d)(4) and 438.206(c)(2) (which apply to CHIP managed care through existing cross-references in §§ 457.1201(d) and 457.1230(a)), we proposed to restore regulatory text to prohibit Medicaid and CHIP managed care plans, which include managed care organizations, prepaid inpatient health plans, prepaid ambulatory health plans, primary care case managers, and primary care case management entities in managed care programs, from discriminating on the basis of sexual orientation and gender identity, and to require managed care plans to promote access and delivery of services in a culturally competent manner to all beneficiaries regardless of sexual orientation or gender identity. Such text was finalized as part of §§ 438.3(d) and 438.206(c)(2) in the Medicaid and CHIP managed care final rule published in the **Federal Register** on May 6, 2016 (2016 Medicaid and CHIP Rule), 81 FR 27498, but was removed as part of the Department's second section 1557 rulemaking (2020 Rule), 85 FR 37160, 37219–37220.

Similarly, in 42 CFR 440.262, for fee-for-service Medicaid programs, we proposed to restore regulatory text to require States to promote access and delivery of services in a culturally competent manner to all beneficiaries regardless of sex, including sexual orientation or gender identity. Again, the text was finalized as part of § 440.262 in the 2016 Medicaid and CHIP Rule but the references to sexual orientation and gender identity were removed by the 2020 Rule. We also proposed to change ''unique'' in 42 CFR 440.262 to ''individualized'' to more accurately reflect Medicaid's goal of providing person-centered care. Finally, we proposed to incorporate 42 CFR 440.262 into CHIP regulations through a cross-reference at 42 CFR 457.495(e),

ensuring alignment across fee-for-service Medicaid and CHIP programs.

The comments received on these proposals and our responses are set forth below.

Comment: We received many comments in support of the reinstatement of prohibitions against discrimination based on sexual orientation and gender identity in Medicaid and CHIP. Commenters stated that restoring the regulation text at 42 CFR 438.3(d)(4), 438.206(c)(2), and 440.262 (and therefore in §§ 457.1201(d) and 457.1230(a)) would promote access to care and the delivery of services in a culturally competent manner, strengthen the Department's commitment to increasing equity, and address discrimination in health programs and activities that can lead to disparate health outcomes.

Response: We appreciate the support for our proposals and believe finalizing revisions to these provisions will be an essential step in promoting culturally competent care that improves access, quality of care, and ultimately health outcomes.

Comment: One commenter that asked CMS to adopt the more detailed description of ''sex discrimination'' in proposed § 92.101(a)(2) pointed out that CMS program rules provide different compliance mechanisms—including prospective as well as complaint-based mechanisms—that complement section 1557's fundamental but essentially retrospective, complaint-based enforcement scheme.

Response: We appreciate the commenter raising this important perspective. There are prospective and retrospective compliance mechanisms reflected as State and managed care plan responsibilities in the Medicaid managed care regulations at 42 CFR part 438. Some provisions explicitly address requirements that must be included in managed care plan contracts and others stipulate State responsibilities. A provision that particularly reflects State responsibilities for proactively monitoring their managed care programs to ensure compliance with Federal regulations is 42 CFR 438.66, which requires States to have a monitoring system for all Medicaid managed care programs that addresses all aspects of the program including the performance of each managed care plan. This provision also requires States to use the data collected from their monitoring activities to improve their program's performance. This example of a prospective and retrospective activity requirement demonstrates how the Medicaid managed care regulations may help states and their managed care programs complement OCR's enforcement actions related to the prohibition of discrimination by providing for more timely monitoring and enforcement of discrimination prohibitions. Consistent regulation text about what sex discrimination means in this context—specifically, it includes discrimination on the basis of sex characteristics, including intersex traits; pregnancy or related conditions; sexual orientation; gender identity; and sex stereotypes—will maximize the effect of these benefits.

In addition, we believe it is critical to ensure consistency in the application of nondiscrimination requirements between Medicaid managed care and fee-for-service programs. Under section 1902(a)(19) of the Social Security Act, states must provide for such safeguards as may be necessary to assure access to care and services in a manner consistent with simplicity of administration and the best interest of beneficiaries. A Medicaid fee-for-service regulation (at 42 CFR 440.262) clarifying the meaning of the term ''sex'' in this context, particularly when that regulation is consistent with 42 CFR 438.3(d)(4) and 438.206(c)(2) facilitates simplicity in administration of nondiscrimination requirements and ensures the best interests of the beneficiaries are met across Medicaid delivery systems for all Medicaid beneficiaries. As we noted in the NPRM, the best interest of beneficiaries is appropriately met when access to care and services are provided in a non-discriminatory manner. A consistent approach on this issue will help protect beneficiaries from discrimination, avoid confusion, and provide for simplicity in administration of State Medicaid programs. To this end, we believe the reference to ''sex'' at 42 CFR 440.262 should be consistent with 42 CFR 438.3(d)(4) and 438.206(c)(2).

For this reason and those stated above, we are finalizing the proposed amendments to 42 CFR 438.3(d)(4), 438.206(c)(2), and 440.262 with revisions to make the discussions of ''sex'' in them consistent with 45 CFR 92.101(a)(2). In 42 CFR 438.3(d)(4) (and therefore § 457.1201(d)), we also are finalizing revisions to improve the readability of the provision by replacing some of the commas with semicolons and moving ''disability'' after ''national origin.'' We have also removed unnecessary parentheses in 42 CFR 438.3(d)(4), 438.206(c)(2), and 440.262.

Comment: One commenter asserted that the Department based the Proposed Rule on general provisions of the Social Security Act requiring that health assistance be provided in the ''best interest of beneficiaries'' (for Medicaid programs) and that the statute cited by the Department does not indicate Congressional intent related to prohibiting discrimination.

Response: The Department undertook this rulemaking to better align the section 1557 regulation with the statutory text of 42 U.S.C. 18116, to reflect recent developments in civil rights case law, and to better address issues of discrimination that contribute to negative health interactions and outcomes. We believe aligning the Medicaid and CHIP regulations in 42 CFR parts 438, 440, and 457, subpart L, with the section 1557 regulations is critical to fulfilling the Department's mission of pursuing health equity and protecting public health. Access to health care that is free from discrimination benefits all communities and people, and is also vital to addressing public health emergencies, such as the COVID–19 pandemic.

CMS possesses statutory authority under section 1902(a)(4) of the SSA (codified at 42 U.S.C. 1396a(a)(4)), which authorizes the Secretary to adopt methods of administration necessary for the proper and efficient operation of the Medicaid State plan; section 1902(a)(19) of the SSA (codified at 42 U.S.C. 1396a(a)(19)), which requires the Medicaid State plan to provide safeguards as necessary to assure that covered services are provided in a manner consistent with the best interests of the recipients; and section 2101(a) of the SSA (codified at 42 U.S.C. 1397aa(a)), which permits provision of funds to States to enable them to initiate and expand the provision of child health assistance to uninsured, low income children in an effective and efficient manner. CMS interprets section 1902(a)(19) of the SSA as prohibiting discrimination in the delivery of services because such discrimination is inconsistent with the best interests of the Medicaid beneficiaries who are eligible for and receive services. CMS interprets sections 1902(a)(4) and 2101(a) of the SSA as authorizing CMS to adopt regulations prohibiting discrimination on the basis of sex because such prohibitions on discrimination are necessary for the proper and efficient operation of a State plan, are in the best interest of beneficiaries, and enable states to provide child health assistance in an effective and efficient manner. For these reasons, we disagree with the commenter and continue to assert that adopting protection against discrimination to address disparities and, ultimately, health outcomes is within the authority granted to CMS by the Act.

Comment: One commenter stated that the proposed regulation text would prohibit physicians or other health professionals from categorically declining to provide gender-affirming treatments due to their religious or moral beliefs guaranteed them under the First Amendment to the U.S. Constitution and could require them to provide services and treatment procedures related to gender-affirming care that they object to performing.

Response: These regulations do not require the provision of any specific services. These regulations are neutral, generally applicable, and do not violate the Free Exercise Clause of the First Amendment. These regulations do not target religiously motivated conduct, but rather, are intended to prohibit sex discrimination generally in order to improve health outcomes for the LGBTQI+ community and fulfill the statutory command of the ACA to prohibit discrimination and remove unreasonable barriers to care. As noted previously in this rule, conduct does not constitute a violation of this rule's prohibition on sex discrimination if there is a legitimate, nondiscriminatory reason for the action. Also, HHS will respect religious freedom and conscience protections in Federal law, particularly with regard to the provision of certain health-related services. For example, when enforcing its nondiscrimination regulations, HHS will comply with laws protecting the exercise of conscience and religion, including RFRA (42 U.S.C. 2000bb through 2000bb–4) and all other applicable legal requirements. Nothing in the nondiscrimination protections at 42 CFR 438.3(d)(4), 438.206(c)(2), and 440.262 (which apply to CHIP managed care through existing cross-references in §§ 457.1201(d) and 457.1230(a) and CHIP fee-for-service through a new cross-reference at § 457.495(e)), displaces those protections. In enforcing the nondiscrimination provisions in the corresponding CMS regulations, the Department will comply with laws protecting the exercise of conscience and religion, including the Religious Freedom Restoration Act (42 U.S.C. 2000bb through 2000bb–4) and all other applicable legal requirements. Finally, we note that physician licensing and discipline are outside the scope of this rulemaking.

Summary of Regulatory Changes

After consideration of the public comments, we are finalizing 42 CFR 438.3(d)(4), 438.206(c)(2), and 440.262 (which apply to CHIP managed care through existing cross-references in §§ 457.1201(d) and 457.1230(a)) with revisions to specify that discrimination based on ''sex'' includes discrimination on the basis of sex characteristics, including intersex traits; pregnancy or related conditions; sexual orientation; gender identity; and sex stereotypes. Similarly, where these regulations require actions to be taken regardless of sex, that includes actions regardless of sex characteristics, including intersex traits; pregnancy or related conditions; sexual orientation; gender identity; and sex stereotypes. We are also finalizing the change of ''unique'' to ''individualized'' in 42 CFR 440.262 as proposed.

B. Programs of All-Inclusive Care for the Elderly (PACE)

In 42 CFR 460.98(b)(3), CMS proposed to add sexual orientation and gender identity to the list of characteristics that may not serve as a basis for discrimination against a PACE participant. Additionally, in 42 CFR 460.112, we proposed to add gender identity to the list of characteristics that may not serve as a basis for discrimination against a PACE participant. This PACE provision is applicable one year after the effective date of this final rule.

Comment: CMS received numerous comments supporting our changes to both provisions.

Response: CMS thanks the commenters for supporting these important changes that will serve to protect CMS' beneficiaries.

Comment: Several commenters did not support CMS' proposal to add sexual orientation and gender identity to the list of characteristics that may not serve as a basis for discrimination against a PACE participant. Some commenters objected to the protections against discrimination on the basis of gender identity, in particular. Some commenters, believing that the proposal requires coverage of gender-affirming care, stated that the Department can adequately protect people from discrimination without mandating this coverage.

Response: This rule does not require entities to cover any particular procedure or treatment. We clarify that, in finalizing the prohibition against discrimination on the basis of sex, the Department is not mandating that PACE organizations include coverage for any particular item or service not already covered. Rather, amending these sections to clarify discrimination on the basis of sex as including sex characteristics, including intersex traits; pregnancy or related conditions; sexual orientation; gender identity; and sex stereotypes will better ensure that all individuals are treated fairly in their access to health care. Without protection from such sex discrimination, transgender individuals may face barriers or be denied medically necessary services that are classified as covered under PACE and made available to other enrolled individuals. These amendments will better clarify nondiscrimination protections for all individuals, while also addressing existing disparities for LGBTQI+ individuals seeking health care. For the reasons discussed here and in the preamble to the Proposed Rule, CMS believes it is important to ensure all PACE participants are protected against unlawful discrimination of any kind, including discrimination based on sex characteristics, including intersex traits; pregnancy or related conditions; sexual orientation; gender identity; and sex stereotypes. Therefore, we are finalizing these revisions.

Summary of Regulatory Changes

We are finalizing the regulatory language with modifications based on comments received. Specifically, we are revising the reference to sex to include additional detail explaining that the reference to ''sex'' includes sex characteristics, including intersex traits; pregnancy or related conditions; sexual orientation; gender identity, including transgender status; and sex stereotypes.

C. Insurance Exchanges and Group and Individual Health Insurance Markets

In the HHS Notice of Benefit and Payment Parameters for 2023 Proposed Rule (2023 Payment Notice NPRM),[397] the Department proposed amendments to the regulations applicable to Exchanges, QHPs, and certain issuers to prohibit discrimination based on sexual orientation and gender identity. The amendments were similar to those proposed in the 2022 NPRM. Those proposed amendments were not finalized in the Notice of Benefit and Payment Parameters for 2023 final rule published on May 6, 2022,[398] because the Department determined that it would be most prudent to address the nondiscrimination proposals related to sexual orientation and gender identity in the 2022 NPRM to ensure consistency across the policies and requirements applicable to entities subject to both

[397] U.S. Dep't of Health & Hum. Servs. Ctrs. for Medicare & Medicaid Servs., Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2023, 87 FR 584 (January 5, 2022).

[398] U.S. Dep't of Health & Hum. Servs. Ctrs. for Medicare & Medicaid Servs., Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2023, 87 FR 27208 (May 6, 2022).

variety of reasons. Some of the commenters stated that the final rule would lead to health care professionals leaving the industry from the lack of conscience or religious exemptions. A couple of commenters stated that future health care professionals would not enter the industry in the future as the final rule would require them to violate the Hippocratic Oath or their religious beliefs.

Response: As discussed in section 2 of the RIA and preamble of the rule, the final rule includes a variety of protections for religious freedom and conscience rights, including a process whereby entities may rely on these protections and seek assurance of them from HHS. See § 92.302.

Comment: Several commenters noted that portions of the data that were used in the RIA, such as the number of covered entities and number of small entities, are outdated and need to be updated for an accurate cost estimate to be made.

Response: OCR agrees with commenters that data sources could be updated from the Proposed Rule. In this final rule RIA, the data for the number of covered entities, number of entities with more than 15 employees, the number of small entities, and hourly wages have been updated to the most recent data available.

Comment: A few commenters expressed concern that the final rule would cause irreparable harm to individuals who regret transitions.

Response: Commenters do not provide supporting evidence or data on the frequency or cost of potential irreparable harm. OCR disagrees with the commenters and did not find studies providing evidence or data on the frequency or cost of what the commenters characterize as irreparable harm, and therefore makes no changes to the final rule.

Comment: One commenter expressed concern that long-term costs associated with gender-affirming care are not accounted for within the RIA and that the studies used may not be accurate. Due to this, the commenter stated that the supplementary information provided is at best speculative.

Response: The main source for costs related to gender-affirming care come from a peer reviewed article in the New England Journal of Medicine, a well-respected medical journal. The cost associated with gender-affirming care is based on actual cost data from the Defense Manpower Data Center, which is part of the Department of Defense (DOD). As noted, the final rule does not mandate the provision of or coverage of gender-affirming care, or any particular health service. However, to the extent a covered entity provides coverage for a particular health service, the covered entity must provide the health service to all individuals in a neutral, nondiscriminatory manner consistent with this rule.

Comment: One commenter stated that the costs of algorithmic discrimination have been quantified and asked OCR to include examples of the costs of such discrimination.

Response: OCR includes a specific provision on algorithmic discrimination in the final rule and qualitatively discusses the potential costs to individuals from discriminatory application of algorithms and other decision support tools in the benefits section.

2. Summary of Costs and Benefits

This analysis quantifies several categories of costs to covered entities and to the Department under the final rule. Specifically, we quantify costs associated with covered entities training employees, revising policies and procedures, and costs associated with notices, including the Notice of Nondiscrimination and Notice of Availability. We quantify costs associated with provisions of the final rule related to documenting training activities performed under the final rule. We also quantify incremental costs associated with coverage for gender-affirming care (which, as noted above, is not mandated by the rule). Our analysis also addresses uncertainty in costs associated with notices and gender-affirming care, which is discussed in greater detail in the notices section of subsection B of section 2 of the RIA. We separately report a full range of cost estimates of about $523 million to $1,302.3 million using a 7 percent discount rate, and a full range of cost estimates of about $511.4 million to $1,290.7 million using a 3 percent discount rate. All cost estimates are in 2022 dollars. We conclude that the final rule would result in annualized costs over a 5-year time horizon of $646.5 million or $637.1 million, corresponding to a 7 percent or a 3 percent discount rate respectively.

In addition to these quantified cost estimates, the main analysis includes a discussion of costs that we do not quantify, and a discussion of the potential benefits under the rule that we similarly do not quantify. In addition to the impacts that we quantify, this final rule could also result in increases in premiums, which would result in increases in Exchange user fees and Federal expenditures for advance payments of the premium tax credit. These increases would be minimal due to the low utilization of gender affirming care and the availability of the services.

TABLE 1—ANNUALIZED COSTS OF THE FINAL RULE

[$ millions/year (percent)]

Primary estimate	Low estimate	High estimate	Year dollars	Discount rate (percent)	Period covered
$646.5	$523	$1,302.3	2022	7	2024–2028
$637.1	511.1	1,290.7	2022	3	2024–2028

a. Baseline Conditions

Section 1557 prohibits an individual from being excluded from participation in, denied the benefits of, or otherwise subjected to discrimination on the basis of race, color, national origin, sex, age, or disability in certain health programs and activities. It applies to any health program or activity, any part of which is receiving Federal financial assistance, and to any program or activity that is administered by an executive agency or any entity established under title I of the ACA.[421] On May 18, 2016, the Department published a final rule to implement section 1557 under the statute5 U.S.C. 301. 81 FR 31375. On June 19, 2020, the Department published a final rule that revised the Department's approach to implementing section 1557. 85 FR 37160. As described in greater detail in the Background section of this preamble, neither final rule was fully implemented as published, and certain provisions of the 2020 Rule remain the subject of ongoing litigation.

[421] 42 U.S.C. 18116.

The baseline scenario of no further regulatory action is substantially informed by the RIAs published with the 2016 and 2020 Rules. The 2016 RIA identified five sources of monetized costs: training and familiarization, enforcement, notice publication, sex discrimination policy and procedure changes, and language access plans. The bulk of the monetary impacts identified in the 2016 RIA occur in the first two years under the 2016 rule, with costs continuing in future years only for enforcement and language access plans.

The 2020 RIA adopted many of the assumptions contained in the 2016 RIA. For example, it assumed that many of the initial activities anticipated under the 2016 Rule were performed, and that the first two years of costs attributable to the 2016 Rule were incurred.[422] The 2020 RIA identifies cost savings only ''from the repeal of (1) the provision on the incentive for covered entities to develop language access plans and (2) the provisions on notice and taglines.'' 85 FR 37224. The 2020 RIA also identifies costs in the first year ''on covered entities' voluntary actions to re-train their employees on, and adopt policies and procedures to implement, the legal requirements of this final rule.'' 85 FR 37224.

In establishing a baseline scenario, this analysis similarly maintains a number of assumptions and estimates contained in prior analyses. For example, the baseline scenario includes some ongoing costs that are attributable to the 2016 Rule, such as the costs of enforcement. The 2016 RIA estimated that the costs of enforcement would be $108.8 million (reported in 2022 dollars), which we adopt as the costs under both the baseline and final rule scenarios. Similarly, we adopt the assumption in the 2020 RIA that covered entities continue to provide ongoing training attributable to the 2016 Rule, which was not impacted by the 2020 Rule. We include these ongoing training activities, including annual refresher training for returning employees and training for new employees, in the baseline scenario of no regulatory action.

The final rule analysis updates baseline conditions on the number of covered entities. The 2016 Rule, 2020 Rule, and 2022 NPRM all used 275,002 covered entities, and 41,250 covered entities that have 15 or more employees. This final rule updates the covered entities to 266,297 and the number of covered entities with 15 or more employees to 63,950. Table 2 presents the updated data on covered entities. To update this data, we identified the source of the original data being the 2012 Statistics of U.S. Businesses (SUSB) Annual Data Tables by Establishment Industry and found the 2020 version of the same dataset. Using the same NAICS codes from the Proposed Rule we identify the number of entities under these NAICS codes in addition to the number of firms with 15 or more employees.

TABLE 2—COVERED ENTITIES

NAICS code	Business type	Firm count 2020	Firms with 15 or more employees
62142	Outpatient mental health and substance abuse centers.	7,649	2,911
621491	HMO medical centers	84	21
621492	Kidney dialysis centers	449	216
621493	Freestanding ambulatory surgical and emergency centers.	4,554	2,204
621498	All other outpatient care centers	6,307	2,766
6215	Medical and diagnostic laboratories	7,200	1,892
6216	Home health care services	25,718	10,901
6219	All other ambulatory health care services	7,091	2,589
62321	Residential intellectual and developmental disability facilities.	6,674	3,628
6221	General medical and surgical hospitals	2,445	2,344
6222	Psychiatric and substance abuse hospitals	434	414
6223	Specialty (except psychiatric and substance abuse) hospitals.	301	280
6231	Nursing care facilities (skilled nursing facilities).	9,824	7,513
45611	Pharmacies and drug stores	19,346	3,436
6211	Offices of physicians	167,294	22,494
524114	Insurance Issuers	869	341
	Navigator grantees	58	
	Total Entities	266,297	63,950

In the next section, we discuss the incremental costs of the final rule, which exclude ongoing costs attributable to prior rulemaking.

b. Costs of the Final Rule

This analysis anticipates that the final rule would result in one-time costs to covered entities to process assurance of exemption requests and revise policies and procedures. The final rule would result in costs associated with a revised approach to notices, including the Notice of Nondiscrimination and Notice of Availability, costs to review new decision support tool requirements, and costs to training employees. The final rule would also result in costs associated with provisions related to documenting training activities performed under the final rule.

The final rule might result in additional costs associated with coverage for gender-affirming care. We discuss the potential costs associated with gender-affirming care coverage and the potential that some or all of these costs would be offset by reductions in spending on other types of care. We

[422] *E.g.,* 85 FR 37235 (''The Department assumes sunk costs cannot be recovered by this rule, and therefore that initial language access plan development costs attributable to the 2016 Rule cannot be recovered.'').

reiterate that the final rule does not mandate the provision of or coverage of gender-affirming care, or any particular health service. However, to the extent a covered entity provides coverage for a particular health service, the covered entity must provide the health service to all individuals in a neutral, nondiscriminatory manner consistent with this rule.

The analysis also discusses other potential costs of the final rule that we do not quantify.

Training

The Department anticipates that some covered entities would incur costs to train or retrain employees under the final rule. To calculate the costs related to training, we followed an approach common to both the 2016 and 2020 RIAs. Both analyses estimate that covered entities would train their employees on the requirements. This final rule uses the updated estimate of covered entities (266,297) as the basis for calculating the total costs. The 2020 RIA adjusted the number of covered entities downward by 50 percent, anticipating that some covered entities would not modify their procedures in response to the 2020 final rule, and would therefore not need to offer new training. Both RIAs anticipated that employers would most likely train employees who interact with the public and recognized that the percentage of employees that interact with patients and the public vary by covered entity. To account for this, the analyses adopted a central estimate of 50 percent of staff at covered entities that received one-time training on the requirements of the regulation.

Both RIAs reported the number of employees at covered entities by occupation category. To monetize the total costs of training, the RIAs adopted a value of time based on the average fully loaded wage rate for each occupation, combined with an assumption about the duration of the training. The 2016 RIA assumed that 50 percent of total employees at covered entities would receive training, while the 2020 RIA assumed that 25 percent of employees would receive training. Both RIAs assumed the typical training would last one (1) hour. For this analysis, we assume that 75 percent of total employees at covered entities would receive training, and that this training would last one (1) hour. This estimate is consistent with an assumption that all covered entities would revise their policies and procedures under the final rule and that most employees at covered entities would receive training.

As a necessary first step in calculating the incremental total costs of training attributable to the final rule, we have collected the most recent available data on the number of employees that would likely undergo training under the final rule, and data on the average wage rate by occupation for these employees.

The first category of health care staff that may receive training comprises health diagnosing and treating practitioners. This category includes physicians, dentists, optometrists, physician assistants, occupational, physical, speech and other therapists, audiologists, pharmacists, registered nurses, and nurse practitioners. The U.S. Bureau of Labor Statistics (BLS) Occupational code for this grouping is 29–1000, and the 2022 reported employment count for this occupational group is approximately 5.96 million, with average loaded wages of $114.42 per hour at the national level.[423]

The second category of health care staff that the Department assumes will receive training comprises degreed technical staff (Occupation code 29–2000) and accounts for 2.95 million employed individuals with average loaded wages of $51.18 per hour at the national level.[424] Technicians work in almost every area of health care: x-ray, physical, speech, psychiatric, dietetic, laboratory, nursing, and records technicians, to name but a few areas.

The third category of health care staff that the Department assumes will receive training comprises non-degreed medical assistants (Occupation code 31–0000), which includes psychiatric and home health aides, orderlies, dental assistants, and phlebotomists. Health care support staff (non-degreed, medical assistants) operate in the same medical disciplines as technicians, but often lack professional degrees or certificates often required for degreed technical staff. There are approximately 6.79 million employed individuals in these occupations in the health care and social assistance sector, with average loaded wages of $34.20 per hour at the national level.[425]

The fourth category of health care staff that the Department assumes will receive training is health care managers (Occupation code 11–9111) and accounts for approximately 0.48 million employed individuals with average loaded wages of $123.06 per hour at the national level.[426]

The fifth category of health care staff that the Department assumes will receive training is office and administrative assistants (Occupation code 43–0000) and accounts for approximately 2.719 million employed individuals with average loaded wages of $41.16 per hour within the Health Care and Social Assistance sector.[427] These workers are often the first staff patients encounter in a health facility and, because of this, covered entities might find it important that staff, such as receptionists and assistants, receive training on the regulatory requirements. The Department assumes that outreach workers are included in the five categories listed above.

The Department estimates that there are a total 18.9 million employees at covered entities, of which we assume 14.2 million, 75 percent, would receive training attributable to the final rule. Across the five occupation categories, we estimate a weighted hourly wage rate of $32.70, or a weighted fully loaded hourly wage rate of $65.41. Assuming that the average training takes one (1) hour and adopting a value of time based on fully loaded wage rates, we estimate total first-year training costs for all covered entities to be approximately $927.3 million.[428] As a sensitivity analysis, we considered the scenario of covered entities providing training to all employees, 18.9 million, not just employees who interact with the public, 14.2 million. Under this scenario, the total cost of training would increase to about $1.2 billion. These costs are likely overstated since this training may supplement or replace expected annual or other ongoing training activities at covered entities. To the extent that covered entities reduce time spent on other training activities, these costs would offset some of the total costs attributable to the final rule.

Lastly, the Department assumes that 91 investigators at OCR, who are equivalent to GS–12 Step 1 employees

[423] U.S. Bureau of Labor Statistics, *May 2022 National Occupational Employment and Wage Estimates, https://www.bls.gov/oes/current/oes_nat.htm.* The average loaded wage for Healthcare Diagnosing or Treating Practitioners is derived by multiplying the mean hourly rate by 200 percent to include the mean hourly wage, the cost of fringe benefits and overhead costs ($57.21 * 200% = $114.42).

[424] U.S. Bureau of Labor Statistics, *May 2022 National Occupational Employment and Wage Estimates, https://www.bls.gov/oes/current/oes_nat.htm.*

[425] U.S. Bureau of Labor Statistics, *May 2022 National Occupational Employment and Wage Estimates, https://www.bls.gov/oes/current/oes_nat.htm.*

[426] U.S. Bureau of Labor Statistics, *May 2022 National Occupational Employment and Wage Estimates, https://www.bls.gov/oes/current/oes_nat.htm.*

[427] U.S. Bureau of Labor Statistics, *National Industry-Specific Occupational Employment and Wage Estimates, Sector 62- Health Care and Social Assistance, https://www.bls.gov/oes/current/naics2_62.htm#43-0000.*

[428] Numbers may not multiply due to rounding.

and whose average hourly loaded wage is $65.46, will receive a one-time training during the first year of the promulgation of this rule.[429] Each individual would receive 8 hours of training for a total of $47,655 (91 x 1 x $65.46) in training costs. This training would not occur in any subsequent years.

In addition to the first-year training costs, we anticipate that the final rule would result in additional costs associated with ongoing training, including annual refresher training for returning employees and training for new employees. As discussed in the Baseline Conditions section, we assume that many covered entities are routinely carrying out these activities, absent further regulatory action. However, we anticipate that the final rule would result in a larger share of employees at covered entities receiving such training. To quantify the change in training activities between the baseline scenario and the final rule scenario, we take the difference between the share of employees receiving training under the baseline scenario and the final rule scenario. We carry through an assumption from the 2016 RIA, which assumed that 50 percent of total employees at covered entities receive training and compare this to an assumption in this final RIA that 75 percent of total employees at covered entities would receive training. This yields an estimate of 25 percent of total employees at covered entities that would receive training in subsequent years under the final rule. We adopt the same weighted hourly wage estimate, number of employees, and estimate the total ongoing annual training costs as $309.1 million. This was calculated by multiplying the total number of employees at covered entities by .25 and multiplying by $65.41.

Finally, the Department assumes covered entities may require employees to undergo one (1) hour of training in response to in OCR investigation. As it is difficult to determine the type of employee that would be required go through additional training, we use the average loaded hourly wage of $65.41 to evaluate the opportunity cost of training time. To estimate the frequency with which covered entities may assume this cost, we reviewed OCR complaints from the 2023 calendar year and identified 60 cases investigated under section 1557 that were closed with a covered entity either engaging in voluntary corrective action in response to the investigation or entering into a Voluntary Resolution Agreement with the agency.[430] Using this as a baseline, the Department assumes that for every year of the observation period there would be 60 potential instances of this additional training, and that it would be conducted in each case. As a result, we estimate that covered entities would incur $3,924 in additional training costs for every year of the observation period.[431]

Revising Policies and Procedures

As discussed above in the previous section, the Department anticipates that all covered entities, or approximately 266,297 entities, would revise their policies and procedures under the final rule, with approximately half of these entities requiring less extensive revisions. For covered entities with more extensive revisions, we adopt the estimates contained in the 2020 RIA, with four (4) total hours spent on revisions per entity. Of these, three (3) would be spent by a mid-level manager equivalent to a first-line supervisor (Occupation code 43–1011), at a cost of $62.98 ($31.49 × 2) per hour after adjusting for the cost of fringe benefits and other indirect costs, while an average of one (1) hour would be spent by executive staff equivalent to a general and operations manager (Occupation code 11–1021), at a cost of $118.14 ($59.07 × 2) per hour at the national level, including the cost of fringe benefits and other indirect costs.[432] For covered entities with less extensive revisions, we assume two (2) total hours spent on revisions per entity. Of these, one (1) would be spent by a mid-level manager, and one (1) would be spent by executive staff.

We monetize the time spent on revising policies and procedures by estimating a total cost per entity of $307.08 or $181.12, depending on the extent of the revisions. For the 133,149 covered entities with more extensive revisions, we estimate a total cost of about $40.8 million. For the 133,149 covered entities with less extensive revisions, we estimate a total cost of about $24.1 million. We estimate the total cost associated with revisions to policies and procedures under the final rule of $65.0 million.

The above estimates of time and number of entities that would choose to revise their policies under the regulation are approximate estimates based on general BLS data. We are unable to precisely estimate the total number of covered entities that would choose to revise their policies and procedures under the new regulation or to what extent they would make these changes due to the wide range of types and sizes of covered entities, from complex multi-divisional hospitals to small neighborhood clinics and physician offices.

In addition to the initial revisions of policies and procedures, the Department assumes some covered entities may elect or be required to revise their policies and procedures following an investigation. We assume that such revisions would cost the same as the original revision that occurs in the first year of the observation period. As discussed above, the Department estimates that during every year of the observation period, there would be an average of 60 instances in which corrective actions may be taken due to a 1557 investigation. As revising policies and procedures is a more significant corrective action compared to corrective training, the Department assumes that it will occur in response to only half of the investigations. The Department continues to use the assumption that half of the entities revising their policies and procedures would be major firms while the other half would be minor firms. The estimated total annual cost for revisions of policies and procedures in response to an OCR investigation is $7,323 (307.08 × 15 + 181.12 × 15) in each year of the observation period.

Notices

The final rule requires the 266,297 covered entities to provide a Notice of Nondiscrimination to participants, enrollees, and beneficiaries, hereafter referred to as beneficiaries of its health program or activity, and members of the public. It also requires covered entities to provide a Notice of Availability. These provisions resemble elements of the 2016 Rule that were repealed in the 2020 Rule; however, the approach under the final rule provides a narrower set of situations where covered entities would be required to provide these notices. Both types of notices are required (1) on an annual basis; (2) upon request; (3) at a conspicuous location on the covered entity's health program or activity website; and (4) in clear and prominent physical locations where the health program or activity interacts with the public.

[429] U.S. Off. of Personnel Mgmt., *Salary Table 2022–GS. GS–12 Step 1 Employee, https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2022/GS_h.pdf/.*

[430] U.S. Dep't of Health & Hum. Servs., Off. for Civil Rts., *Complaints Closed During Calendar Year 2023 within the Section 1557 Program Area.*

[431] $3,924 = ($65.41 × 1 × 60).

[432] U.S. Bureau of Labor Statistics, *Occupational Employment and Wages, May 2022, 43–1011 First-Line Supervisors of Office and Administrative Support Workers, https://www.bls.gov/oes/current/oes431011.htm.*

The Notice of Availability is also required in the following electronic and written communications related to the covered entity's health programs and activities: (1) notice of nondiscrimination required by final § 92.10; (2) notice of privacy practices required by 45 CFR 164.520; (3) application and intake forms; (4) notices of denial or termination of benefits or services, including Explanations of Benefits (EOBs) and notices of appeal and grievance rights; (5) communications related to an individual's rights, eligibility benefits, or services that require or request a response from a beneficiary; (6) communications related to a public health emergency; (7) consent forms and instructions related to medical procedures or operations, medical power of attorney, or living will (with an option of providing only one notice for all documents bundled together); (8) discharge papers; (9) communications related to the cost and payment of care with respect to an individual, including good faith estimates and medical billing and collections materials; (10) complaint forms; and (11) patient and member handbooks.

For the purposes of the Notice of Availability analysis, we base our estimates of the number of communications containing these notices on a subset of the communications identified in the 2020 RIA. We include communications that are EOBs. The Department received feedback regarding the financial burden imposed by applying the Notice of Availability requirements to EOBs. EOBs are typically an individual's first, and often only, notice of a denial or termination of benefits or services, and as such, the Notice of Availability requirement is essential in this context to ensure timely and equitable access to appeals processes. The final rule at § 92.11(d) permits covered entities to provide individuals with the option to opt out of receiving the Notice of Availability on an annual basis, which will reduce the cost and burden associated with these requirements. In addition, as beneficiaries increasingly elect to receive EOBs and other types of communications electronically, we expect the cost of these requirements to decrease over time. We adopt the other estimates as a reasonable proxy for the number of communications that would be anticipated under the final rule. These estimates are intended to encompass all categories of Notices of Availability required under the final rule. We have increased the total number of communications containing notices by 10 percent to account for the additional communications related to the cost and payment of care with respect to an individual, including good faith estimates and medical billing and collections materials, which were not included in the Proposed Rule.[433]

Table 3 below reports the number of communications containing notices anticipated under the final rule and presents the costs of these communications. Our cost estimates reflect a wide range of uncertainty in the cost per communication. For our primary scenario, we adopt a central estimate of the average costs to print and fold paper forms containing prescribing information of $0.05 (calculated as the midpoint estimate of a range from $0.03 to $0.07), reported in 2010 dollars.[434] We explore the sensitivity of the overall cost estimates under a low-cost ($0.035 per unit) and high-cost ($0.32 per unit) scenario, reported in 2018 dollars, which matches the range contained in the 2020 RIA. We adjust these per-unit cost inputs for inflation to 2022 price levels using the Implicit Price Deflator, resulting in a primary per-unit cost estimate of about $0.067 and a full range of about $0.045 to $0.37.[435] Combining these per-unit cost estimates with the count of each notice results in a primary estimate of $93.2 million, with a range of estimates between $57.2 million and $522.8 million. Following the approach in the 2020 RIA, we adjust this figure downward by 50 percent to account for the lower cost of electronic communications. For this adjustment, we adopt a measure of the share of respondents reporting that they used a ''Digital (mobile app or website)'' method to contact or interact with their health insurance issuer or plan in the last year when viewing an online statement.[436] We anticipate that the share of communications occurring online will increase over time but have not accounted for a trend for the 5-year time horizon of this analysis. This adjustment results in a primary estimate of the adjusted annual total of $46.6 million, with a range of costs between $28.6 million and $261.4 million. These costs would occur in each year of the time horizon of the analysis.

TABLE 3—COST OF NOTICE PROVISIONS

[2022 Dollars]

Cost element	Count (millions)	Cost scenario ($ millions)		
		Low	Primary	High
Eligibility and enrollment communications	19.5	$0.8	$1.3	$7.2
Annual notice of benefits	135.3	5.5	8.9	49.9
Explanations of benefits—hospital admissions	105.6	4.3	6.9	39.0
Explanations of benefits—physician visits	1035.1	41.8	68.1	382.0
Medical bills—hospital admissions	12.1	0.5	0.8	4.5
Medical bills—physician visits	108.9	4.4	7.2	40.2
Total, Unadjusted	1416.5	57.2	93.2	522.8
Total, Adjusted for Electronic Delivery	1133.2	28.6	46.6	261.4

[433] This reflects the increase from 10 categories accounted for by communications and notices in the Proposed Rule RIA to 11 categories, or an increase of 10 percent.

[434] U.S. Dep't of Health & Hum. Servs., Food & Drug Admin., *Electronic Distribution of Prescribing Information for Human Prescriptions Drugs, Including Biological Products,* Proposed Rule, 79 FR 75506 (Dec. 18, 2014).

[435] Fed. Reserve Bank of St. Louis, *Gross Domestic Product: Implicit Price Deflator* (GFPDEF), *https://fred.stlouisfed.org/series/GDPDEF.*

[436] Saurabh Gupta et al., *HFS Rsch. & Cognizant, Health Consumers Want Digital: It's Time for Health Plans to Deliver,* p. 4 (2021), *https://www.cognizant.com/en_us/general/documents/cognizant-hfs-health-consumers-want-digital-its-time-for-health-plans-to-deliver.pdf.*

Documentation Requirements

The final rule requires covered entities to contemporaneously document certain other activities performed under the final rule. This includes activities such as employees' completion of the training required by this section in written or electronic form. The final rule also requires covered entities to retain certain records. These and other requirements, and the associated cost estimates, are discussed in greater detail in the PRA section.

The costs associated with retaining records related to grievances filed with a covered entity is the time spent by the staff of covered entities to store the complaints for no less than three (3) years. We calculate the costs of labor as one (1) employee per covered entity with more than 15 employees (63,950) spending 10 hours to store complaints and the associated records required under final § 92.8(c)(2) each year.[437] We assume that administrative or clerical support personnel would perform these functions. The mean hourly wage for this occupation is $19.02 per hour, which we double to account for overhead and other indirect costs. We estimate the costs of retaining records related to grievances filed at all covered entities would be $24.3 million annually ($19.02 × 2 × 10 × 63,950). This estimation approach will overstate the costs if many covered entities already retain complaint information.

The costs associated with documenting employee training is the time spent by the staff of covered entities to (a) create training attendance forms, and (b) store the training sign-up sheet. We calculate the costs of labor as one (1) employee spending 15 minutes (0.25 hours) to create the sign-up sheet during the first year and one (1) employee spending one (1) hour collecting and storing the attendance forms the first year and subsequent years. We assume that administrative or clerical support personnel would perform these functions. The mean hourly wage for this occupation is $19.02 per hour, which we double to account for overhead and other indirect costs. We estimate the costs of documenting employee training would be $12.6 million in the first year ($19.02 × 2 × 1.25 × 266,297) and $10.1 million in subsequent years ($19.02 × 2 × 1 × 266,297).

Coverage for Gender-Affirming Care

In addition to the cost some covered health insurance issuers and plans may incur for revising policies and procedures to comply with the rule, there is a possibility that such issuers and plans may incur a de minimis cost related to the cost of coverage for gender-affirming care. Various studies, however, suggest that any such increased costs will likely be negligible, and that any increases may be offset by savings from decreased utilization of other services. The likelihood of significant costs is low both because transgender individuals make up a very small percentage of the population and because many transgender individuals do not seek gender-affirming surgeries or other types of care.[438]

In April 2012, the California Department of Insurance conducted an Economic Impact Assessment on Gender Nondiscrimination in Health Insurance that found that prohibiting discrimination on the basis of gender identity in health insurance plans would have an ''insignificant and immaterial'' impact on costs.[439] This conclusion was based on evidence of low utilization and the estimated number of transgender individuals in California. The transgender population of California was estimated to range between 0.0022 percent and 0.0173 percent.[440] The study revealed that, contrary to common assumptions, not all transgender individuals seek surgical intervention, and that gender-affirming health care differs according to the needs and pre-existing conditions of each individual.[441] Despite expecting a possible spike in demand for benefits due to former or current unmet demand, the California Insurance Department concluded that any increased utilization that might occur over time is likely to be so low that any resulting costs remain actuarially immaterial.[442] The Assessment notes the experience of one employer that initially established premium surcharges to cover the anticipated cost of gender-affirming care, reporting that the employer subsequently eliminated the surcharges because they found that the funds collected were nearly 15 times the amount expended on care.[443] While it did not analyze any original data, a 2018 analysis by the State of Wisconsin's Department of Employee Trust Funds cited numerous studies finding that the cost of coverage was minimal, and noted that ''[w]hile it is challenging to predict the costs of care averted for any condition, there is some evidence that the costs associated with providing transgender-inclusive plans is met with reduced costs related to comorbidities.'' [444] Other studies looking at both public and private sector plans have reached similar conclusions. One study published in the New England Journal of Medicine projected that the cost for providing gender-affirming care benefits to members of the military would result in an annual increase of 0.012 percent of health care costs, ''little more than a rounding error in the military's $47.8 billion annual health care budget.'' [445] A 2013 study of 34 public and private sector employers that provided nondiscriminatory health care coverage found that providing coverage of gender-affirming care had ''zero to very low costs.'' [446] An

[437] This estimate is consistent with the 2016 Rule's Regulatory Impact Analysis: ''Of the 275,002 covered entities, approximately 15 percent employ more than 15 employees, resulting in approximately only slightly more than 41,250 covered entities being required to have grievance procedures and designate a responsible official.'' 81 FR 31375, 31452 (May 18, 2016).

[438] *See, e.g.,* U.S. Health & Hum. Servs., Ctrs. for Medicare & Medicaid Servs., *Colorado 2023 EHB-Benchmark Plan Actuarial Report, https://www.cms.gov/CCIIO/Resources/Data-Resources/ehb.* Suite of Gender-affirming care benefits to treat gender dysphoria resulted cost estimate was 0.04 percent of the total allowed claims assuming utilization would be for adults.

[439] State of Cal., Dep't of Ins., *Economic Impact Assessment Gender Nondiscrimination in Health Insurance,* p. 1 (Apr. 13, 2012), *http://translaw.wpengine.com/wp-content/uploads/2013/04/Economic-Impact-Assessment-Gender-Nondiscrimination-In-Health-Insurance.pdf.*

[440] *Id.* at p. 3. More recent estimates indicate that a higher share of the population in the United States identifies as transgender (0.6 percent of the U.S. adult population). Andrew R. Flores et al., The Williams Inst., UCLA Sch. of Law, *Race and Ethnicity of Adults Who Identify as Transgender in the United States,* p. 2 (2016), *https://williamsinstitute.law.ucla.edu/wp-content/uploads/Race-Ethnicity-Trans-Adults-US-Oct-2016.pdf.*

[441] State of Cal., Dep't of Ins., Dep't of Ins., *Economic Impact Assessment Gender Nondiscrimination in Health Insurance,* p. 8 (Apr. 13, 2012), *http://translaw.wpengine.com/wp-content/uploads/2013/04/Economic-Impact-Assessment-Gender-Nondiscrimination-In-Health-Insurance.pdf.*

[442] State of Cal., Dep't of Ins., *Economic Impact Assessment Gender Nondiscrimination in Health Insurance,* p. 9 (Apr. 13, 2012), *http://translaw.wpengine.com/wp-content/uploads/2013/04/Economic-Impact-Assessment-Gender-Nondiscrimination-In-Health-Insurance.pdf.*

[443] State of Cal., Dep't of Ins., *Economic Impact Assessment Gender Nondiscrimination in Health Insurance,* pp. 6–7 (Apr. 13, 2012), *http://translaw.wpengine.com/wp-content/uploads/2013/04/Economic-Impact-Assessment-Gender-Nondiscrimination-In-Health-Insurance.pdf.*

[444] Wis., Dep't of Employee Trust Funds, *Correspondence Memorandum Re: Transgender Services Coverage,* pp. 6–8 (Aug. 14, 2018), *https://etf.wi.gov/boards/groupinsurance/2018/08/22/item6a1/download?inline=.*

[445] Aaron Belkin, *Caring for Our Transgender Troops—The Negligible Cost of Transition-Related Care,* 373 New Eng. J. Med. 1089 (2015), *https://www.nejm.org/doi/pdf/10.1056/NEJMp1509230?articleTools=true.*

[446] Jody Herman, The Williams Inst., UCLA Sch. of Law, *Cost and Benefits of Providing Transition-Related Health Care Coverage in Employee Health Benefits Plans: Findings from a Survey of Employers,* p. 2 (Sept. 2013), *http://*

additional study comparing costs and potential savings associated with covering gender-transition-related care concluded that ''additional expenses hold good value for reducing the risk of negative endpoints—HIV, depression, suicidality, and drug abuse'' and noted that ''provider coverage was cost-effective in 85 percent of simulations.'' [447] More recently, a 2021 survey of employers conducted by the Human Rights Campaign noted that most employers who covered gender-affirming care reported only ''marginal increases'' in cost, on the order of ''a fraction of a decimal point of cost calculations.'' [448]

In recent years, some legal challenges to coverage exclusions have also considered issues of cost and concluded that covering gender-affirming care does not significantly increase costs for plans. In discussing the parties' experts on the issue of the cost, one court noted that, ''[f]rom an actuarial perspective, there appears to be no dispute that the cost of coverage is immaterial.'' [449] Another court reviewing expert testimony called any cost savings from excluding coverage for gender-affirming care ''both practically and actuarially immaterial.'' [450]

Based on the studies discussed above, we estimate that providing transgender individuals nondiscriminatory insurance coverage and treatment would have a small impact on the overall cost of care and on health insurance premiums in terms of the percentage of overall spending. We reiterate that the final rule does not mandate the provision or coverage of gender-affirming care, or any particular health service. However, to the extent a covered entity provides coverage for a particular health service, the covered entity must provide the health service to all individuals in a neutral, nondiscriminatory manner consistent with this rule. The utilization rate of covered services, whatever those services may be, is likely to be extremely low because transgender individuals represent a small minority in the general population and because not all transgender individuals will seek medical care in the course of their transition.[451]

As described in this section, the costs associated with gender-affirming care are likely to be small on a percentage basis of total health care costs; however, when these estimates are combined with measures of overall health care spending, they would likely result in incremental costs that could be substantial. As an initial estimate, we pair the Belkin (2015) estimate of 0.012 percent of incremental health care costs with $4,255.1 billion in total health expenditures in calendar year 2021.[452] When this is grown to 2022 dollars, total health care costs are $4,550.0 billion. Combining these yields our upper-bound estimate of $546 million in annual costs associated with additional coverage. As a lower-bound estimate, we adopt an assumption that these costs will be fully offset by reductions in spending on other medical care. This lower bound of $0 is broadly consistent with a cost-effectiveness analysis that includes the probability of negative incremental costs associated with coverage.[453] For our primary estimate, we start with the midpoint of the lower-bound and upper-bound cost estimate of about $273.24 million annually. We reduce this figure by half to account for several factors, such as some covered entities already covering gender-affirming care under the baseline scenario. The coverage from § 92.207(b)(1) through (5) and (6) have delayed applicability dates of the first day of the first plan year beginning on or after January 1, 2025. Therefore, there is no cost from coverage in year 1 (2024). This results in a primary estimate of about $138 million per year starting in year 2 in incremental annual costs associated with additional coverage under the final rule, with a full range of cost estimates including $0 million and $546 million.

In addition, health plans and issuers could incur overall costs if total health care utilization increases as a result of this final rule. Any potential increase in costs as a result of increased health care utilization as a result of decreased discrimination could be passed on to beneficiaries in the form of increased premiums. However, this cost would be minimal due to the low utilization of gender affirming care along with the availability of the services.

Assessing Decision Support Tools for Discrimination

Section 92.210 sets a minimum requirement for each covered entity to make reasonable efforts to mitigate the risk of discrimination resulting from the covered entity's use of a decision support tool. This will impose a cost on covered entities to review for potential discrimination in their decision support tools and to then make reasonable steps to mitigate the risk of discrimination. To estimate the cost of review, the Department assumes that all covered entities, or 266,297 entities, would on average take 1 hour to review decision support tools in year 1 and 0.5 hours in each year 2–5. The Department assumes the time burden is halved after year 1 because entities would only be reviewing new decision support tools or changes made to preexisting ones in the past year. Evidence suggests that larger entities, such as insurers, health systems and national labs, are more likely to use decision support tools while some types of entities may not use them at all.[454] It is therefore likely that entities will have a large variance in time burden in practice as some entities will need to spend more time reviewing and others much less. OCR assumes that the hour of review consists of a 1557 coordinator (SOC code 43–4071) spending 0.5 hours coordinating a request for information on the potential for discrimination in decision support tools used by the covered entity and a Management Analyst (13–1111) or equivalent employee with knowledge of the decision support tools spending 0.5 hours responding to that request. After adjusting for fringe benefits and other indirect costs, the hourly wages for the Management Analyst and Section 1557 Coordinator come to $100.64 and $38.04 respectively. We monetize the time spent on reviewing decision support tools by estimating a total cost per entity

williamsinstitute.law.ucla.edu/wp-content/uploads/Herman-Cost-Benefit-of-Trans-Health-Benefits-Sept-2013.pdf.

[447] William V. Padula et al., *Societal Implications of Health Insurance Coverage for Medically Necessary Services in the U.S. Transgender Population: A Cost-Effectiveness Analysis,* 31 J. of Gen. Internal Med. 394 (2015), *https://pubmed.ncbi.nlm.nih.gov/26481647/.*

[448] Hum. Rts. Campaign, *Corporate Equality Index 2021* (2021), *https://reports.hrc.org/corporate-equality-index-2021?_ga=2.206988627.1166715317.1639876655-819100514.1639876655.*

[449] *Boyden* v. *Conlin,* 341 F. Supp. 3d 979, 1000 (W.D. Wis. 2018).

[450] *Flack* v. *Wis. Dep't of Health Servs.,* 395 F. Supp. 3d 1001, 1021 (W.D. Wis. 2019); *see also Kadel* v. *Folwell,* No. 1:19–cv–00272, 2022 WL 2106270, at *22 (finding that the cost of covering gender-affirming care ''pales in comparison'' to the Defendant state health plan's overall cash balance and that excluding such coverage would only save each plan member' ''about one dollar each'').

[451] State of Cal., Dep't of Ins., *Economic Impact Assessment Gender Nondiscrimination in Health Insurance,* pp. 2, 5 (Apr. 13, 2012), *http://translaw.wpengine.com/wp-content/uploads/2013/04/Economic-Impact-Assessment-Gender-Nondiscrimination-In-Health-Insurance.pdf.*

[452] U.S. Dep't of Health & Hum. Servs., Ctrs. for Medicare & Medicaid Servs., *Table 19. National Health Expenditure Accounts: Methodology Paper,* 2022, *https://www.cms.gov/files/document/definitions-sources-and-methods.pdf.*

[453] William V. Padula et al., *Societal Implications of Health Insurance Coverage for Medically Necessary Services in the U.S. Transgender Population: A Cost-Effectiveness Analysis,* 31 J. of Gen. Internal Med. 394 (2015), *https://pubmed.ncbi.nlm.nih.gov/26481647/.*

[454] Xia Jing et al., *Availability and Usage of Clinical Decision Support Systems (CDSSs) in Office-Based Primary Care Settings in the USA,* BMJ Health Care Inform. (2019), *https://pubmed.ncbi.nlm.nih.gov/31818828.*

of $69.34 ($100.64 × 0.5 + $38.04 × 0.5). The estimated total cost to review decision support tools for all covered entities is $18,465,034 ($69.34 × 266,297) in year 1. In years 2–5, OCR estimates that the time burden will be half of what it was in year 1. This will lead to a total cost per entity of $34.67 ($100.64 × 0.25 + $38.04 × 0.25) in years 2–5. The estimated total cost to review decision support tools for all covered entities is $9,232,517 ($34.67 × 266,297) in each year 2–5.

If an entity reviews their decision support tools and determines that there is no evidence that use of the tools may result in discriminatory outputs, then it is likely that no further action will be taken, and no additional cost will be incurred. If the entity determines that there is evidence that the decision support tools used by the covered entity could result in discriminatory outputs, then the entity will have to make reasonable mitigation steps to be in compliance with the final rule. OCR has determined that there are a large variety of actions that a covered entity can take to satisfy the requirements of the final rule and that these steps likely depend on the specific scenario. One aspect that will affect what a covered entity would do is if the decision support tool that is being used is a third-party product that the covered entity pays for or was developed and is owned by the covered entity itself. In the first scenario, the covered entity could notify the third party that the decision support tool may result in outputs that could be in violation of the rule, take mitigation steps in the use of the tool to ensure decisions made using that tool account for the potential for bias, or switch to a different product if the cost to do so is not prohibitive. If the covered entity maintains their own decision support tool, then they might take time to update the decision support tool, change policies and procedures about its use, or take other reasonable mitigation measures to ensure that it is not used in a discriminatory manner. The cost of all these actions may vary greatly, and OCR does not have data to assess what the costs may be. Generally, OCR assumes that larger entities, such as multihospital health systems and insurers will have a higher cost to resolve these issues since they are more likely to use decision support tools.[455] In addition, OCR does not have data on how likely any given decision support tool is to be discriminatory and therefore necessitate taking reasonable mitigation steps. Due to these data limitations, OCR does not quantify the cost of taking reasonable mitigation steps.

Exemption Requests

We also identify a cost related to covered entities submitting a request for assurance of an exemption based on Federal conscience or religious freedom laws. We model this potential cost associated with exemption assurance requests as the time spent by covered entities to (a) assess the need for an exemption; (b) write the exemption assurance request; and (c) submit such a request to OCR. As an initial calculation, we assume that this would involve two (2) employees spending two (2) hours each assessing the need for an exemption and one employee spending three (3) hours writing and submitting the exemption assurance request to OCR. We further assume that legal personnel, including lawyers and legal assistants, would perform these functions. The mean hourly wage for these occupations is $70.55 per hour for each employee, which we double to account for overhead and other indirect costs. We multiply these factors together and estimate the cost per exemption request of $987.70 ($141.10 × 7 = $70.55 × 2 × 7).

OCR has revised the estimate of the number of religious exemptions from the Proposed Rule RIA, which assumed 27 religious exemptions. OCR has increased this estimate to provide a more conservative estimate of the cost of religious exemptions, given significant uncertainty in the number of requests that will be submitted. OCR revises its assumptions to assume that 707 religious hospitals and 2 percent of all other covered entities will request assurance of religious exemptions. This results in a total of 6,019 of such requests (707 + ((266,297 − 707) × 0.02)) in the first year. OCR estimates the cost to covered entities for the 6,019 of such requests as $5,944,792 (6,019 × $987.73).

We estimate the cost to OCR comprising the time it would take to review the request and determine if the exemption assurance should be given. We estimate that it would take a single lawyer equivalent employee (Occupation code 23–1011), with a wage of $70.55 per hour, 3 hours to complete this review. We double the mean hourly wage to account for overhead and fringe benefits. OCR estimates the cost to review 6,019 assurance of exemption requests as $2,547,768 ($141.10 × 3 × 6,019). The total estimated cost of this process is $8,492,559.

c. Total Quantified Costs

Table 4 below presents the total annual costs anticipated under the final rule for which estimates have been developed. For the purposes of this analysis, we assume that the regulatory requirements begin to take effect in the middle of 2024. In the first year under the final rule, these estimated costs include $927.4 million in training, $8.5 million to process religious assurance of exemption requests, $18.5 million to review decision support tools, and $65.0 million to revise policies and procedures. For all years in the analysis, we estimate recurring costs of $46.6 million related to notices. We estimate a first-year cost of $37 million related to documentation, with ongoing costs in future years of $10.1 million. We also report a primary recurring cost estimate of $136.6 million associated with coverage of gender-affirming care starting in year 2 and $9.2 million in reviewing decision support tools starting in year 2. The total costs in year 1 amount to $1,102.9 million, with ongoing annual costs of $511.7 million in subsequent years.

TABLE 4—PRIMARY ESTIMATE OF TOTAL ANNUAL COSTS

[$ Millions, 2022 dollars]

Cost element	2024	2025	2026	2027	2028
Training	$927.4	$309.1	$309.1	$309.1	$309.1
Policies and Procedures	65.0	0.0	0.0	0.0	0.0
Notices	46.6	46.6	46.6	46.6	46.6
Documentation	37.0	10.1	10.1	10.1	10.1
Gender-affirming Care Coverage	0	136.6	136.6	136.6	136.6

[455] Robert. S. Rudin & Shira H. Fischer, *Trends in the Use of Clinical Decision Support by Health System-Affiliated Ambulatory Clinics in the United States 2014–2016,* Am. J. of Accountable Care (2019), *https://www.ajmc.com/view/trends-in-the-use-of-clinical-decision-support-by-health-system-affiliated-ambulatory-clinics-in-the-united-states-20142016.*

TABLE 4—PRIMARY ESTIMATE OF TOTAL ANNUAL COSTS—Continued

[$ Millions, 2022 dollars]

Cost element	2024	2025	2026	2027	2028
Assurance of Exemption Requests	8.5	0.0	0.0	0.0	0.0
Decision Support Tool Review	18.5	9.2	9.2	9.2	9.2
Total Costs *	1,102.9	511.7	511.7	511.7	511.7

This rulemaking also revises the Department's interpretation of whether Medicare Part B payments constitute Federal financial assistance by answering that question in the affirmative. Thus, the requirements of section 1557 and other civil rights statutes apply to entities that receive payments through Medicare Part B. We are currently unable to quantify the number of covered entities that are enrolled in Medicare Part B but that receive no other forms of Federal financial assistance. The 2016 Rule discussed several of the challenges associated with estimating the number of these entities. For example, the 2016 Rule notes that, ''although we have data, by program, for the number of physicians receiving payment from each program, there is no single, unduplicated count of physicians across multiple programs.'' We adopt the finding of the 2016 Rule that almost all practicing physicians were likely covered by the rule because they accept Federal financial assistance from sources other than Medicare Part B.[456]

3. Discussion of Benefits

Quantifying benefits for this final rule presents significant challenges. One notable challenge relates to attribution: several sources of benefits discussed in the preambles of the 2016 and 2020 Rules overlap with and may be attributable to prior existing civil rights regulation, to the ACA rather than the 2016 and 2020 rulemakings that implement section 1557, or to nondiscrimination policies based on State law or institutional policies prohibiting discrimination generally.

A second challenge relates to identifying a quantitative relationship between nondiscrimination policies and important outcomes such as improvements in public health outcomes. For example, we anticipate that this regulation would reduce the incidence of providers refusing to treat patients based on the patient's gender identity. This would result in fewer instances of delayed or denied care, which in turn would lead to reductions in mortality and morbidity risks. However, we are not able to estimate the changes in the magnitude of these discriminatory events that would be attributable to the final rule, and thus are unable to quantify or monetize these health improvements. Similarly, we anticipate that the final rule will result in other sources of benefits that we are unable to quantify. These include a reduction in suicidal ideation and attempts, improvements to mental health, reductions in substance use, and generally align with a discussion of the economic impacts of a California regulation relating to gender nondiscrimination in health insurance.[457]

In addition to these health improvements, we anticipate benefits to covered entities from additional regulatory clarity on how OCR will enforce the ACA's nondiscrimination protections, particularly in light of ongoing litigation related to the 2020 Rule, interpretation of the Supreme Court's *Bostock* decision, and the Department's Bostock Notification. The training provisions represent one mechanism by which the final rule would reduce discriminatory events. This would, in turn, reduce the number of enforcement actions, representing a potential cost-saving benefit for covered entities. We also anticipate benefits to covered entities from the establishment of a grievance process, which would reduce the number of complaints filed with OCR, though this may be offset somewhat from covered entities with fewer than 15 employees referring complaints to OCR in lieu of adopting their own grievance procedure.

We also anticipate that beneficiaries could benefit from reduced obstacles to accessing health care, including fewer language barriers and a reduction in discriminatory behavior related to sexual orientation and gender identity, resulting in a potential increase in overall health care utilization. These benefits relate to individuals' ability to access care and the quality of care they receive. For example, the provisions related to language access for individuals with LEP and accessibility for individuals with disabilities could reduce instances of negative outcomes, including death, due to a lack of understanding between patient and doctor or between patient and pharmacist, as well as lack of access to services. We also anticipate that the process by which individuals and recipients may seek assurance of an exemption based on Federal conscience or religious freedom laws will result in benefits from reduced litigation, which we do not capture in the benefit analysis. In addition, the prohibition on discrimination through the use of decision support tools is also likely to have a direct benefit on the health of individuals who are suffering from delayed or denied medical care due to discriminatory application of decision support tools. An example of this would be an incorrect diagnosis for skin cancer for a Black patient, which could lead to greater medical costs in the future and negative health outcomes for the patient.[458] Furthermore, the positive effects of using decision support tools, such as identifying those at risk for cardiovascular disease at an earlier date, will be a benefit across populations experiencing discrimination.[459]

4. Analysis of Regulatory Alternatives to the Final Rule

The Department considered various alternatives while developing this regulation, including adopting the compliance timeline of the Proposed Rule. As discussed in the preamble, the final rule will allow additional time for covered entities to comply with certain procedural requirements, as compared to the timeline of the Proposed Rule. For example, covered entities must comply with the § 92.9 Training requirements by no later than 300 days of effective

[456] 81 FR 31375, 31445–46 (May 18, 2016).

[457] State of Cal., Dep't of Ins., *Economic Impact Assessment Gender Nondiscrimination in Health Insurance,* pp. 9–11 (Apr. 13, 2012), *http://translaw.wpengine.com/wp-content/uploads/2013/04/Economic-Impact-Assessment-Gender-Nondiscrimination-In-Health-Insurance.pdf.*

[458] Thomas Grote & Geoff Keeling, *On Algorithmic Fairness in Medical Practice,* Cambridge Quarterly of Healthcare Ethics, January 2022. *https://pubmed.ncbi.nlm.nih.gov/35049447/.*

[459] Rachel Gold et al., *Effect of Clinical Decision Support at Community Health Centers on the Risk of Cardiovascular Disease: A Cluster Randomized Clinical Trial,* JAMA Network Open (2022), *https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2788645.*

date. This revised timeline will postpone certain costs incurred by covered entities; however, since this analysis reports annual impacts, the revised timeline does not affect the quantified cost estimates. This section discusses several other alternatives OCR considered.

The Department analyzed several regulatory alternatives to the final rule related to the notice requirements. The first alternative considered retaining the 2020 Rule's repeal of the notices and taglines provisions. The Department considered concerns raised in response to the 2016 Rule notice and tagline requirements, as well as concerns raised in response to the removal of those requirements in the 2020 Rule. Though the Department acknowledges the burden placed on covered entities through the 2016 Rule notice requirements, the Department believes the 2020 Rule did not adequately consider the confusion and uncertainty placed on individuals or the unnecessary ambiguity that covered entities face by the 2020 Rule's repeal of the notices and taglines provisions in their entirety. As described earlier, we estimate that these provisions under the final rule would cost covered entities, as an aggregate, $46.6 million for each year. While excluding the provisions relating to the notices would reduce the cost of the final rule by $46.6 million, the Department rejected this option because it believes that the final provisions strike an appropriate balance between providing greater access for beneficiaries, while maximizing efficiency and economies of scale for covered entities.

The second alternative considered by the Department would require covered entities to provide notices only at their first encounter with a beneficiary. For this alternative, we adopt the quantity and cost estimates associated with eligibility and enrollment communication included in Table 5 above. Under our primary cost scenario, this policy alternative would result in annual costs of notices of $0.7 million, which is about $45.9 million lower than the final rule. The Department rejected this option however, because this policy alternative, while posing a significantly reduced cost and burden on covered entities, would be too narrow and substantially reduce the information available to beneficiaries, likely resulting in beneficiaries not being aware of their civil rights, including whether they have experienced a prohibited discriminatory practice by a covered entity.

The third alternative considered by the Department would require a more expansive notice provision, extending the requirements to include pharmacy-related notices. For this alternative, we adopt the 2020 RIA estimate of 3.2 billion annual pharmacy-related notices. This would result in $169.7 million in costs per year, or an increase of $123.1 million compared to the final rule. While this alternative related to notices would increase the number of notices available to beneficiaries, and therefore increase beneficiaries' opportunity to receive information regarding nondiscrimination and civil rights protections, the Department believes this alternative would neither address nor remedy the burden placed on covered entities through the 2016 Rule notice requirements. For this reason, the Department rejected this alternative.

Finally, the Department also considered not including a process for covered entities to submit a request for assurance of a religious or conscience exemption. As described in the cost section, we estimate that this policy alternative would reduce the quantified costs by $8.5 million. The Department did not choose this alternative because of its obligations to enforce a range of statutory protections, including Federal religious freedom and conscience laws. OCR remains committed to educating patients, providers, and other covered entities about their rights and obligations under these statutes, to protecting patients' health and dignity, and to providing a clear administrative process that respects the right to raise objections to the provision of certain kinds of care.

We have not quantified the benefits associated with this information for the final rule or for these policy alternatives.

Table 5 reports the total costs of these policy alternatives in present value and annualized terms, adopting a 3 percent and 7 percent discount rate. Table 6 reports the difference between the total cost of the alternatives compared to the provisions of the final rule, using the same accounting methods and discount rates. All estimates are presented in millions of year-2022 dollars, using 2024 as the base year for discounting.

TABLE 5—TOTAL COST OF POLICY ALTERNATIVES CONSIDERED

[$ Millions, 2022 dollars]

Accounting method discount rate	Present value		Annualized	
	3%	7%	3%	7%
Final Rule	$2,917.6	$2,650.8	$637.1	$646.5
Alternative 1: No Notice Provision	2,704.1	2,459.7	590.5	599.9
Alternative 2: Single Notice Provision	2,707.4	2,462.6	591.2	600.6
Alternative 3: Pharmacy-Related Notices	3,481.3	3,155.4	760.1	769.6
Alternative 4: No Exemption Provision	2,909.4	2,642.8	635.3	644.6

TABLE 6—COMPARISON OF ALTERNATIVES TO FINAL RULE

[$ Millions, 2022 dollars]

Accounting method discount rate	Present value		Annualized	
	3%	7%	3%	7%
Alternative 1: No Notice Provision	−$213.5	−$191.1	−$46.6	−$46.6
Alternative 2: Single Notice Provision	−210.2	−188.2	−45.9	−45.9
Alternative 3: Pharmacy-related Notices	563.7	504.6	123.1	123.1
Alternative 4: No Exemption Provision	−8.2	−7.9	−1.8	−1.9

The Department also considered whether to require covered entities to collect the self-identified race, ethnicity, primary language (spoken and written), sex (consistent with the categories of sex discrimination described at § 92.101(a)(2)), age, and disability status data for beneficiaries in any health program or activity. The Department believes, however, that our current authorities under section 1557, title VI, section 504, title IX, and the Age Act already provide us the ability to collect these data to ensure compliance.[460]

B. Regulatory Flexibility Act—Final Small Entity Analysis

The RFA requires agencies issuing a regulation to analyze options for regulatory relief of small businesses if a rule will have a significant impact on a substantial number of small entities. The RFA generally defines a ''small entity'' as:

(1) A proprietary firm meeting the size standards of the Small Business Administration (SBA);

(2) A nonprofit organization that is not dominant in its field; or

(3) A small government jurisdiction with a population of less than 50,000 (States and individuals are not included in the definition of ''small entity'').

OCR uses as its measure of significant economic impact on a substantial number of small entities a change in revenues of more than 3 percent for 5 percent or more of affected small entities. In instances where OCR judged that the final rule would have a significant impact on a substantial number of small entities, we considered alternatives to reduce the burden. To accomplish our task, we first identified all the small entities that may be impacted, and then evaluated whether the economic burden we determined in the RIA represents a significant economic impact.

1. Entities That Will Be Affected

OCR has traditionally classified most providers as small entities even though some nonprofit providers would not meet the definition of ''small entity'' were they proprietary firms. Nonprofit entities are small if they are independently owned and operated and are not dominant in their fields. The CMS Provider of Service file has indicators for profit and nonprofit entities, but these have proven to be unreliable. The Census data identifies firms' tax status by profit and non-profit status but only reports revenues and does not report them by the profit and non-profit status of the entity.

a. Physicians

One class of providers we do not automatically classify as small businesses is physician practices. Physician practices are businesses and therefore are ''small'' if they meet the SBA's definition. The current size standard for physicians (excluding mental health specialists) (North American Industry Classification System code 62111) is annual receipts of less than $16 million.[461] Using the Census data showing the number of firms, employees and payroll, we selected physicians that reported fewer than 20 employees as the top end for small physician offices. This equaled 16,361 entities or 9.8 percent of all physician offices defined as ''large.'' This left 150,933 offices or 90.2 percent as ''small.'' [462]

b. Pharmacies

Pharmacies also are businesses, and the size standard for them is annual receipts of less than $37.5 million. According to Census Statistics of U.S. Businesses, there are 19,346 pharmacy and drug store firms (North American Industry Classification System code 456110). Because of the lack of revenue or receipt data for pharmacies, we are unable to estimate the number of small pharmacies based on the SBA size standard. However, using the number of employees taken from the Statistics of U.S. Businesses as a proxy for revenues, the data is divided by number of employees per firm and shows the number of employers with fewer than 20 employees and those with more than 20 employees.[463] There are 17,160 pharmacy firms with fewer than 20 employees, representing 88.7 percent of the total number of pharmacy firms. It seemed reasonable to assume that firms with fewer than 20 employees satisfy the SBA size standard and thus we accepted that the number of small pharmacy firms equaled 17,160. As with the number of small physician offices, our method can only identify the minimum number of ''small'' pharmacies that meet the SBA size standard. We cannot determine the actual number of ''small'' pharmacies.

c. Health Insurance Issuers

Another class of covered entities that are business enterprises is health insurance issuers. The SBA size standard for health insurance issuers is annual receipts of $47 million. Based on the analysis below, we conclude that there are few small health insurance issuers.

In 2021, there were 483 issuers in the U.S. health insurance market.[464] Health insurance issuers are generally classified under the North American Industry Classification System (NAICS) code 524114 (Direct Health and Medical Insurance Carriers). According to SBA size standards,[465] entities with average annual receipts of $47 million or less are considered small entities for this NAICS code. The Departments expect that few, if any, insurance companies underwriting health insurance policies fall below these size thresholds. Due to the lack of recent Census data based on enterprise receipt size, HHS used the Census 2017 SUSB data as a proxy since it was the last year in which this data is available. Based on data from SUSB annual report submissions for the 2017 SUSB reporting year, approximately 443 out of 745 issuers of health insurance coverage nationwide, approximately 59.46%, had total premium revenue of $40.0 million or less.[466] OCR decided to use a value slightly higher than the 2017 SBA standard to account for slight changes in the industry in addition to inflation. We then apply this percentage to the current number of insurance Issuers to estimate the number of small entities for the business type, which is approximately 517 of 869 entities. However, this estimate may overstate the actual number of small health insurance issuers that may be affected due to changes in the health care industry since 2017. To produce a conservative estimate, for the purposes of this analysis, the Departments assumes 59.5 percent, or 517 issuers are considered small entities.

d. Local Government Entities

We also excluded local governmental entities from our count of small entities

[460] *See, e.g.,* 45 CFR 80.6, 86.71, 91.34, and 84.61.

[461] U.S. Small Business Admin., *Table of Small Business Size Standards Matched to North American Industry Classification System Codes, Small Business Administration* (March 2023), *https://www.sba.gov/document/support-table-size-standards.*

[462] Physician practices may earn more than $16 million per year and that would increase the number of ''large'' practices in the analysis. But as we will later show, large practices will have proportionally larger workforce staff that must be excluded from the analysis.

[463] U.S. Census Bureau, *Statistics of U.S. Businesses, https://www.census.gov/programs-surveys/susb.html.*

[464] U.S. Health & Hum. Servs., Ctrs. for Medicare & Medicaid Servs. (2022), *Medical Loss Ratio Data and System Resources, https://www.cms.gov/CCIIO/Resources/Data-Resources/mlr.*

[465] U.S. Small Business Admin., *Table of Size Standards* (March 17, 2023), *https://www.sba.gov/document/support--table-size-standards.*

[466] U.S. Health & Hum. Servs., Ctrs. for Medicare & Medicaid Servs., *Medical Loss Ratio Data and System Resources* (2017), *https://www.cms.gov/marketplace/resources/data/medical-loss-ratio-data-systems-resources.*

because we lack the data to classify them by populations of fewer than 50,000. The following table shows the number of small, covered entities we estimated could be affected by the final rule.

TABLE 8—SMALL ENTITIES

NAICS code	Business type	Small entities
62142	Outpatient mental health and substance abuse centers	7,649
621491	HMO medical centers	84
621492	Kidney dialysis centers	449
621493	Freestanding ambulatory surgical and emergency centers	4,554
621498	All other outpatient care centers	6,307
6215	Medical and diagnostic laboratories	7,200
6216	Home health care services	25,718
6219	All other ambulatory health care services	7,091
62321	Residential intellectual and developmental disability facilities	6,674
6221	General medical and surgical hospitals	2,445
6222	Psychiatric and substance abuse hospitals	434
6223	Specialty (except psychiatric and substance abuse) hospitals	301
6231	Nursing care facilities (skilled nursing facilities)	9,824
45611	Pharmacies and drug stores	17,160
6211	Offices of physicians	150,933
524114	Insurance Issuers	517
	Navigator grantees	58
	Total Entities	247,398

2. Whether the Rule Will Have a Significant Economic Impact on Covered Small Entities

The Department generally considers a rule to have a significant impact on a substantial number of small entities if it has at least a 3 percent impact on revenue on at least 5 percent of small entities. We performed a threshold analysis to determine whether the quantified impacts of the final rule will exceed these thresholds. As described earlier in this analysis, we estimate the total annualized costs of the final rule would be about $637.1 million. Dividing these total costs by the 247,398 small entities gives a cost per entity of $2,575. This cost estimate would only exceed the 3 percent ''significant impact'' threshold on revenue for any covered small businesses with revenue below $85,836. We conclude that very few small businesses covered by the final rule will have revenues below $85,836, and that this number is very likely to be smaller than the 5 percent ''substantial number'' threshold.

As an additional consideration, we note that the costs of the final rule are mostly proportional to the size of the covered entity. For example, the costs associated with training, which account for more than 70 percent of the total costs of the final rule, are mostly proportional to the number of employees receiving training. In the main analysis, we estimate an incremental impact of one (1) hour per employee trained. The opportunity cost of training each employee represents 0.05 percent of a full-time employee's annual labor productivity, assuming a full-time employee works 2,080 hours per year.[467] This finding, that the cost of training represents 0.05 percent of the share of employees receiving training, is constant across firm size.

Because the costs of the final rule are small relative to the revenue of covered entities, including covered small entities, and because even the smallest affected entities would be unlikely to face a significant impact, we certify that the final rule will not have a significant economic impact on a substantial number of small entities.

C. Executive Order 12250 on Leadership and Coordination of Nondiscrimination Laws

Pursuant to E.O. 12250, the Department of Justice has the responsibility to ''review . . . proposed rules . . . of the Executive agencies'' implementing nondiscrimination statutes such as section 1557 ''in order to identify those which are inadequate, unclear or unnecessarily inconsistent.''The Department of Justice has reviewed and approved this final rule.

D. Paperwork Reduction Act

Information Collection Requirements

This final rule contains information collection requirements (ICRs) that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act (PRA) of 1995.[468] In order to evaluate whether an information collection should be approved by OMB, the PRA requires that the Department solicits comment on the following issues:

1. Whether the information collection is necessary and useful to carry out the proper functions of the agency;
2. The accuracy of the agency's estimate of the information collection burden;
3. The quality, utility, and clarity of the information to be collected; and
4. Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.[469]

The PRA requires consideration of the time, effort, and financial resources necessary to meet the information collection requirements referenced in this section. The Department previously published a notice of a proposed data collection on August 4, 2022, at 87 FR 47907–08, as part of an NPRM entitled ''Nondiscrimination in Health Programs and Activities'' (RIN 0945–AA17), to invite public comment. OCR solicited comment on the issues listed above for the sections that contain ICRs. The following paragraphs describe these provisions, with an estimate of the annual burden, summarized in Table 1. OCR did not receive comments related to the previous notice but has adjusted the estimated respondent burden in this request to reflect revised assumptions based on updated information available at the time of the final rule's

[467] 40 hours per week × 52 weeks = 2,080 hours. 0.05% = 0.0005 = 1 hour ÷ 2080 hours.

[468] 44 U.S.C. 3501–3520.

[469] 44 U.S.C. 3506(c)(2)(A).

E. Assessment of Federal Regulation and Policies on Families

Section 654 of the Treasury and General Government Appropriations Act of 1999 requires Federal departments and agencies to determine whether a proposed policy or regulation could affect family well-being. If the determination is affirmative, then the Department or agency must prepare an impact assessment to address criteria specified in the law.

The final rule would not negatively affect family wellbeing and would strengthen the stability of the family by promoting the ability of all individuals and families to receive health care free from discrimination. As research demonstrates that experiencing discrimination can have a negative impact on health and wellbeing, this rule addresses the immediate and long-term effects of discriminatory actions and establishes a set of practices to remove barriers to accessing care among entities that receive Federal funds. Addressing and preventing discrimination in health care can also improve the financial stability of the family unit by increasing access to nondiscriminatory health insurance coverage and other health-related coverage, aiding parents in their ability to provide for and nurture their children. The rule may be carried out only by the Federal Government because it would implement Federal nondiscrimination law, ensuring that American families have access to health care information and services, regardless of the State where they are located.

List of Subjects

42 CFR Part 438

Citizenship and naturalization, Civil rights, Grant programs-health, Individuals with disabilities

Medicaid, Reporting and recordkeeping requirements, Sex discrimination.

42 CFR Part 440

Citizenship and naturalization, Civil rights, Grant programs-health, Individuals with disabilities, Medicaid, Sex discrimination.

42 CFR Part 457

Administrative practice and procedure, Grant programs-health, Health insurance, Reporting and recordkeeping requirements.

42 CFR Part 460

Aged, Citizenship and naturalization, Civil rights, Health, Health care, Health records, Individuals with disabilities, Medicaid, Medicare, Religious discrimination, Reporting and recordkeeping requirements, Sex discrimination.

45 CFR Part 80

Civil rights, Individuals with disabilities, Sex discrimination, Vocational education.

45 CFR Part 84

Civil rights, Equal educational opportunity, Equal employment opportunity, Health care, Individuals with disabilities, Infants and children, Reporting and recordkeeping requirements.

45 CFR Part 92

Administrative practice and procedure, Aged, Citizenship and naturalization, Civil rights, Communications equipment, Health facilities, Health insurance, Health programs or activities, Healthcare, Individuals with disabilities, Reporting and recordkeeping requirements, Sex discrimination.

45 CFR Part 147

Aged, Citizenship and naturalization, Civil rights, Health care, Health insurance, Individuals with disabilities, Intergovernmental relations, Reporting and recordkeeping requirements, Sex discrimination.

45 CFR Part 155

Administrative practice and procedure, Advertising, Aged, Brokers, Citizenship and naturalization, Civil rights, Conflict of interests, Consumer protection, Grant programs-health, Grants administration, Health care, Health insurance, Health maintenance organizations (HMO), Health records, Hospitals, Indians, Individuals with disabilities, Intergovernmental relations, Loan programs-health, Medicaid, Organization and functions (Government agencies), Public assistance programs, Reporting and recordkeeping requirements, Sex discrimination, State and local governments, Taxes, Technical assistance, Women, Youth.

45 CFR Part 156

Administrative practice and procedure, Advertising, Advisory committees, Brokers, Conflict of interests, Consumer protection, Grant programs-health, Grants administration, Health care, Health insurance, Health maintenance organization (HMO), Health records, Hospitals, Indians, Individuals with disabilities, Loan programs-health, Medicaid, Organization and functions (Government agencies), Public assistance programs, Reporting and recordkeeping requirements, State and local governments, Sunshine Act, Technical assistance, Women, Youth.

Dated: April 18, 2024.

Xavier Becerra,

Secretary, Department of Health and Human Services.

For the reasons set forth in the preamble, the Department of Health and Human Services amends 42 CFR parts 438, 440, 457, and 460 and 45 CFR parts 80, 84, 92, 147, 155, and 156 as follows:

Title 42—Public Health

PART 438—MANAGED CARE

■ 1. The authority citation for part 438 continues to read as follows:

Authority: 42 U.S.C. 1302.

■ 2. Amend § 438.3 by revising paragraph (d)(4) to read as follows:

§ 438.3 Standard contract requirements.

* * * * *

(d) * * *

(4) The MCO, PIHP, PAHP, PCCM or PCCM entity will not discriminate against individuals eligible to enroll on the basis of race; color; national origin; disability; or sex which includes sex characteristics, including intersex traits; pregnancy or related conditions; sexual orientation; gender identity; and sex stereotypes; and will not use any policy or practice that has the effect of discriminating on the basis of race; color; national origin; disability; or sex which includes discrimination on the basis of sex characteristics, including intersex traits; pregnancy or related conditions; sexual orientation; gender identity; and sex stereotypes.

* * * * *

■ 3. Amend § 438.206 by revising paragraph (c)(2) to read as follows:

§ 438.206 Availability of services.

* * * * *

(c) * * *

(2) *Access and cultural considerations.* Each MCO, PIHP, and PAHP participates in the State's efforts to promote the delivery of services in a culturally competent manner to all enrollees, including those with limited English proficiency and diverse cultural and ethnic backgrounds, disabilities, and regardless of sex which includes sex characteristics, including intersex traits; pregnancy or related conditions; sexual orientation; gender identity and sex stereotypes.

* * * * *

PART 440—SERVICES: GENERAL PROVISIONS

■ 4. The authority citation for part 440 continues to read as follows:

Authority: 42 U.S.C. 1302.

■ 5. Revise § 440.262 to read as follows:

§ 440.262 Access and cultural conditions.

The State must have methods to promote access and delivery of services in a culturally competent manner to all beneficiaries, including those with limited English proficiency, diverse cultural and ethnic backgrounds, disabilities, and regardless of sex which includes sex characteristics, including intersex traits; pregnancy or related conditions; sexual orientation; gender identity; and sex stereotypes. These methods must ensure that beneficiaries have access to covered services that are delivered in a manner that meets their individualized needs.

PART 457—ALLOTMENTS AND GRANTS TO STATES

■ 6. The authority citation for part 457 continues to read as follows:

Authority: 42 U.S.C. 1302.

■ 7. Amend § 457.495 by adding paragraph (e) to read as follows:

§ 457.495 State assurance of access to care and procedures to assure quality and appropriateness of care.

* * * * *

(e) Access to and delivery of services in a culturally competent manner to all beneficiaries, as described in 42 CFR 440.262.

PART 460—PROGRAMS OF ALL-INCLUSIVE CARE FOR THE ELDERLY (PACE)

■ 8. The authority citation for part 460 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395, 1395eee(f), and 1396u–4(f).

■ 9. Amend § 460.98 by revising paragraph (b)(3) to read as follows:

§ 460.98 Service delivery.

* * * * *

(b) * * *

(3) The PACE organization shall not discriminate against any participant in the delivery of required PACE services based on race, ethnicity, national origin, religion, sex (including sex characteristics, including intersex traits; pregnancy or related conditions; sexual orientation; gender identity; and sex stereotypes), age, mental or physical disability, or source of payment.

* * * * *

■ 10. Amend § 460.112 by revising paragraph (a) introductory text to read as follows:

§ 460.112 Specific rights to which a participant is entitled.

(a) *Respect and nondiscrimination.* Each participant has the right to considerate, respectful care from all PACE employees and contractors at all times and under all circumstances. Each participant has the right not to be discriminated against in the delivery of required PACE services based on race, ethnicity, national origin, religion, sex (including sex characteristics, including intersex traits; pregnancy or related conditions; sexual orientation; gender identity; and sex stereotypes), age, mental or physical disability, or source of payment. Specifically, each participant has the right to the following:

* * * * *

Title 45—Public Welfare

PART 80—NONDISCRIMINATION UNDER PROGRAMS RECEIVING FEDERAL ASSISTANCE THROUGH THE DEPARTMENT OF HEALTH AND HUMAN SERVICES EFFECTUATION OF TITLE VI OF THE CIVIL RIGHTS ACT OF 1964

■ 11. The authority citation for part 80 continues to read as follows:

Authority: Sec. 602, 78 Stat. 252; 42 U.S.C. 2000d–1.

■ 12. Amend appendix A to part 80 under part 1 by adding entry 155 in numerical order to read as follows:

Appendix A to Part 80—Federal Financial Assistance To Which These Regulations Apply Part 1. Assistance Other Than Continuing Assistance to States

* * * * *

155. Supplementary medical insurance benefits for the aged (Title XVIII, Part B, Social Security Act, 42 U.S.C. 1395j–1395w–6).

* * * * *

PART 84—NONDISCRIMINATION ON THE BASIS OF HANDICAP IN PROGRAMS OR ACTIVITIES RECEIVING FEDERAL FINANCIAL ASSISTANCE

■ 13. The authority citation for part 84 continues to read as follows:

Authority: 20 U.S.C. 1405; 29 U.S.C. 794; 42 U.S.C. 290dd–2; 21 U.S.C. 1174.

■ 14. Amend appendix A to part 84 in subpart a, under Definitions, by revising section 2 to read as follows:

Appendix A to Part 84—Analysis of Final Regulation

Subpart A—General Provisions

Definitions * * *

2. ''Federal financial assistance''. In § 84.3(h), defining Federal financial assistance, a clarifying change has been made: procurement contracts are specifically excluded. They are covered, however, by the Department of Labor's regulation under section 503. The Department has never considered such contracts to be contracts of assistance; the explicit exemption has been added only to avoid possible confusion.

The proposed regulation's exemption of contracts of insurance or guaranty has been retained. A number of comments argued for its deletion on the ground that section 504, unlike title VI and title IX, contains no statutory exemption for such contracts. There is no indication, however, in the legislative history of the Rehabilitation Act of 1973 or of the amendments to that Act in 1974, that Congress intended section 504 to have a broader application, in terms of Federal financial assistance, than other civil rights statutes. Indeed, Congress directed that section 504 be implemented in the same manner as titles VI and IX. In view of the long established exemption of contracts of insurance or guaranty under title VI, we think it unlikely that Congress intended section 504 to apply to such contracts.

* * * * *

■ 15. Revise part 92 to read as follows:

PART 92—NONDISCRIMINATION IN HEALTH PROGRAMS OR ACTIVITIES

Subpart A—General Provisions

Sec.
92.1 Purpose and effective date.
92.2 Application.
92.3 Relationship to other laws.
92.4 Definitions.
92.5 Assurances required.
92.6 Remedial action and voluntary action.
92.7 Designation and responsibilities of a Section 1557 Coordinator.
92.8 Policies and procedures.
92.9 Training.
92.10 Notice of nondiscrimination.
92.11 Notice of availability of language assistance services and auxiliary aids and services.

Subpart B—Nondiscrimination Provisions

92.101 Discrimination prohibited.

Subpart C—Specific Applications to Health Programs and Activities

92.201 Meaningful access for individuals with limited English proficiency.
92.202 Effective communication for individuals with disabilities.
92.203 Accessibility for buildings and facilities.
92.204 Accessibility of information and communication technology for individuals with disabilities.
92.205 Requirement to make reasonable modifications.

92.206 Equal program access on the basis of sex.
92.207 Nondiscrimination in health insurance coverage and other health-related coverage.
92.208 Prohibition on sex discrimination related to marital, parental, or family status.
92.209 Nondiscrimination on the basis of association.
92.210 Nondiscrimination in the use of patient care decision support tools.
92.211 Nondiscrimination in the delivery of health programs and activities through telehealth services.

Subpart D—Procedures

92.301 Enforcement mechanisms.
92.302 Notification of views regarding application of Federal religious freedom and conscience laws.
92.303 Procedures for health programs and activities conducted by recipients and State Exchanges.
92.304 Procedures for health programs and activities administered by the Department.

Authority: 42 U.S.C. 18116.

PART 92—NONDISCRIMINATION IN HEALTH PROGRAMS OR ACTIVITIES

Subpart A—General Provisions

§ 92.1 Purpose and effective date.

(a) *Purpose.* The purpose of this part is to implement section 1557 of the Patient Protection and Affordable Care Act (ACA) (42 U.S.C. 18116), which prohibits discrimination on the basis of race, color, national origin, sex, age, and disability in certain health programs and activities. Section 1557 provides that, except as otherwise provided in title I of the ACA, an individual shall not, on the grounds prohibited under title VI of the Civil Rights Act of 1964, title IX of the Education Amendments of 1972, the Age Discrimination Act of 1975, or section 504 of the Rehabilitation Act of 1973, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under, any health program or activity, any part of which is receiving Federal financial assistance, including credits, subsidies, or contracts of insurance, or under any program or activity that is administered by an executive agency or any entity established under title I of the ACA. This part applies to health programs or activities administered by recipients of Federal financial assistance from the Department, Department-administered health programs or activities, and title I entities that administer health programs or activities.

(b) *Effective date.* The regulations in this part are effective beginning July 5, 2024, unless otherwise provided in the following schedule:

TABLE 1 TO PARAGRAPH (b)

Section 1557 requirement and provision	Date by which covered entities must comply
§ 92.7	Within 120 days of July 5, 2024.
§ 92.8	Within one year of July 5, 2024.
§ 92.9	Following a covered entity's implementation of the policies and procedures required by § 92.8, and no later than one year of July 5, 2024.
§ 92.10	Within 120 days of July 5, 2024.
§ 92.11	Within one year of July 5, 2024.
§ 92.207(b)(1) through (5).	For health insurance coverage or other health-related coverage that was not subject to this part as of July 5, 2024, by the first day of the first plan year (in the individual market, policy year) beginning on or after January 1, 2025.
§ 92.207(b)(6)	By the first day of the first plan year (in the individual market, policy year) beginning on or after January 1, 2025.
§ 92.210(b) and (c)	Within 300 days of July 5, 2024.

§ 92.2 Application.

(a) Except as otherwise provided in this part, this part shall apply to:

(1) Every health program or activity, any part of which receives Federal financial assistance, directly or indirectly, from the Department;

(2) Every health program or activity administered by the Department; and

(3) Every health program or activity administered by a title I entity.

(b) The provisions of this part shall not apply to any employer or other plan sponsor of a group health plan, including but not limited to, a board of trustees (or similar body), association or other group, with regard to its employment practices, including the provision of employee health benefits.

(c) Any provision of this part held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, shall be severable from this part and shall not affect the remainder thereof or the application of the provision to other persons not similarly situated or to other, dissimilar circumstances.

§ 92.3 Relationship to other laws.

(a) Neither section 1557 nor this part shall be construed to apply a lesser standard for the protection of individuals from discrimination than the standards applied under title VI of the Civil Rights Act of 1964, title IX of the Education Amendments of 1972, section 504 of the Rehabilitation Act of 1973, the Age Discrimination Act of 1975, or the regulations issued pursuant to those laws.

(b) Nothing in this part shall be construed to invalidate or limit the rights, remedies, procedures, or legal standards available under title VI of the Civil Rights Act of 1964, title VII of the Civil Rights Act of 1964, title IX of the Education Amendments of 1972, section 504 of the Rehabilitation Act of 1973, or the Age Discrimination Act of 1975.

(c) Insofar as the application of any requirement under this part would violate applicable Federal protections for religious freedom and conscience, such application shall not be required. For example, 42 U.S.C. 18023 provides (among other things) that nothing in section 1557 shall be construed to have any effect on Federal laws regarding conscience protection; willingness or refusal to provide abortion; and discrimination on the basis of the willingness or refusal to provide, pay for, cover, or refer for abortion or to provide or participate in training to provide abortion.

(d) Nothing in this part shall be construed to supersede State or local laws that provide additional protections against discrimination on any basis described in § 92.1.

§ 92.4 Definitions.

As used in this part, the term—

1991 Standards means the 1991 ADA Standards for Accessible Design, published at appendix A to 28 CFR part 36 on July 26, 1991, and republished as appendix D to 28 CFR part 36 on September 15, 2010.

2010 Standards means 36 CFR part 1191, appendices B and D (2009), in conjunction with 28 CFR 35.151.

ACA means the Patient Protection and Affordable Care Act (Pub. L. 111–148, 124 Stat. 119 (2010) as amended by the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152, 124 Stat. 1029) (codified in scattered sections of U.S.C.)).

ADA means the Americans with Disabilities Act of 1990 (42 U.S.C. 12101 *et seq.*), as amended.

Age means how old a person is, or the number of elapsed years from the date of a person's birth.

Age Act means the Age Discrimination Act of 1975 (42 U.S.C. 6101 *et seq.*), as amended.

Applicant means a person who applies to participate in a health program or activity.

Auxiliary aids and services include, for example:

(1) Qualified interpreters on-site or through video remote interpreting (VRI) services, as defined in 28 CFR 35.104 and 36.104; note takers; real-time computer-aided transcription services; written materials; exchange of written notes; telephone handset amplifiers; assistive listening devices; assistive listening systems; telephones compatible with hearing aids; closed caption decoders; open and closed captioning, including real-time captioning; voice, text, and video-based telecommunications products and systems, including text telephones (TTYs), videophones, and captioned telephones, or equally effective telecommunications devices; videotext displays; accessible information and communication technology (ICT); or other effective methods of making aurally delivered information available to persons who are deaf or hard of hearing;

(2) Qualified readers; taped texts; audio recordings; Braille materials and displays; screen reader software; magnification software; optical readers; secondary auditory programs (SAP); large print materials; accessible information and communication technology; or other effective methods of making visually delivered materials available to persons who are blind or have low vision;

(3) Acquisition or modification of equipment and devices; and

(4) Other similar services and actions.

Companion means a family member, friend, or associate of an individual seeking access to a service, program, or activity of a covered entity, who along with such individual, is an appropriate person with whom a covered entity should communicate.

Covered entity means:

(1) A recipient of Federal financial assistance;

(2) The Department; and

(3) An entity established under title I of the ACA.

Department means the U.S. Department of Health and Human Services.

Director means the Director of the Office for Civil Rights (OCR) of the Department, or their designee(s).

Disability means, with respect to an individual, a physical or mental impairment that substantially limits one or more major life activities of such individual; a record of such an impairment; or being regarded as having such an impairment, as defined and construed in the Rehabilitation Act, 29 U.S.C. 705(9)(B), which incorporates the definition of ''disability'' in the ADA, 42 U.S.C. 12102, as amended and adopted at 28 CFR 35.108.

Exchange means the same as ''Exchange'' defined in 45 CFR 155.20.

Federal financial assistance, as used in this part:

(1) Federal financial assistance means any grant, loan, credit, subsidy, contract (other than a procurement contract but including a contract of insurance), or any other arrangement by which the Federal Government, directly or indirectly, provides assistance or otherwise makes assistance available in the form of:

(i) Funds;

(ii) Services of Federal personnel; or

(iii) Real or personal property or any interest in or use of such property, including:

(A) Transfers or leases of such property for less than fair market value or for reduced consideration; and

(B) Proceeds from a subsequent transfer or lease of such property if the Federal share of its fair market value is not returned to the Federal Government.

(2) Federal financial assistance the Department provides or otherwise makes available includes Federal financial assistance that the Department plays a role in providing or administering, including advance payments of the premium tax credit and cost-sharing reduction payments under title I of the ACA, as well as payments, subsidies, or other funds extended by the Department to any entity providing health insurance coverage for payment to or on behalf of a person obtaining health insurance coverage from that entity or extended by the Department directly to such person for payment to any entity providing health insurance coverage.

Federally-facilitated Exchange means the same as ''Federally-facilitated Exchange'' defined in 45 CFR 155.20.

Health program or activity means:

(1) Any project, enterprise, venture, or undertaking to:

(i) Provide or administer health-related services, health insurance coverage, or other health-related coverage;

(ii) Provide assistance to persons in obtaining health-related services, health insurance coverage, or other health-related coverage;

(iii) Provide clinical, pharmaceutical, or medical care;

(iv) Engage in health or clinical research; or

(v) Provide health education for health care professionals or others.

(2) All of the operations of any entity principally engaged in the provision or administration of any health projects, enterprises, ventures, or undertakings described in paragraph (1) of this definition, including, but not limited to, a State or local health agency, hospital, health clinic, health insurance issuer, physician's practice, pharmacy, community-based health care provider, nursing facility, residential or community-based treatment facility, or other similar entity or combination thereof. A health program or activity also includes all of the operations of a State Medicaid program, Children's Health Insurance Program, and Basic Health Program.

Individual with limited English proficiency means an individual whose primary language for communication is not English and who has a limited ability to read, write, speak, or understand English. An individual with limited English proficiency may be competent in English for certain types of communication (*e.g.,* speaking or understanding), but still be limited English proficient for other purposes (*e.g.,* reading or writing).

Information and communication technology (ICT) means information technology and other equipment, systems, technologies, or processes, for which the principal function is the creation, manipulation, storage, display, receipt, or transmission of electronic data and information, as well as any associated content. Examples of ICT include, but are not limited to: computers and peripheral equipment; information kiosks and transaction machines; telecommunications equipment; telehealth interfaces or applications; customer premises equipment; multifunction office machines; software; mobile applications; websites; videos; and electronic documents.

Language assistance services may include, but are not limited to:

(1) Oral language assistance, including interpretation in non-English languages provided in-person or remotely by a qualified interpreter for an individual with limited English proficiency, and the use of qualified bilingual or multilingual staff to communicate directly with individuals with limited English proficiency;

(2) Written translation, performed by a qualified translator, of written content in paper or electronic form into or from languages other than English; and

(3) Written notice of availability of language assistance services.

Machine translation means automated translation, without the assistance of or review by a qualified human translator, that is text-based and provides instant translations between various languages, sometimes with an option for audio input or output.

National origin includes, but is not limited to, a person's, or their ancestors', place of origin (such as country or world region) or a person's manifestation of the physical, cultural, or linguistic characteristics of a national origin group.

OCR means the Office for Civil Rights of the Department.

Patient care decision support tool means any automated or non-automated tool, mechanism, method, technology, or combination thereof used by a covered entity to support clinical decision-making in its health programs or activities.

Qualified bilingual/multilingual staff means a member of a covered entity's workforce who is designated by the covered entity to provide in-language oral language assistance as part of the person's current, assigned job responsibilities and who has demonstrated to the covered entity that they are:

(1) Proficient in speaking and understanding both spoken English and at least one other spoken language, including any necessary specialized vocabulary, terminology and phraseology; and

(2) Able to effectively, accurately, and impartially communicate directly with individuals with limited English proficiency in their primary languages.

Qualified individual with a disability means an individual with a disability who, with or without reasonable modifications to rules, policies, or practices, the removal of architectural, communication, or transportation barriers, or the provision of auxiliary aids and services, meets the essential eligibility requirements for the receipt of services or the participation in programs or activities provided by the covered entity.

Qualified interpreter for an individual with a disability means an interpreter who, via a video remote interpreting service (VRI) or an on-site appearance:

(1) Has demonstrated proficiency in communicating in, and understanding:

(i) Both English and a non-English language (including American Sign Language, other sign languages); or

(ii) Another communication modality (such as cued-language transliterators or oral transliteration);

(2) Is able to interpret effectively, accurately, and impartially, both receptively and expressively, using any necessary specialized vocabulary or terms without changes, omissions, or additions and while preserving the tone, sentiment, and emotional level of the original statement; and

(3) Adheres to generally accepted interpreter ethics principles including client confidentiality.

(4) Qualified interpreters include, for example, sign language interpreters, oral transliterators, and cued-language transliterators.

Qualified interpreter for an individual with limited English proficiency means an interpreter who via a remote interpreting service or an on-site appearance:

(1) Has demonstrated proficiency in speaking and understanding both spoken English and at least one other spoken language (qualified interpreters for relay interpretation must demonstrate proficiency in two non-English spoken languages);

(2) Is able to interpret effectively, accurately, and impartially to and from such language(s) and English (or between two non-English languages for relay interpretation), using any necessary specialized vocabulary or terms without changes, omissions, or additions and while preserving the tone, sentiment, and emotional level of the original oral statement; and

(3) Adheres to generally accepted interpreter ethics principles, including client confidentiality.

Qualified reader means a person who is able to read effectively, accurately, and impartially using any necessary specialized vocabulary.

Qualified translator means a translator who:

(1) Has demonstrated proficiency in writing and understanding both written English and at least one other written non-English language;

(2) Is able to translate effectively, accurately, and impartially to and from such language(s) and English, using any necessary specialized vocabulary or terms without changes, omissions, or additions and while preserving the tone, sentiment, and emotional level of the original written statement; and

(3) Adheres to generally accepted translator ethics principles, including client confidentiality.

Recipient means any State or its political subdivision thereof; or any instrumentality of a State or political subdivision thereof; any public or private agency, institution, or organization; other entity; or any person, to whom Federal financial assistance is extended directly or indirectly, including any subunit, successor, assignee, or transferee of a recipient. Such term does not include any ultimate beneficiary.

Relay interpretation means interpreting from one language to another through an intermediate language. This mode of interpretation is often used for monolingual speakers of languages of limited diffusion, including select indigenous languages. In relay interpreting, the first interpreter listens to the speaker and renders the message into the intermediate language. The second interpreter receives the message in the intermediate language and interprets it into a third language for the speaker who speaks neither the first nor the second language.

Section 504 means section 504 of the Rehabilitation Act of 1973 (Pub. L. 93–112; 29 U.S.C. 794), as amended.

Section 1557 means section 1557 of the ACA (42 U.S.C. 18116).

State includes each of the several States, the District of Columbia, the Commonwealth of Puerto Rico, Guam, American Samoa, the United States Virgin Islands, and the Commonwealth of the Northern Mariana Islands.

State Exchange means an Exchange established by a State and approved by the Department pursuant to 45 CFR part 155, subpart B.

Telehealth means the use of electronic information and telecommunications technologies to support long-distance clinical health care, patient and professional health-related education, public health, and health administration. Technologies include videoconferencing, the internet, store-and-forward imaging, streaming media, and terrestrial and wireless communications.

Title I entity means any entity established under title I of the ACA, as amended, including State Exchanges and Federally-facilitated Exchanges.

Title VI means title VI of the Civil Rights Act of 1964 (Pub. L. 88–352; 42 U.S.C. 2000d *et seq.*), as amended.

Title VII means title VII of the Civil Rights Act of 1964 (Pub. L. 88–352; 42 U.S.C. 2000e *et seq.*), as amended.

Title IX means title IX of the Education Amendments of 1972 (Pub. L. 92–318; 20 U.S.C. 1681 *et seq.*), as amended.

UFAS means the Uniform Federal Accessibility Standards (Pub. L. 90–480; 42 U.S.C. 4151 *et seq.*), as amended.

§ 92.5 Assurances required.

(a) *Assurances.* An entity applying for Federal financial assistance to which this part applies must, as a condition of any application for Federal financial assistance, submit an assurance, on a form specified by the Director, that the entity's health programs and activities will be operated in compliance with section 1557 and this part. A health insurance issuer seeking certification to participate in an Exchange or a State seeking approval to operate a State Exchange to which section 1557 or this part applies must, as a condition of certification or approval, submit an assurance, on a form specified by the Director, that the health insurance issuer's or State's health program or activity will be operated in compliance with section 1557 and this part. An applicant or entity may incorporate this assurance by reference in subsequent applications to the Department for Federal financial assistance or requests for certification to participate in an Exchange or approval to operate a State Exchange.

(b) *Duration of obligation.* The duration of the assurances required by this section is the same as the duration of the assurances required in the Department's regulations implementing section 504, 45 CFR 84.5(b).

(c) *Covenants.* When Federal financial assistance is provided in the form of real property or interest, the same conditions apply as those contained in the Department's regulations implementing section 504, at 45 CFR 84.5(c), except that the nondiscrimination obligation applies to discrimination on all bases covered under section 1557 and this part.

§ 92.6 Remedial action and voluntary action.

(a) *Remedial action.* (1) If the Director finds that a recipient or State Exchange has discriminated against an individual on the basis of race, color, national origin, sex, age, or disability, in violation of section 1557 or this part, such recipient or State Exchange must take such remedial action as the Director may require to overcome the effects of the discrimination.

(2) Where a recipient is found to have discriminated against an individual on the basis of race, color, national origin, sex, age, or disability, in violation of section 1557 or this part, and where another recipient exercises control over the recipient that has discriminated, the Director, where appropriate, may require either or both entities to take remedial action.

(3) The Director may, where necessary to overcome the effects of discrimination in violation of section 1557 or this part, require a recipient, in its health programs and activities, or State Exchange to take remedial action with respect to:

(i) Persons who are no longer participants in the recipient's or State Exchange's health program or activity but who were participants in the health program or activity when such discrimination occurred; or

(ii) Persons who would have been participants in the health program or activity had the discrimination not occurred.

(b) *Voluntary action.* A covered entity may take nondiscriminatory steps, in addition to any action that is required by section 1557 or this part, to overcome the effects of conditions that result or resulted in limited participation in the covered entity's health programs or activities by persons on the basis of race, color, national origin, sex, age, or disability.

§ 92.7 Designation and responsibilities of a Section 1557 Coordinator.

(a) *Section 1557 Coordinator and designees.* A covered entity that employs fifteen or more persons must designate and authorize at least one employee, a ''Section 1557 Coordinator,'' to coordinate the covered entity's compliance with its responsibilities under section 1557 and this part in its health programs and activities, including the investigation of any grievance communicated to it alleging noncompliance with section 1557 or this part or alleging any action that would be prohibited by section 1557 or this part. As appropriate, a covered entity may assign one or more designees to carry out some of these responsibilities, but the Section 1557 Coordinator must retain ultimate oversight for ensuring coordination with the covered entity's compliance with this part.

(b) *Responsibilities of a Section 1557 Coordinator.* A covered entity must ensure that, at minimum, the Section 1557 Coordinator:

(1) Receives, reviews, and processes grievances, filed under the grievance procedure as set forth in § 92.8(c);

(2) Coordinates the covered entity's recordkeeping requirements as set forth in § 92.8(c);

(3) Coordinates effective implementation of the covered entity's language access procedures as set forth in § 92.8(d);

(4) Coordinates effective implementation of the covered entity's effective communication procedures as set forth in § 92.8(e);

(5) Coordinates effective implementation of the covered entity's reasonable modification procedures as set forth in § 92.8(f); and

(6) Coordinates training of relevant employees as set forth in § 92.9, including maintaining documentation required by such section.

§ 92.8 Policies and procedures.

(a) *General requirement.* A covered entity must implement written policies and procedures in its health programs and activities that are designed to comply with the requirements of this part. The policies and procedures must include an effective date and be reasonably designed, taking into account the size, complexity, and the type of health programs or activities undertaken by a covered entity, to ensure compliance with this part.

(b) *Nondiscrimination policy.* (1) A covered entity must implement a written policy in its health programs and activities that, at minimum, states the covered entity does not discriminate on the basis of race, color, national origin (including limited English proficiency and primary language), sex (consistent with the scope of sex discrimination described at § 92.101(a)(2)), age, or disability; that the covered entity provides language assistance services and appropriate auxiliary aids and services free of charge, when necessary for compliance with section 1557 or this part; that the covered entity will provide reasonable modifications for individuals with disabilities; and that provides the current contact information for the Section 1557 Coordinator required by § 92.7 (if applicable).

(2) OCR considers it a best practice toward achieving compliance for a covered entity to provide information that it has been granted a temporary exemption or granted an assurance of exemption under § 92.302(b) in the nondiscrimination policy required by paragraph (b)(1) of this section.

(c) *Grievance procedures.* (1) A covered entity that employs fifteen or more persons must implement written grievance procedures in its health programs and activities that provide for the prompt and equitable resolution of grievances alleging any action that would be prohibited by section 1557 or this part.

(2) A covered entity to which this paragraph applies must retain records related to grievances filed pursuant to the covered entity's grievance procedures required under paragraph (c)(1) of this section that allege discrimination on the basis of race, color, national origin, sex, age, or disability for no less than three (3) calendar years from the date the covered entity resolves the grievance. The records must include the grievance; the name and contact information of the complainant (if provided by complainant); the alleged discriminatory action and alleged basis (or bases) of discrimination; the date the grievance was filed; the date the grievance was resolved; grievance resolution; and any other pertinent information.

(3) A covered entity to which this paragraph (c) applies must keep confidential the identity of an individual who has filed a grievance under this part except as required by law or to the extent necessary to carry out the purposes of this part, including the conduct of any investigation.

(d) *Language access procedures.* A covered entity must implement written language access procedures in its health programs and activities describing the covered entity's process for providing language assistance services to individuals with limited English proficiency when required under § 92.201. At a minimum, the language access procedures must include current contact information for the section 1557 Coordinator (if applicable); how an employee identifies whether an individual has limited English proficiency; how an employee obtains the services of qualified interpreters and translators the covered entity uses to communicate with an individual with limited English proficiency; the names of any qualified bilingual staff members; and a list of any electronic and written translated materials the covered entity has, the languages they are translated into, date of issuance, and how to access electronic translations.

(e) *Effective communication procedures.* A covered entity must implement written effective communication procedures in its health programs and activities describing the covered entity's process for ensuring effective communication for individuals with disabilities when required under § 92.202. At a minimum, a covered entity's effective communication procedures must include current contact information for the Section 1557 Coordinator (if applicable); how an employee obtains the services of qualified interpreters the covered entity uses to communicate with individuals with disabilities, including the names of any qualified interpreter staff members; and how to access appropriate auxiliary aids and services.

(f) *Reasonable modification procedures.* A covered entity must implement written procedures in its health programs and activities describing the covered entity's process for making reasonable modifications to its policies, practices, or procedures when necessary to avoid discrimination on the basis of disability as required under § 92.205. At a minimum, the reasonable modification procedures must include current contact information for the covered entity's Section 1557 Coordinator (if applicable); a description of the covered entity's process for responding to requests from individuals with disabilities for changes, exceptions, or adjustments to a rule, policy, practice, or service of the covered entity; and a process for determining whether making the modification would fundamentally alter the nature of the health program or activity, including identifying an alternative modification that does not result in a fundamental alteration to ensure the individual with a disability receives the benefits or services in question.

(g) *Combined policies and procedures.* A covered entity may combine the content of the policies and procedures required by paragraphs (b) through (f) of this section with any policies and procedures pursuant to title VI, section 504, title IX, and the Age Act if section 1557 and the provisions in this part are clearly addressed therein.

(h) *Changes to policies and procedures.* (1) Covered entities must review and revise the policies and procedures required by paragraphs (b) through (g) of this section, as necessary, to ensure they are current and in compliance with section 1557 and this part; and

(2) A covered entity may change a policy or procedure required by paragraphs (b) through (g) of this section at any time, provided that such changes comply with section 1557 and this part.

§ 92.9 Training.

(a) A covered entity must train relevant employees of its health programs and activities on the civil rights policies and procedures required by § 92.8, as necessary and appropriate for the employees to carry out their functions within the covered entity consistent with the requirements of this part.

(b) A covered entity must provide training that meets the requirements of paragraph (a) of this section, as follows:

(1) To each relevant employee of the health program or activity as soon as possible, but no later than 30 days following a covered entity's implementation of the policies and procedures required by § 92.8, and no later than 300 days following July 5, 2024;

(2) Thereafter, to each new relevant employee of the health program or activity within a reasonable period of time after the employee joins the covered entity's workforce; and

(3) To each relevant employee of the health program or activity whose functions are affected by a material change in the policies or procedures required by § 92.8 and any other civil rights policies or procedures the covered entity has implemented within a reasonable period of time after the material change has been made.

(4) For purposes of this section, ''relevant employees'' includes permanent and temporary employees whose roles and responsibilities entail interacting with patients and members of the public; making decisions that directly or indirectly affect patients' health care, including the covered entity's executive leadership team and legal counsel; and performing tasks and making decisions that directly or indirectly affect patients' financial obligations, including billing and collections.

(c) A covered entity must contemporaneously document its employees' completion of the training required by paragraphs (a) and (b) of this section in written or electronic form and retain said documentation for no less than three (3) calendar years.

§ 92.10 Notice of nondiscrimination.

(a) A covered entity must provide a notice of nondiscrimination to participants, beneficiaries, enrollees, and applicants of its health programs and activities, and members of the public.

(1) The notice required under this paragraph (a) must include the following information relating to the covered entity's health programs and activities:

(i) The covered entity does not discriminate on the basis of race, color, national origin (including limited English proficiency and primary language), sex (consistent with the scope of sex discrimination described at § 92.101(a)(2)), age, or disability;

(ii) The covered entity provides reasonable modifications for individuals with disabilities, and appropriate

auxiliary aids and services, including qualified interpreters for individuals with disabilities and information in alternate formats, such as braille or large print, free of charge and in a timely manner, when such modifications, aids, and services are necessary to ensure accessibility and an equal opportunity to participate to individuals with disabilities;

(iii) The covered entity provides language assistance services, including electronic and written translated documents and oral interpretation, free of charge and in a timely manner, when such services are a reasonable step to provide meaningful access to an individual with limited English proficiency;

(iv) How to obtain from the covered entity the reasonable modifications, appropriate auxiliary aids and services, and language assistance services in paragraphs (a)(1)(ii) and (iii) of this section;

(v) The contact information for the covered entity's Section 1557 Coordinator designated pursuant to § 92.7 (if applicable);

(vi) The availability of the covered entity's grievance procedure pursuant to § 92.8(c) and how to file a grievance (if applicable);

(vii) Details on how to file a discrimination complaint with OCR in the Department; and

(viii) How to access the covered entity's website, if it has one, that provides the information required under this paragraph (a)(1).

(2) The notice required under this paragraph (a) must be provided in a covered entity's health program or activity, as follows:

(i) On an annual basis to participants, beneficiaries, enrollees (including late and special enrollees), and applicants of its health program or activity;

(ii) Upon request;

(iii) At a conspicuous location on the covered entity's health program or activity website, if it has one; and

(iv) In clear and prominent physical locations, in no smaller than 20-point sans serif font, where it is reasonable to expect individuals seeking service from the health program or activity to be able to read or hear the notice.

(b) A covered entity may combine the content of the notice required by paragraph (a) of this section with the notices required by 45 CFR 80.6(d), 84.8, 86.9, and 91.32 if the combined notice clearly informs individuals of their civil rights under section 1557 and this part, so long as it includes each of the elements required by paragraph (a)(1) of this section.

§ 92.11 Notice of availability of language assistance services and auxiliary aids and services.

(a) A covered entity must provide a notice of availability of language assistance services and auxiliary aids and services that, at minimum, states that the covered entity, in its health programs or activities, provides language assistance services and appropriate auxiliary aids and services free of charge, when necessary for compliance with section 1557 or this part, to participants, beneficiaries, enrollees, and applicants of its health program or activities, and members of the public.

(b) The notice required under paragraph (a) of this section must be provided in English and at least the 15 languages most commonly spoken by individuals with limited English proficiency of the relevant State or States in which a covered entity operates and must be provided in alternate formats for individuals with disabilities who require auxiliary aids and services to ensure effective communication.

(c) The notice required under paragraph (a) of this section must be provided in a covered entity's health program or activity, as follows:

(1) On an annual basis to participants, beneficiaries, enrollees (including late and special enrollees), and applicants of its health program or activity;

(2) Upon request;

(3) At a conspicuous location on the covered entity's health program or activity website, if it has one;

(4) In clear and prominent physical locations, in no smaller than 20-point sans serif font, where it is reasonable to expect individuals seeking service from the health program or activity to be able to read or hear the notice; and

(5) In the following electronic and written communications when these forms are provided by a covered entity:

(i) Notice of nondiscrimination required by § 92.10;

(ii) Notice of privacy practices required by 45 CFR 164.520;

(iii) Application and intake forms;

(iv) Notices of denial or termination of eligibility, benefits or services, including Explanations of Benefits, and notices of appeal and grievance rights;

(v) Communications related to an individual's rights, eligibility, benefits, or services that require or request a response from a participant, beneficiary, enrollee, or applicant;

(vi) Communications related to a public health emergency;

(vii) Consent forms and instructions related to medical procedures or operations, medical power of attorney, or living will (with an option of providing only one notice for all documents bundled together);

(viii) Discharge papers;

(ix) Communications related to the cost and payment of care with respect to an individual, including medical billing and collections materials, and good faith estimates required by section 2799B–6 of the Public Health Service Act;

(x) Complaint forms; and

(xi) Patient and member handbooks.

(d) A covered entity shall be deemed in compliance with this section with respect to an individual if it exercises the option to:

(1) On an annual basis, provide the individual with the option to opt out of receipt of the notice required by this section in their primary language and through any appropriate auxiliary aids and services, and:

(i) Does not condition the receipt of any aid or benefit on the individual's decision to opt out;

(ii) Informs the individual that they have a right to receive the notice upon request in their primary language and through the appropriate auxiliary aids and services;

(iii) Informs the individual that opting out of receiving the notice is not a waiver of their right to receive language assistance services and any appropriate auxiliary aids and services as required by this part;

(iv) Documents, on an annual basis, that the individual has opted out of receiving the notice required by this section for that year; and

(v) Does not treat a non-response from an individual as a decision to opt out; or

(2) Document the individual's primary language and any appropriate auxiliary aids and services and:

(i) Provides all materials and communications in that individual's primary language and through any appropriate auxiliary aids and services; or

(ii) Provides the notice required by paragraph (a) of this section in that individual's primary language and through any appropriate auxiliary aids and services in all communications that are identified in paragraph (c)(5) of this section.

Subpart B—Nondiscrimination Provisions

§ 92.101 Discrimination prohibited.

(a) *General.* (1) Except as provided in title I of the ACA, an individual must not, on the basis of race, color, national origin, sex, age, disability, or any combination thereof, be excluded from

participation in, be denied the benefits of, or otherwise be subjected to discrimination under any health program or activity operated by a covered entity.

(2) Discrimination on the basis of sex includes, but is not limited to, discrimination on the basis of:

(i) Sex characteristics, including intersex traits;

(ii) Pregnancy or related conditions;

(iii) Sexual orientation;

(iv) Gender identity; and

(v) Sex stereotypes.

(b) *Specific prohibitions on discrimination.* (1) In any health program or activity to which this part applies:

(i) A recipient and State Exchange must comply with the specific prohibitions on discrimination in the Department's implementing regulations for title VI, section 504, title IX, and the Age Act, found at 45 CFR parts 80, 84, 86 (subparts C and D), and 91 (subpart B), respectively. Where this paragraph (b) cross-references regulatory provisions that use the term ''recipient,'' the term ''recipient or State Exchange'' shall apply in its place. Where this paragraph (b) cross-references regulatory provisions that use the term ''student,'' ''employee,'' or ''applicant,'' these terms shall be replaced with ''individual.''

(ii) The Department, including Federally-facilitated Exchanges, must comply with specific prohibitions on discrimination in the Department's implementing regulations for title VI, section 504, title IX, and the Age Act, found at 45 CFR parts 80, 85, 86 (subparts C and D), and 91 (subpart B), respectively. Where this paragraph (b) cross-references regulatory provisions that use the term ''a recipient,'' the term ''the Department or a Federally-facilitated Exchange'' shall apply in its place. Where this paragraph (b) cross-references regulatory provisions that use the term ''student,'' ''employee,'' or ''applicant,'' these terms shall be replaced with ''individual.''

(2) The enumeration of specific prohibitions on discrimination in paragraph (b)(1) of this section does not limit the general applicability of the prohibition in paragraph (a) of this section.

Subpart C—Specific Applications to Health Programs and Activities

§ 92.201 Meaningful access for individuals with limited English proficiency.

(a) *General requirement.* A covered entity must take reasonable steps to provide meaningful access to each individual with limited English proficiency (including companions with limited English proficiency) eligible to be served or likely to be directly affected by its health programs and activities.

(b) *Language assistance services requirements.* Language assistance services required under paragraph (a) of this section must be provided free of charge, be accurate and timely, and protect the privacy and the independent decision-making ability of the individual with limited English proficiency.

(c) *Specific requirements for interpreter and translation services.* (1) When interpretation services are required under this part, a covered entity must offer a qualified interpreter in its health programs and activities.

(2) When translation services are required under this part, a covered entity must utilize the services of a qualified translator in its health programs and activities.

(3) If a covered entity uses machine translation when the underlying text is critical to the rights, benefits, or meaningful access of an individual with limited English proficiency, when accuracy is essential, or when the source documents or materials contain complex, non-literal or technical language, the translation must be reviewed by a qualified human translator.

(d) *Evaluation of compliance.* In evaluating whether a covered entity has met its obligation under paragraph (a) of this section, the Director shall:

(1) Evaluate, and give substantial weight to, the nature and importance of the health program or activity and the particular communication at issue, to the individual with limited English proficiency; and

(2) Take into account other relevant factors, including the effectiveness of the covered entity's written language access procedures for its health programs and activities, that the covered entity has implemented pursuant to § 92.8(d).

(e) *Restricted use of certain persons to interpret or facilitate communication.* A covered entity must not, in its health programs and activities:

(1) Require an individual with limited English proficiency to provide their own interpreter, or to pay the cost of their own interpreter;

(2) Rely on an adult, not qualified as an interpreter, to interpret or facilitate communication, except:

(i) As a temporary measure, while finding a qualified interpreter in an emergency involving an imminent threat to the safety or welfare of an individual or the public where there is no qualified interpreter for the individual with limited English proficiency immediately available and the qualified interpreter that arrives confirms or supplements the initial communications with an initial adult interpreter; or

(ii) Where the individual with limited English proficiency specifically requests, in private with a qualified interpreter present and without an accompanying adult present, that the accompanying adult interpret or facilitate communication, the accompanying adult agrees to provide such assistance, the request and agreement by the accompanying adult is documented, and reliance on that adult for such assistance is appropriate under the circumstances;

(3) Rely on a minor child to interpret or facilitate communication, except as a temporary measure while finding a qualified interpreter in an emergency involving an imminent threat to the safety or welfare of an individual or the public where there is no qualified interpreter for the individual with limited English proficiency immediately available and the qualified interpreter that arrives confirms or supplements the initial communications with the minor child; or

(4) Rely on staff other than qualified interpreters, qualified translators, or qualified bilingual/multilingual staff to communicate with individuals with limited English proficiency.

(f) *Video remote interpreting services.* A covered entity that provides a qualified interpreter for an individual with limited English proficiency through video remote interpreting services in the covered entity's health programs and activities must ensure the modality allows for meaningful access and must provide:

(1) Real-time, full-motion video and audio over a dedicated high-speed, wide-bandwidth video connection or wireless connection that delivers high quality video images that do not produce lags, choppy, blurry, or grainy images, or irregular pauses in communication;

(2) A sharply delineated image that is large enough to display the interpreter's face and the participating person's face regardless of the person's body position;

(3) A clear, audible transmission of voices; and

(4) Adequate training to users of the technology and other involved persons so that they may quickly and efficiently set up and operate the video remote interpreting.

(g) *Audio remote interpreting services.* A covered entity that provides a qualified interpreter for an individual with limited English proficiency through audio remote interpreting

services in the covered entity's health programs and activities must ensure the modality allows for meaningful access and must provide:

(1) Real-time audio over a dedicated high-speed, wide-bandwidth connection or wireless connection that delivers high-quality audio without lags or irregular pauses in communication;

(2) A clear, audible transmission of voices; and

(3) Adequate training to users of the technology and other involved persons so that they may quickly and efficiently set up and operate the remote interpreting services.

(h) *Acceptance of language assistance services is not required.* Nothing in this section shall be construed to require an individual with limited English proficiency to accept language assistance services.

§ 92.202 Effective communication for individuals with disabilities.

(a) A covered entity must take appropriate steps to ensure that communications with individuals with disabilities (including companions with disabilities), are as effective as communications with non-disabled individuals in its health programs and activities, in accordance with the standards found at 28 CFR 35.130 and 35.160 through 35.164. Where the regulatory provisions referenced in this section use the term ''public entity,'' the term ''covered entity'' shall apply in its place.

(b) A covered entity must provide appropriate auxiliary aids and services where necessary to afford individuals with disabilities an equal opportunity to participate in, and enjoy the benefits of, the health program or activity in question. Such auxiliary aids and services must be provided free of charge, in accessible formats, in a timely manner, and in such a way to protect the privacy and the independence of the individual with a disability.

§ 92.203 Accessibility for buildings and facilities.

(a) No qualified individual with a disability shall, because a covered entity's facilities are inaccessible to or unusable by individuals with disabilities, be denied the benefits of, be excluded from participation in, or otherwise be subjected to discrimination under any health program or activity to which this part applies.

(b) Each facility or part of a facility in which health programs or activities are conducted that is constructed or altered by or on behalf of, or for the use of, a recipient or State Exchange must comply with the 2010 Standards if the construction or alteration was commenced on or after July 18, 2016, except that if a facility or part of a facility in which health programs or activities are conducted that is constructed or altered by or on behalf of, or for the use of, a recipient or State Exchange, was not covered by the 2010 Standards prior to July 18, 2016, such facility or part of a facility must comply with the 2010 Standards if the construction or alteration was commenced after January 18, 2018. If construction or alteration was begun on or after July 18, 2016, and on or before January 18, 2018, in conformance with UFAS, and the facility or part of the facility was not covered by the 2010 Standards prior to July 18, 2016, then it shall be deemed to comply with the requirements of this section and with 45 CFR 84.23(a) and (b). Departures from particular technical and scoping requirements by the use of other methods are permitted where substantially equivalent or greater access to and usability of the facility is provided. All newly constructed or altered buildings or facilities subject to this section must comply with the requirements for a ''public building or facility'' as defined in section 106.5 of the 2010 Standards.

(c) Each facility or part of a facility in which health programs or activities under this part are conducted that is constructed or altered by or on behalf of, or for the use of, a recipient or State Exchange in conformance with the 1991 Standards at appendix D to 28 CFR part 36 or the 2010 Standards shall be deemed to comply with the requirements of this section and with 45 CFR 84.23(a) and (b) with respect to those facilities, if the construction or alteration was commenced before July 18, 2016. Each facility or part of a facility in which health programs or activities are conducted that is constructed or altered by or on behalf of, or for the use of, a recipient or State Exchange in conformance with UFAS shall be deemed to comply with the requirements of this section and with 45 CFR 84.23(a) and (b), if the construction or alteration was commenced before July 18, 2016, and such facility would not have been required to conform with a different accessibility standard under 28 CFR 35.151.

§ 92.204 Accessibility of information and communication technology for individuals with disabilities.

(a) A covered entity must ensure that its health programs and activities provided through information and communication technology are accessible to individuals with disabilities, unless doing so would result in undue financial and administrative burdens or a fundamental alteration in the nature of the health programs or activities. If an action required to comply with this section would result in such an alteration or such burdens, a covered entity shall take any other action that would not result in such an alteration or such burdens but would nevertheless ensure that, to the maximum extent possible, individuals with disabilities receive the benefits or services of the health program or activity provided by the covered entity.

(b) A recipient or State Exchange shall ensure that its health programs and activities provided through websites and mobile applications comply with the requirements of section 504 of the Rehabilitation Act, as interpreted consistent with title II of the ADA (42 U.S.C. 12131 through 12165).

§ 92.205 Requirement to make reasonable modifications.

A covered entity must make reasonable modifications to policies, practices, or procedures in its health programs and activities when such modifications are necessary to avoid discrimination on the basis of disability, unless the covered entity can demonstrate that making the modifications would fundamentally alter the nature of the health program or activity. For the purposes of this section, the term ''reasonable modifications'' shall be interpreted in a manner consistent with the term as set forth in the ADA title II regulation at 28 CFR 35.130(b)(7).

§ 92.206 Equal program access on the basis of sex.

(a) A covered entity must provide individuals equal access to its health programs and activities without discriminating on the basis of sex.

(b) In providing access to health programs and activities, a covered entity must not:

(1) Deny or limit health services, including those that have been typically or exclusively provided to, or associated with, individuals of one sex, to an individual based upon the individual's sex assigned at birth, gender identity, or gender otherwise recorded;

(2) Deny or limit, on the basis of an individual's sex assigned at birth, gender identity, or gender otherwise recorded, a health care professional's ability to provide health services if such denial or limitation has the effect of excluding individuals from participation in, denying them the benefits of, or otherwise subjecting them

to discrimination on the basis of sex under a covered health program or activity;

(3) Adopt or apply any policy or practice of treating individuals differently or separating them on the basis of sex in a manner that subjects any individual to more than de minimis harm, including by adopting a policy or engaging in a practice that prevents an individual from participating in a health program or activity consistent with the individual's gender identity; or

(4) Deny or limit health services sought for purpose of gender transition or other gender-affirming care that the covered entity would provide to an individual for other purposes if the denial or limitation is based on an individual's sex assigned at birth, gender identity, or gender otherwise recorded.

(c) Nothing in this section requires the provision of any health service where the covered entity has a legitimate, nondiscriminatory reason for denying or limiting that service, including where the covered entity typically declines to provide the health service to any individual or where the covered entity reasonably determines that such health service is not clinically appropriate for a particular individual. A covered entity's determination must not be based on unlawful animus or bias, or constitute a pretext for discrimination. Nothing in this section is intended to preclude a covered entity from availing itself of protections described in §§ 92.3 and 92.302.

(d) The enumeration of specific forms of discrimination in paragraph (b) of this section does not limit the general applicability of the prohibition in paragraph (a) of this section.

§ 92.207 Nondiscrimination in health insurance coverage and other health-related coverage.

(a) A covered entity must not, in providing or administering health insurance coverage or other health-related coverage, discriminate on the basis of race, color, national origin, sex, age, disability, or any combination thereof.

(b) A covered entity must not, in providing or administering health insurance coverage or other health-related coverage:

(1) Deny, cancel, limit, or refuse to issue or renew health insurance coverage or other health-related coverage, or deny or limit coverage of a claim, or impose additional cost sharing or other limitations or restrictions on coverage, on the basis of race, color, national origin, sex, age, disability, or any combination thereof;

(2) Have or implement marketing practices or benefit designs that discriminate on the basis of race, color, national origin, sex, age, disability, or any combination thereof, in health insurance coverage or other health-related coverage;

(3) Deny or limit coverage, deny or limit coverage of a claim, or impose additional cost sharing or other limitations or restrictions on coverage, to an individual based upon the individual's sex assigned at birth, gender identity, or gender otherwise recorded;

(4) Have or implement a categorical coverage exclusion or limitation for all health services related to gender transition or other gender-affirming care;

(5) Otherwise deny or limit coverage, deny or limit coverage of a claim, or impose additional cost sharing or other limitations or restrictions on coverage, for specific health services related to gender transition or other gender-affirming care if such denial, limitation, or restriction results in discrimination on the basis of sex; or

(6) Have or implement benefit designs that do not provide or administer health insurance coverage or other health-related coverage in the most integrated setting appropriate to the needs of qualified individuals with disabilities, including practices that result in the serious risk of institutionalization or segregation.

(c) Nothing in this section requires coverage of any health service where the covered entity has a legitimate, nondiscriminatory reason for denying or limiting coverage of the health service or determining that such health service fails to meet applicable coverage requirements, including reasonable medical management techniques such as medical necessity requirements. Such coverage denial or limitation must not be based on unlawful animus or bias, or constitute a pretext for discrimination. Nothing in this section is intended to preclude a covered entity from availing itself of protections described in §§ 92.3 and 92.302.

(d) The enumeration of specific forms of discrimination in paragraph (b) of this section does not limit the general applicability of the prohibition in paragraph (a) of this section.

§ 92.208 Prohibition on sex discrimination related to marital, parental, or family status.

In determining whether an individual satisfies any policy or criterion regarding access to its health programs or activities, a covered entity must not take an individual's sex, as defined in § 92.101(a)(2), into account in applying any rule concerning an individual's current, perceived, potential, or past marital, parental, or family status.

§ 92.209 Nondiscrimination on the basis of association.

A covered entity must not exclude from participation in, deny the benefits of, or otherwise discriminate against an individual or entity in its health programs and activities on the basis of the respective race, color, national origin, sex, age, or disability of the individual and another person with whom the individual or entity has a relationship or association.

§ 92.210 Nondiscrimination in the use of patient care decision support tools.

(a) *General prohibition.* A covered entity must not discriminate on the basis of race, color, national origin, sex, age, or disability in its health programs or activities through the use of patient care decision support tools.

(b) *Identification of risk.* A covered entity has an ongoing duty to make reasonable efforts to identify uses of patient care decision support tools in its health programs or activities that employ input variables or factors that measure race, color, national origin, sex, age, or disability.

(c) *Mitigation of risk.* For each patient care decision support tool identified in paragraph (b) of this section, a covered entity must make reasonable efforts to mitigate the risk of discrimination resulting from the tool's use in its health programs or activities.

§ 92.211 Nondiscrimination in the delivery of health programs and activities through telehealth services.

A covered entity must not, in delivery of its health programs and activities through telehealth services, discriminate on the basis of race, color, national origin, sex, age, or disability.

Subpart D—Procedures

§ 92.301 Enforcement mechanisms.

The enforcement mechanisms available for and provided under title VI of the Civil Rights Act of 1964, title IX of the Education Amendments of 1972, section 504 of the Rehabilitation Act of 1973, and the Age Discrimination Act of 1975 shall apply for purposes of section 1557 as implemented by this part.

§ 92.302 Notification of views regarding application of Federal religious freedom and conscience laws.

(a) *General application.* A recipient may rely on applicable Federal protections for religious freedom and conscience, and consistent with § 92.3(c), application of a particular

Dkt. 12-2

EXHIBIT B

IN THE UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
TAMPA DIVISION

STATE OF FLORIDA; FLORIDA AGENCY FOR HEALTH CARE ADMINISTRATION; FLORIDA DEPARTMENT OF MANAGEMENT SERVICES, CATHOLIC MEDICAL ASSOCIATION, on behalf of its current and future members,

Plaintiffs,

No. 8:24-cv-01080-WFJ-TGW

DEPARTMENT OF HEALTH AND HUMAN SERVICES; XAVIER BECERRA, in his official capacity as Secretary of the Department of Health and Human Services; MELANIE FONTES RAINER, in her official capacity as the Director of the Office for Civil Rights; THE CENTERS FOR MEDICARE AND MEDICAID; CHIQUITA BROOKS-LASURE, in her official capacity as Administrator of the Centers for Medicare and Medicaid Services,

Defendants.

DECLARATION OF J. KEVIN BAILEY

I, J. Kevin Bailey, declare as follows:

1. My name is J. Kevin Bailey and I have personal knowledge of the following statements. I am employed by the Florida Agency for Persons with Disabilities ("APD") as the Agency Operated Facilities Manager.

2. As part of my duties, I oversee the management of two state-operated Intermediate Care Facilities for the Developmentally Disabled ("ICF/DD"), also known as Developmental Disabilities Centers ("DDC"), which are responsible for the

active treatment care, room and board, residential habilitation, medical assistance, and assistance with activities of daily living of its residents.

3. APD is the state agency responsible for providing all services provided to persons with developmental disabilities under Florida Statutes, Chapter 393, including the operation and programmatic management of Home and Community Based Medicaid waivers established to provide services to persons with developmental disabilities in Florida, and the operation of all state institutional programs. Fla. Stat. § 20.197(3).

Intermediate Care Facilities for the Developmentally Disabled

4. An ICF/DD is a residential facility licensed and certified in accordance with state law, and certified by the federal government pursuant to the Social Security Act, as a provider of Medicaid services to persons who have developmental disabilities. Fla. Stat. § 400.960(6).

5. In Florida, ICF/DDs are licensed by the Agency for Health Care Administration ("AHCA"). Fla. Stat. § 400.962(1).

6. ICF/DDs must comply with all rules adopted by AHCA for facility licensing and operation. Fla. Stat. § 400.967.

7. AHCA promulgated Florida Administrative Code, Chapter 59A-26 for ICF/DD facility operation.

8. For coverage of services and reimbursement by Medicaid, AHCA promulgated Florida Administrative Code, Rule 59G-4.170, which incorporates by

reference the Intermediate Care Facility for Individuals with Intellectual Disabilities Services Coverage Policy ("ICF/DD Handbook").

9. In order to reside in an ICF/DD, and receive covered services reimbursable by Medicaid, a Resident must first be a Medicaid recipient. ICF/DD Handbook § 2.2.

10. An ICF/DD must provide the following services to its Residents: activity services, dental services, dietary services (including therapeutic diets), nursing services, pharmacy services, physician services, rehabilitative services (including physical, speech, occupational, mental health therapies, and intensive behavioral therapy, as applicable), room/bed and maintenance services, routine personal hygiene items, and social services. ICF/DD Handbook § 4.2.

11. An ICF/DD Resident's Level of Care must be assessed to evaluate the Resident's required medical and related needs to see which services are necessary to meet those needs. This is done through an Active Treatment Plan.

12. "Active treatment" means the provision of services by an interdisciplinary team which are necessary to maximize a client's individual independence or prevent regression or loss of functional status. Fla. Stat. § 400.960(1).

13. As part of the Active Treatment Plan required to reside in an ICF/DD, Residents must be assessed for medically necessary physical, psychological, and behavioral needs. An Interdisciplinary Team ("IDT") conducts this assessment. Fla. Admin. Code R. 59A-26.001(10).

14. An IDT must be composed of a Resident or Resident's representative, Qualified Intellectual Disability Professional, social worker, a licensed nurse, the Resident's physician and other staff in disciplines determined by the individual Resident's needs to develop a care plan to include prevention and management interventions with measurable goals. The team will determine that it is safe for the Resident to self-administer drugs before the Resident may exercise that right. *Id.*

15. Among other things, the Active Treatment Plan is for the benefit of both the Resident being assessed and the other Residents who share the same living space. This is evidenced by the sophistication and variety of professionals required to be a part of the IDT.

16. The Active Treatment Plan assessment will sometimes indicate special behavioral or physical considerations, such as psychological distress or condition, violence, sexual aggression, or a lack of rational understanding of foreseeable consequences of behavior.

17. This may necessitate enhanced services for behavior or supervision, or special considerations for living space.

18. Residents with developmental disabilities must be placed in an environment and given a living space which considers their own needs, and keeps them free from harm. Fla. Stat. § 393.13.

19. Due to the institutional nature of the setting, APD is required to approve any admission into an ICF/DD and to counsel an individual on other Home and Community Based options.

Developmental Disabilities Centers

20. A DDC is a state-owned and state-operated ICF/DD, and was formerly known as a "Sunland Center." Fla. Stat. § 393.063(10).

21. One of the DDCs the Agency operates is located in Marianna, Florida. It is known as Sunland Center Marianna.

22. Sunland Center Marianna is a 535-acre campus with 5 licensed ICF/DD homes, holding AHCA license numbers 4078096, 4079096, 4080096, 4107096, and 4081096. It serves approximately 152 Residents.

23. The other facility the Agency operates is located in Gainesville, Florida. It is known as Sunland Center Tacachale ("Tacachale").

24. Tacachale has an approximately 500-acre campus with 6 licensed ICF/DD homes with AHCA license numbers, 028004600, 028006200, 028015100, 028024100, 028026700, 028055100. It serves approximately 224 Residents.

25. Where appropriate, and in accordance with Resident needs, both facilities utilize dual-occupancy rooms.

The 2024 Rules

26. APD's DDCs receive federal financial assistance through HHS and are therefore covered entities under Section 1557.

27. The 2024 Rules prohibit discriminating based on gender identity. 89 Fed. Reg. at 37,699, *to be codified at* 45 C.F.R. § 92.101(a)(2). Section 206 of Part 92, would require covered entities to ensure "equal access" without discriminating based on sex. 89 Fed. Reg. at 37,700, *to be codified at* 45 C.F.R. § 92.206(a).

28. Among other things, Section 206 prohibits any policy or practice that separates or treats persons based on sex, including any policy or practice that prevents an individual from being treated "consistent with the individual's gender identity," if this causes the person harm—including emotional or dignitary harm—that is more than *de minimis*. *Id.* at 37,701, *to be codified at* 45 C.F.R. § 92.206(b)(3). For example, HHS explains, a hospital that assigns patients to dual-occupancy rooms based on their sex would be *required* to allow a male who identifies as a woman to share a room with a female. *Id.* at 37,593; NPRM, 87 Fed. Reg.at 47,866–67.

29. Other aspects of the 2024 Rules would prohibit any categorical limits on gender-transition treatments and would require APD to justify every denial of transition treatments on an individualized basis, following medical guidelines for gender transitions. *See* 89 Fed. Reg. at 37,701, *to be codified at* 45 C.F.R. § 92.206(b)(1), (4), (5).

30. The 2024 Rules will affect APD's operation of its DDCs in two ways. First, APD will need to redesign its campus to accommodate the 2024 Rules and hire more personnel for supervision of Residents. Second, APD will be forced to cover procedures that are otherwise prohibited under Florida law.

Dual Occupancy Rooms and Health and Safety

31. The 2024 Rules would impose significant fiscal costs on Florida by requiring the entire redesign of both of its DDC Campuses as well as additional staffing to supervise Residents and ensure health and safety.

32. The Agency currently utilizes dual-occupancy rooms which are separated by sex. A female Resident cannot share a room with a male, and a male cannot share a room with a female.

33. The Agency, in its judgment as operator of the DDCs, does so primarily to promote the health and safety of its Residents by providing a safe and appropriate abode as recommended by the IDT in the Active Treatment plan.

34. APD also employs this policy in order to facilitate treatment of its Residents most efficiently, as well as to create as much of a home-like and community environment as possible for all Residents.

35. Most of the homes at the DDCs are separated by sex themselves. However, Sunland Center Marianna currently has two homes for medically fragile Residents who are either wheelchair or bed bound. Sunland Center Tacachale has one home with medically fragile Residents who are wheelchair or bedbound. Because of the mobility considerations of the Residents in these homes, these homes are the only ones which have males and females living in the same home. In one of these medically fragile homes, all Residents have a private, single-occupancy room. At the two other homes, some residents have single occupancy rooms, and other residents share dual occupancy rooms. In both of the homes where residents share a dual occupancy room, no rooms are shared by members of the opposite sex. In both of those same homes the wings are separated by sex, with administrative rooms and offices between the two wings.

36. The reasons for separating rooms based on sex are obvious and are directly related to the health and safety of all Residents. Many Residents at the DDCs are seriously disabled and lack the cognitive ability to consent to activities, let alone activities with potentially serious consequences, such as medical procedures, or sexual activity. This is often one of the reasons why an ICF/DD is the least restrictive setting to meet a Resident's needs. As the administrator and operator of these facilities, APD has a duty to ensure it is anticipating and accounting for such needs and scenarios.

37. The DDCs care for several Residents who have sexually aggressive or inappropriate behaviors, histories of violence, and histories of felony criminal charges.

38. Indeed, this is compounded by the fact that the needs of one Resident are not a facsimile of another's. Residents often show a great variety in the levels of their sophistication and their understanding of consent.

39. Separating by sex allows for the physical safety of all Residents, particularly those who may be physically stronger and have more behavioral needs than other Residents.

40. APD will be irreparably injured by having to accommodate requests to have a Resident share a room with the opposite sex. To avoid loss of funds, and to preserve Resident safety and continued separating rooms based on sex, APD would have to overhaul its existing facilities to single-occupant rooms, incurring irrecoverable costs.

41. In the alternative, APD will undoubtedly have to employ additional personnel to maintain the health and safety of all Residents.

Medicaid Services

42. AHCA's state Medicaid program currently does not cover gender-transition interventions for the public at large. In August 2022, AHCA promulgated Florida Administrative Code, Rule 59G-1.050(7). That Rule provides that Florida Medicaid does not cover the following interventions for the treatment of gender dysphoria: (1) puberty blockers; (2) hormones and hormone antagonists; (3) gender-reassignment surgeries; and (4) any other procedures that are intended to alter primary or secondary sexual characteristics.

43. In May 2023, Governor Ron DeSantis signed into law Senate Bill 254, which prohibits the use of state funds for "sex-reassignment prescriptions or procedures"—including puberty blockers, hormones, hormone antagonists, or any medical procedure, including a surgical procedure, used "in order to affirm a person's perception of his or her sex if that perception is inconsistent with the person's sex." Fla. Stat. §§ 286.311, 456.001(9)(a).

44. AHCA's programs currently do not cover the cost of puberty blockers, hormones, hormone antagonists, or any medical procedure, including a surgical procedure, used as part of a sex-reassignment protocol.

45. Under state law, APD therefore cannot provide these services. But the 2024 Rules may require APD to do so, forcing APD to choose between following state law and HHS's regulations. Should APD refuse to comply with HHS's regulations, APD will be subject to penalties.

46. Combined with the forced redesign and need to hire additional personnel, APD will be similarly irreparably harmed by being forced to cover services that conflict with Florida law in order to avoid penalties by CMS.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on this 15th day of May 2024.

J. Kevin Bailey

Dkt. 12-3

EXHIBIT C

IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF FLORIDA
TAMPA DIVISION

State of Florida, et al. *Plaintiffs*, v. **U.S. Department of Health and Human Services**, et al., *Defendants*.	)	**Civil Action No. 8:24-cv-01080**

DECLARATION OF ANGELI MAUN AKEY, M.D.

I, Angeli Maun Akey, M.D., declare as follows:

1. I am over 21 and I am fully competent to make this declaration.

2. These facts are true, correct, and within my personal knowledge. If called to testify, I could and would testify competently to them.

3. I am a Florida medical doctor seeing Medicare patients at my independent practice in Gainesville, Florida. If my patients need hospitalization, I provide care at a local hospital that receives Medicare, Medicaid, and CHIP funding.

4. I am board-certified in Internal Medicine, Integrative and Holistic Medicine, Anti-aging and Regenerative Medicine, and certified in Functional Medicine. I hold a Bachelor of Science, a Bachelor of Arts and Doctor of Medicine degree from the University of Florida, where I graduated from the Jr. Honors Medical Program with Alpha Omega Alpha honors. I completed my internship, residency and chief residency at the Yale School of Medicine. I am the founding medical director of the Palm Beach Institute of Preventative Medicine and I teach doctors at conferences nationally and

internationally. I have written a book for patients on understanding hormones called *Fine-Tune Your Hormone Symphony*.

5. I have been in active medical practice in Gainesville for 25 years and I specialize in prevention, early detection, treatment and management of diseases associated with aging. My practice is organized as North FL Internal Medicine PA, doing business as North Florida Integrative Medicine. North Florida Integrative Medicine is a primary care practice that serves around 3,500 patients, many of whom suffer from chronic diseases. I opened North Florida Integrative Medicine in 2000 and I manage a staff of nearly 20 people serving this practice. We serve an area designated by the federal government to be a primary care shortage area.

6. If my patients need hospitalization, I provide my services in conjunction with other providers at HCA Florida North Florida Hospital, which is located 3.5 miles from the University of Florida campus in my hometown of Gainesville. HCA Florida North Florida Hospital is a 510-bed, full-service medical and surgical acute care center serving North Central Florida. HCA Florida North Florida Hospital accepts all forms of government insurance including Medicare, Medicaid, and CHIP.

7. I am a member of the Catholic Medical Association (CMA) but I am not a member of the Christian Employers Alliance or the Christian Medical & Dental Associations. I share CMA's positions.

8. I care for all patients with respect and without unlawful discrimination. No matter how a patient identifies, I provide the best medical care possible.

9. But, as a matter of sound medical judgment, good conscience, and religious belief, I categorically object to providing, referring for, or affirming any procedures to "transition" a patient's gender. It is a scientific fact, which

informs my medical judgment, that cross-sex hormones have not been proven safe by any reliable studies or data. It is a scientific fact that removing healthy body parts, such as by performing a mastectomy or hysterectomy, can lead to serious permanent damage. Providing gender-transition procedures of any kind is not the standard of care, and doing so would violate our medical oath to do no harm.

10. Doctors seeking to perform these procedures to address gender identity incongruence deny the realities of the body, and I cannot be a part of this as a medical doctor. As we remember to "first do no harm," we cannot change how we practice medicine based on weak scientific evidence.

11. I categorically oppose asking for or using a patient's self-selected gender identity or pronouns for any purpose, including for coding or charting.

12. I categorically oppose allowing males in female private spaces or vice versa.

13. I categorically oppose adopting, following, or providing a policy or notice that says (or is interpreted by federal rules to mean) that I do not "discriminate" based on gender identity.

14. I hold these positions as a matter of sound medical judgment as well as sincere Catholic religious exercise and conscience. If the government requires me to speak or act against my convictions, it would seek to stop me from speaking and acting in the way that my medical judgment and my religious faith requires of me.

15. I have regularly cared and expect to continue to care for patients who identify as transgender, non-binary, or otherwise contrary to their sex. I provide the same excellent medical care for these patients as I do for all my patients.

16. I regularly provide sex hormones for medical reasons. I prescribe hormone replacement therapy for postmenopausal women and some older men. But as a matter of sound medical judgment and good conscience, I do not and will not provide or refer for hormones for gender-transition purposes.

17. I have received new patient inquiries for management of hormones for gender-transition purposes. I expect to keep receiving similar patient inquiries. Were I to offer hormonal management for gender-transition purposes, I expect that many patients would request hormonal management for gender-transition purposes from me as I have reason to believe that there is demand in my community for doctors like me to provide hormonal management for gender-transition purposes.

18. I regularly provide referrals to oncologists for breast cancer treatment, including for mastectomies as appropriate. But as a matter of sound medical judgment and good conscience, I do not and will not refer for mastectomies for gender-transition purposes.

19. I regularly provide referrals to gynecologists for consideration for aberrant bleeding, which sometimes leads to medically indicated hysterectomies. But as a matter of sound medical judgment and good conscience, I do not and will not refer for hysterectomies for gender-transition purposes. Although there are some diagnoses that require a hysterectomy, it is always preferable to preserve the organ if possible. A gender-dysphoria diagnosis is not a medical diagnosis indicating a hysterectomy because a gender-dysphoria diagnosis does not indicate that the uterus is not healthy.

20. I expect patients will continue to attempt to consult me about gender-transition procedures and I expect that they may seek my medical opinion about gender-transition procedures. I expect that I will receive future requests for referrals for gender-transition purposes. I declined to provide

these procedures in the past, and I wish to be free to share my complete medical judgment on such procedures with these patients in the future. I want to be able explain that such procedures are unsafe, harmful, experimental, and cosmetic. In particular, I want to warn patients that these procedures do not reduce the risk of suicide—in fact, they increase it. Because I want to provide patients with complete information, I will not self-censor my medical opinions in patient consultations.

21. I regularly use pronouns for patients that accord with biological and binary sex. I code and chart patients by sex. I do not and will not ask for self-selected pronouns. I do not and will not use pronouns contrary to biology.

22. I have provided ongoing care to multiple patients who identify as transgender. These patients may very well expect me to use self-selected pronouns contrary to the patients' sex in conversation or in medical records but I do not ask for or use their self-selected pronouns. Because I seek to build a strong relationship with my patients, when I speak with these patients, I simply try to use first names. I try to avoid any pronouns in these conversations, but I may not always succeed. Outside the presence of the patient, I speak and write about the patient using biological pronouns.

23. I direct and manage operations within my office. No person other than me exercises oversight over my medical care for patients. I am solely responsible for office policy and for deciding what notices to give patients.

24. With the administrative help of my staff, my practice bills for Medicare. My affiliated hospital also serves Medicare, Medicaid, and CHIP patients. To the best of my knowledge, each time when we signed up to obtain credentials to receive federal funding, we provided all required paperwork, including signing any required assurances of compliance with federal regulations.

25. I have adopted an official written policy statement for my office that explains that I do not offer, refer for, or endorse gender-transition efforts. This policy says,

> In medicine, we bring our best knowledge about the body and healing to patient care in an integrative approach. Sound medicine teaches that each patient has a sex as a biological male or female.
>
> Doctors should always prioritize the health and well-being of their patients and doctors should always recognize biological reality. For this reason, we categorically do not provide medical interventions or referrals for "gender transition." Cross-sex hormones have not been proven safe by any reliable studies or data. These hormone treatments and related surgeries can permanently sterilize and there are no long term studies of outcomes for individuals who had gender-transition procedures. The best evidence shows that gender-transitions procedures do not reduce the risk of suicide—these procedures increase it. We cannot speak in favor of these experimental and cosmetic procedures, such as by offering medical opinions in favor of these procedures or by using pronouns that are contrary to a patient's sex. Our mission is to heal and not to harm.

26. I wish to retain this policy for my practice and to keep this policy in my book that employees may consult for information about office policies.

27. The rule forces me to abandon this policy and adopt a new gender-identity "nondiscrimination" policy for my office. This new policy must be consistent with the federal government's redefinition of sex to include gender identity, and I must revise my existing policy to ensure that it is consistent with following the rule's gender-identity requirements. Under the new policy, I must provide access based on a person's gender identity, treat each person according to gender identity, and be open to providing and referring for gender-transition procedures.

28. The rule will make me force all my employees to follow such a gender-identity policy. Then my staff and I will have to give patients notice of such a gender-identity policy and post the gender-identity policy prominently in our office. My affiliated hospital also must adopt and make me follow this kind of a gender-identity policy. I will refuse to adopt, post, or follow such a gender-identity policy.

29. The rule will force me to provide training on such a gender-identity policy to myself and to all employees to ensure my office's compliance with the rule's gender-identity requirements. My affiliated hospital also must make me attend training on such a policy. But for the rule, this training would not be a condition of federal funding or of my hospital affiliations.

30. I will not arrange or provide this training. I will not reeducate myself, nor will I reeducate my employees. Nor will I attend this training when scheduled by my hospital.

31. I object to attending training on such a policy. The government should respect my views and respect my position as a leader in my community. It should not coerce me to say things I do not believe or pressure me in a reeducation session to adopt a policy at odds with my beliefs. Being forced to provide or attend this training thus would substantially burden me in the free exercise of my medical judgment, my conscientious objections, and my religious beliefs.

32. Because I earn income based on the number of patients I see, I will bear the financial cost of the rule's compliance requirements in terms of my lost hours and productivity (not to mention lost staff productivity).

33. I have already spent time and resources to learn about the rule. If the rule goes into effect, I will spend even more resources to avoid noncompliance. I estimate that it would take me at least one hour to revise

my policies to comply with the rule, at least two hours to plan training and create an attendance sign-up sheet, and at least one hour to provide training to staff on new policies. I would not spend my time in this way but for the rule.

34. Florida restricts gender-transition procedures. The rule potentially forces me to choose between following the rule or following state law. I will not violate state law or harm my patients.

35. I also will not knowingly violate federal regulations or my conscience. So if this rule is enforced against me, I would rather stop seeing Medicare patients and lose my local hospital affiliation than adopt a policy under which I would harm a patient.

36. If I cannot participate in Medicare, if I lose my hospital affiliation, or if I have to close my office doors due to the burdens of government regulations, investigations, and penalties, my patients would suffer the loss of their trusted doctor and I would lose my income derived from Medicare, which will cause me a substantial financial loss this year.

37. The nationwide Change Healthcare cyberattack of February 21, 2024 has thrown my practice into serious financial chaos, and so any disruption in Medicare reimbursements in the next several months in particular would have an unusually disruptive impact on my practice. The outages from the cyberattack reduced my practice's cash flow by more than 80% for six weeks. As of early April, I had amassed more than $130,000 worth of insurance claims that I had not been able to get reimbursed for. In order to make payroll, I liquidated my retirement investments as an extra precaution. Payments have begun flowing back into my practice, though levels are still down between 30% and 40% from where they normally are. The adverse financial impact from this cyberattack is still in effect, making

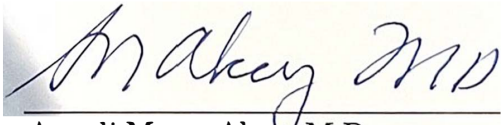
any short-term disruption in Medicare reimbursements particularly difficult. Indeed, this serious difficulty with reliable reimbursement mechanisms is part of why I have made the hard decision to transition away from accepting Medicare payments next year (outside of the hospital setting) and will start asking Medicare patients to provide payment by alternative means. I intend to opt out of Medicare for my private office beginning on January 1, 2025.

38. I intend to continue my hospital affiliations for as long as my hospital will allow me to do so. I am currently in the process of renewing my longstanding hospital privileges, a process that I expect to be completed very soon.

39. When I have to decide whether to follow the rule—or risk losing my Medicare patients this year, my hospital affiliations, and my livelihood—I won't know whether my hospital and my practice will be required to follow the rule's requirements.

I declare under 28 U.S.C. § 1746 and under penalty of perjury that this declaration is true and correct based on my personal knowledge.

Executed May 8, 2024 at New York, NY



Angeli Maun Akey, M.D.,

MAY 9TH, 2024

Dkt. 12-4

EXHIBIT D

IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF FLORIDA
TAMPA DIVISION

State of Florida, et al.
Plaintiffs,

v.

U.S. Department of Health and Human Services, et al.,
Defendants.

Civil Action No. _____

DECLARATION OF RACHEL T. KAISER, M.D.

I, Rachel T. Kaiser, M.D., declare as follows:

1. I am over 21 and I am fully competent to make this declaration.

2. These facts are true, correct, and within my personal knowledge. If called to testify, I could and would testify competently to them.

3. I am an emergency room (ER) doctor who sees Medicaid, Medicare, and CHIP patients on a contract basis at Ascension St. Thomas West Hospital in Nashville, TN. I am employed by a physician group, Middle Tennessee Emergency Physicians. My hospital collects patient insurance information, and my physician group handles insurance reimbursement.

4. I am a member of the Catholic Medical Association (CMA) but not a member of the Christian Employers Alliance or the Christian Medical & Dental Associations. I share CMA's positions. I am a past president of CMA's Nashville Guild and its current Tennessee State Director.

5. I care for all patients with respect and without unlawful discrimination. I provide the best medical treatment possible to all.

6. I categorically object to providing, referring for, or affirming any procedures to "transition" a patient's gender.

7. I categorically oppose asking for or using a patient's self-selected gender identity or pronouns for any purpose, including for coding or charting.

8. I categorically oppose allowing males in female private spaces, or vice versa, or following a policy that says (or is interpreted by federal rules to mean) that I do not "discriminate" based on gender identity.

9. I will not provide or refer for "gender transitions."

10. I want to remain free to follow and share my positions when these issues are relevant. For example, I want to be able to warn patients that experimental high-dose cross-sex hormones have not been proven safe.

11. I hold these positions as a matter of sound medical judgment as well as Catholic religious exercise and conscience. If the government requires me to speak or act against my positions, it would require me to speak or act against my religious faith. But I cannot do that, nor will I self-censor. It would cause me immeasurable emotional distress to speak or act against my beliefs, or in any way to harm my patients.

12. My charts always record each patient's biological sex. In conversation I only use pronouns that accord with the patient's biological sex.

13. I treat with increasing frequency patients who identify as transgender, non-binary, or contrary to their sex. I am regularly asked (and expect to continue to be asked) by these patients to use self-selected pronouns, as well as to chart or affirm them in ways contrary to sex. In these cases, I add to the chart that the patient identifies as another sex and I avoid using any pronouns in conversation. But I will not describe a patient's sex incorrectly or use a patient's self-selected pronouns. Using incorrect terms or pronouns can create confusion and result in incorrect care.

14. I have cared for a male patient who identified as female and whose diagnosis was a prostate issue. My chart recorded that he is a

biological male who identifies as female. I avoided pronouns altogether with him.

15. In another case, another doctor in the same ER where I was employed at the time treated a girl under 18 years of age whose mother wanted a testosterone prescription refilled for the girl. Had I been treating that patient, I would not have refilled that prescription. State law has since made doing so illegal. I will not violate state law.

16. I have spent time planning to avoid liability under the new rule.

17. The rule seeks to force my hospital and my physician billing group to make me and other employees follow a "nondiscrimination" policy on gender identity and make me attend training on it. But for the rule, this would not be a condition of my employment.

18. I will not follow such a policy. Nor do I want to attend training on such a policy. But I will attend any required training as scheduled. If the rule did not require this training, I would not attend it. I am paid based on how many patients I see. If I miss patient care to attend training, I will receive less compensation than if I were seeing patients. If I work overtime so that no patients miss care, I will be forced to bear the full burden of each hour of mandatory unpaid extra work.

19. Each time my employer requests Medicaid or Medicare payment for my services, the federal government will deem it to be certifying that my employer and I comply with the rule. But I will not fully comply with the rule. No person can certify on my behalf, without making a false or misleading statement, that I will follow the rule, given that I am not and will not be in full compliance with the rule's gender-identity provisions.

20. I will retire rather than harm my patients or lie to them.

21. When I have to decide whether to follow the rule—or risk losing my medical practice—I won't know whether the federal government will exempt my hospital, my physician group, or me.

I declare under 28 U.S.C. § 1746 and under penalty of perjury that this declaration is true and correct based on my personal knowledge.

Executed this 5th day of MAY, 2024 at 5:00, PM.

Rachel Kaiser MD

Rachel T. Kaiser, M.D.

Dkt. 33

IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF FLORIDA

STATE OF FLORIDA, *et al.*,
Plaintiffs,

v.

DEPARTMENT OF HEALTH AND HUMAN SERVICES, *et al.*,
Defendants.

Case No. 8:24-CV-01080-WFJ-TGW

DEFENDANTS' OPPOSITION TO PLAINTIFFS' MOTION FOR A STAY OR PRELIMINARY INJUNCTION

Section 1557 of the Affordable Care Act ("ACA"), 42 U.S.C. § 18116, prohibits recipients of Federal financial assistance from excluding individuals from health programs or activities—or otherwise discriminating against them—on the basis of race, color, national origin, sex, age, or disability. The U.S. Department of Health and Human Services ("HHS") promulgated a new rule that implements Section 1557's nondiscrimination obligations (the "Rule"). As relevant here, the Rule provides that sex discrimination that violates Section 1557 includes discrimination on the basis of gender identity.

Plaintiffs the State of Florida, two Florida agencies, and the Catholic Medical Association ("CMA") filed this lawsuit against HHS challenging the Rule. Their suit is premised on several misapprehensions regarding the Rule. For example, they say that the Rule establishes a federal standard of medical care and categorically requires the provision of particular treatments, like puberty blockers or hormones. ECF No. 12 at 3, 6. Not so. Contrary to Plaintiffs' allegations, the "final rule does not promote any

particular medical treatment, require provision of particular procedures, mandate coverage of any particular care, or set any standard of care; rather, the final rule implements the nondiscrimination requirements of section 1557." *Nondiscrimination in Health Programs and Activities*, 89 Fed. Reg. 37,522, 37,533 (May 6, 2024). In fact, nothing in the Rule requires the provision of or insurance coverage for any particular health service where the covered entity has a legitimate, nondiscriminatory reason for denying or limiting the service or coverage, such as, for example, a clinician's medical judgment. 45 C.F.R. §§ 92.206(c), 92.207(c).[1] And although Plaintiffs repeatedly invoke the World Professional Association for Transgender Health ("WPATH"), the Rule does not mention WPATH, and nothing in the Rule mandates that any clinician follow any organization's standards of care or clinical practice guidelines. Moreover, the Rule repeatedly makes clear that § 1557 does not apply insofar as any nondiscrimination obligation it creates would violate applicable Federal protections for religious freedom and conscience, including the Religious Freedom Restoration Act ("RFRA"). 45 C.F.R. § 92.3(c).

Plaintiffs' motion for a stay or preliminary injunction should be denied. First, Plaintiffs have failed to establish likelihood of success on the merits. Plaintiffs claim the Rule's statement that prohibited discrimination includes discrimination on the basis of gender identity, 45 C.F.R §92.101(a)(2)(iv), is contrary to § 1557. But § 1557 precludes discrimination on the basis of sex. Interpreting materially identical language

[1] Provisions of the Rule cited in this brief refer to those published at 89 Fed. Reg. 37,691-703.

in Title VII, the Supreme Court held that "it is impossible to discriminate against a person for being . . . transgender without discriminating against that individual based on sex." *Bostock v. Clayton Cnty.*, 590 U.S. 644, 660 (2020). The Rule provides that discrimination on the basis of gender identity is prohibited sex discrimination under § 1557, 45 C.F.R. § 92.101(a)(2)(iv), for that same reason, 89 Fed. Reg. at 37,574. Plaintiffs' arguments to the contrary ignore the statutory language and are rooted in hypothetical future disagreements with HHS about possible applications of the Rule that do not reflect anything in the Rule itself.

Second, Plaintiffs have failed to demonstrate imminent irreparable harm. The Rule does not include a determination that any of Plaintiffs' particular laws or policies violate § 1557. And Congress required extensive procedures, culminating in judicial review, before HHS may terminate any entity's federal funding. Thus, no Plaintiff or CMA member faces an imminent prospect of losing Federal financial assistance.

Finally, the public interest and the potential harms to third parties outweigh any hypothetical future injuries to Plaintiffs from specific applications of the Rule. At its core, the Rule precludes providers and insurance issuers from denying patients medically necessary care they typically provide—whether for, *e.g.*, a sore throat, a broken bone, or cancer—because of traits or actions that they would not have questioned in members of a different sex. There is a significant public interest in permitting HHS to enforce § 1557 to protect patients from discrimination in all of the programs and activities to which § 1557 applies, as Congress intended. For all these reasons, Defendants respectfully request that the Court deny Plaintiffs' motion.

BACKGROUND

I. STATUTORY AND REGULATORY BACKGROUND

A. Section 1557 of the Affordable Care Act and its Statutory Enforcement Mechanisms

Through reference to longstanding civil rights statutes, such as Title VI of the Civil Rights Act of 1964 and Title IX of the Education Amendments of 1972, § 1557 prohibits discrimination on the ground of race, color, national origin, sex, age, or disability in any health program or activity any part of which is receiving Federal financial assistance. 42 U.S.C. § 18116(a).[2]

Section 1557 incorporates the "enforcement mechanisms provided for and available under" the referenced civil rights statutes. 42 U.S.C. § 18116(a). For administrative enforcement, those mechanisms provide layers of process and opportunities for congressional and judicial review before any entity faces a potential termination of any Federal financial assistance. *E.g.* 20 U.S.C. § 1682 (Title IX); 42 U.S.C. § 2000d-1 (Title VI). HHS's enforcement is typically a complaint-driven process, though HHS's Office for Civil Rights ("OCR") has authority to initiate investigations on its own. *See, e.g.* 45 C.F.R. §§ 80.7 (Title VI); 86.71 (Title IX), 92.303(a) (Section 1557, incorporating by reference § 80.7). As part of an investigation, OCR considers all "factors relevant to a determination as to whether the recipient has failed to comply" with § 1557. *Id.* § 80.7(c) (incorporated by § 92.303(a)).

[2] Section 1557 also addresses discrimination occurring under any program or activity administered by an Executive Agency or any entity established under Title I of the ACA.

If, following an investigation, OCR finds a "failure to comply," first, HHS must advise the covered entity of a potential violation and make a good faith effort to come to a voluntary resolution without the need for administrative or judicial litigation. 20 U.S.C. § 1682. If that negotiation is unsuccessful, HHS, if it wishes to proceed further, must initiate the formal agency adjudication procedures of the Administrative Procedure Act ("APA"), which require an opportunity for a hearing and "an express finding on the record" of a failure to comply. *Id.*[3] And if that process results in a determination to withhold federal funding, HHS must submit a "full written report" to congressional committees before any funding withdrawal can take effect. *Id.*

Moreover, the statutory enforcement mechanism makes any HHS decision to terminate or suspend Federal financial assistance subject to judicial review. 20 U.S.C. § 1683. Any entity seeking judicial review can invoke the court's power to postpone further the effective date of any termination of funding if such postponement is required to avoid irreparable harm. 5 U.S.C. § 705. Accordingly, the ultimate arbiters of any violation of § 1557 and the Rule are Article III courts.

B. HHS's 2024 Rule Implementing § 1557

HHS published the Rule in the Federal Register on May 6, 2024. *See* 89 Fed. Reg. 37,522 (codifying 45 C.F.R. pt. 92). As relevant here, the Rule provides that discrimination on the basis of sex includes discrimination on the basis of gender

[3] Alternatively, HHS may refer the matter to the Department of Justice to secure compliance "by any other means authorized by law." 20 U.S.C. § 1682. This alternative, however, also cannot take place until there has been a determination "that compliance cannot be secured by voluntary means." *Id.*

identity. 45 C.F.R. § 92.101(a)(2)(iv).[4]

In § 92.206, addressing equal access to health programs and activities on the basis of sex, the Rule includes provisions that primarily relate to covered entities that are directly engaged in the provision of health care services, such as hospitals, physical and mental health care providers, and pharmacies. Among other specific provisions, § 92.206(b)(3) precludes providers from "treating individuals differently or separating them on the basis of sex in a manner that subjects any individual to more than de minimis harm[.]" *Id.* § 92.206(b)(3). This provision clarifies that the Rule does not prohibit "a covered entity from operating sex separated programs and facilities[.]" 89 Fed. Reg. at 37,593. For example, merely providing separate bathrooms labeled for men and women is not discrimination on the basis of sex. "Although differential treatment on the basis of sex is generally prohibited, [HHS] acknowledges that there are certain circumstances in which § 1557 does not prohibit separation by sex or differential medical treatment on the basis of sex[.]" *Nondiscrimination in Health Programs and Activities*, 87 Fed. Reg. 47,824, 47,866 (Aug. 4, 2022).

Section 92.206(b)(4) precludes providers from denying health services sought for the purpose of gender-affirming care "that the covered entity would provide to an individual for other purposes if the denial or limitation is based on an individual's sex

[4] Because Plaintiffs seek to enjoin only 45 C.F.R. §§ 92.101, 92.206, 92.207 and 42 C.F.R. § 438.3(d)(4), ECF No. 12-5, the discussion that follows is limited accordingly. Although Plaintiffs seek to enjoin 45 C.F.R. § 92.101, most provisions of that section are not meaningfully challenged here, including those concerning discrimination on the basis of race, color, national origin, age, disability, and sexual orientation, 45 C.F.R. § 92.101.

assigned at birth, gender identity, or gender otherwise recorded." But § 92.206 makes clear that this provision does not require

> the provision of any health service where the covered entity has a legitimate, nondiscriminatory reason for denying or limiting that service, including where the covered entity typically declines to provide the health service to any individual or where the covered entity reasonably determines that such health service is not clinically appropriate for a particular individual.

Id. § 92.206(c).

In § 92.207, the Rule includes provisions governing nondiscrimination in health insurance coverage and other health-related coverage. *Id.* § 92.207. Among other specific prohibitions, § 92.207(b)(4) precludes insurance issuers from having or "implement[ing] a categorical coverage exclusion or limitation for all health services related to gender transition or other gender-affirming care[.]" *Id.* § 92.207(b)(4). Section 92.207 makes clear that nothing in the section "requires coverage of any health service where the covered entity has a legitimate, nondiscriminatory reason for denying or limiting coverage of the health service or determining that such health service fails to meet applicable coverage requirements, including reasonable medical management techniques such as medical necessity requirements." *Id.* § 92.207(c). For example, "a nondiscriminatory determination that care is not medically necessary based on a patient's anatomy or medical need is permissible." 89 Fed. Reg. at 37,607.

The Rule also includes revisions to nondiscrimination provisions of regulations issued by the Centers for Medicare & Medicaid Services ("CMS") governing Medicaid and the Children's Health Insurance Program ("CHIP"). 89 Fed. Reg. at 37,691 (revising 42 C.F.R. § 438.3). HHS revised those regulations "based on Section 1557"

as well as separate statutory authority under 42 U.S.C. §§ 1396a(a)(4), 1396(a)(19), and 1397aa(a). 87 Fed. Reg. at 47,892. These regulatory provisions require contracts between states and Medicaid and CHIP managed care plans to include provisions precluding those plans from discriminating against individuals eligible to enroll in these managed care programs. 45 C.F.R. § 438.3(d). The Rule's revisions to that section, as relevant here, add discrimination on the basis of gender identity to the list of grounds of prohibited discrimination. 89 Fed. Reg. at 37,691.

II. Plaintiffs' Incorrect Claims Concerning the Rule

Plaintiffs misapprehend the Rule's scope and what it requires. At the outset, two general points deserve emphasis. First, as HHS repeatedly emphasized in the preamble, the Rule does not set a standard of care or require the provision of any particular service. Nothing in the Rule overrides a clinician's medical judgment as to whether a service is medically necessary or appropriate for any patient. *See* 89 Fed. Reg. at 37,595-96 ("There is no part of section 1557 that compels clinicians to provide a service that they do not believe is medically appropriate for a patient or that they are not qualified to provide."); *see also* 89 Fed. Reg. at 37,533; 37,596.

Second, and relatedly, Plaintiffs suggest that the Rule reflects an HHS determination "that 'gender transition' is medically necessary[.]" ECF No. 12 at 7. Not so. The Rule does not displace the judgment of providers as to the medical necessity of gender affirming care, so long as a refusal of care is not based on animus or bias or a pretext for discrimination. In response to comments, HHS eliminated a proposed provision of § 92.206(c), which read: "however, a provider's belief that

gender transition or other gender-affirming care can never be beneficial for such individuals (or its compliance with a state or local law that reflects a similar judgment) is not a sufficient basis for a judgment that a health service is not clinically appropriate[.]" 89 Fed. Reg. at 37,597. In the Rule, HHS replaced it with "[a] covered entity's determination must not be based on unlawful animus or bias, or constitute a pretext for discrimination." *Id.*; *see also id.* ("the [R]ule does not (and cannot) set a standard of care for gender-affirming care"); *id.* ("OCR understands that a provider may have a legitimate nondiscriminatory reason not to provide a health service, which the newly revised § 92.206(c) makes clear.").

III. Procedural Background

Plaintiffs filed this lawsuit on May 6, 2024. Compl. for Declaratory Relief and Prelim. and Permanent Inj. Relief ("Compl."), ECF No. 1. Plaintiffs consist of the State of Florida, two Florida agencies, and CMA, a membership association suing on behalf of its 2,500 members. *Id.* ¶¶ 17-21. On May 15, 2024, Plaintiffs filed a motion for a stay or preliminary injunction. ECF No. 12.

LEGAL STANDARDS

"A preliminary injunction is an extraordinary remedy never awarded as of right." *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 24 (2008). To justify this "drastic remedy[,]" Plaintiffs must "clearly establish[] the burden of persuasion" on the following four elements: (1) a substantial likelihood of success on the merits; (2) a substantial threat that Movants will suffer irreparable injury absent an injunction; (3) the threatened injury to Movants outweighs the damage an injunction would cause

to Defendants; and (4) the injunction would not be adverse to the public interest. *Davidoff & CIE, S.A. v. PLD Int'l Corp.*, 263 F.3d 1297, 1300 (11th Cir. 2001). The same standard applies to a plaintiff seeking relief under 5 U.S.C. § 705. *Sampson v. Murray*, 415 U.S. 61, 68 n.15 (1974); *Va. Petrol. Jobbers Ass'n v. FPC*, 259 F.2d 921, 925 (D.C. Cir. 1958).

A plaintiff seeking an order precluding enforcement of a regulation, or any "distinct provision" of a regulation, in all of its applications, must "meet an especially demanding standard." *Am. Federation of State, County, and Mun. Employees Council 79 v. Scott*, 717 F.3d 851, 863, 865 (11th Cir. 2023) ("*AFSCME Council 79*"). Specifically, he "must establish that no set of circumstances exists under which the [regulation] would be valid." *Id*. at 863 (citation omitted); *see Reno v. Flores*, 507 U.S. 292, 300 (1993).

ARGUMENT

I. Plaintiffs Are Not Likely to Succeed on the Merits.

Plaintiffs' motion seeks to stay or enjoin enforcement of all applications of 45 C.F.R. §§ 92.101, 92.206, 92.207 and 42 C.F.R. § 438.3(d)(4) during the pendency of this litigation. ECF No. 12-5. That relief would authorize Florida and CMA members to deny health services, whether for a sore throat, a broken bone, or cancer, to transgender Americans on the basis of sex—for example, because of traits or actions that the provider would not have questioned in members of a different sex—in any conceivable circumstance. But the provisions of the Rule HHS promulgated are compelled by the Supreme Court's reasoning in *Bostock*.

The relief Plaintiffs seek is not warranted by the arguments Plaintiffs raise and is not available under the "especially demanding" legal standard: that "no set of circumstances exists under which [each challenged provision of] the [regulation] would be valid." *AFSCME Council 79*, 717 F.3d at 863 (citation omitted).[5] Rather than attempting to sustain their burden, Plaintiffs thrust several hypothetical applications of § 1557 before the Court—*i.e.*, hypotheticals about bathroom policies and policies governing puberty blockers. Plaintiffs then seek to force the Government to address those applications in litigation briefs in response to a purported challenge to the Rule. But "nothing in the [challenged] Rule itself speaks to" any of those applications. *Anderson v. Edwards*, 514 U.S. 143, 155 n.6 (1995).

Plaintiffs have not sought, and thus the Court should not entertain, entry of a preliminary injunction that would enjoin HHS from enforcing the Rule against particular policies or practices. The Rule does not reflect a determination that any of Plaintiffs' particular laws or policies violate § 1557 and thus judicial review is only available after final agency action and completion of the administrative procedures mandated by Congress. *Florida v. CMS*, No 8:24-cv-317-WFJ-AAS, 2024 WL 2803298, at *3-6 (M.D. Fla. May 31, 2024).[6]

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[5] *Reno v. Flores*, 507 U.S. 292, 301 (1993); *Children's Health Def. v. FCC*, 25 F.4th 1045, 1052 (D.C. Cir. 2022); *Associated Builders and Contractors of Tex., Inc. v. NLRB*, 826 F.3d 215, 220 (5th Cir. 2016); *Ass'n of Private Sector Colleges and Univs. v. Duncan*, 681 F.3d 427, 442 (D.C. Cir. 2012); *Sherley v. Sebelius*, 644 F.3d 388, 397 & n. ** (D.C. Cir. 2011).

[6] CMA is also unlikely to succeed on the merits of its claims in this action because, as another court already held, CMA lacks standing to press them. *Am. College of Pediatricians v. Becerra*, No. 1:21-cv-195, 2022 WL 17084365, at *12-18 (E.D. Tenn. Nov. 18, 2022) ("*ACP*"). *Compare id.* *10-11, *with*, Compl. ¶ 195. Although CMA has asked the Sixth Circuit to vacate that court's decision, the Sixth Circuit has

A. Section 92.101(a)(2)(iv)

Plaintiffs' claim that 45 C.F.R § 92.101(a)(2)(iv) is contrary to § 1557 fails. Again, § 92.101(a)(2)(iv) explains that discrimination on the basis of sex includes discrimination on the basis of gender identity. This provision is lawful because the Supreme Court's reasoning in *Bostock* that Title VII's prohibition against sex discrimination encompasses discrimination on the basis of gender identity applies to prohibitions against sex discrimination in Title IX and § 1557.

The Supreme Court explained in *Bostock* that "it is impossible to discriminate against a person for being . . . transgender without discriminating against that individual based on sex." 590 U.S. at 660.[7] *Bostock* concerned Title VII's provision making it unlawful for an employer "to discriminate against any individual . . . because of such individual's . . . sex," 590 U.S. at 655 (quoting 42 U.S.C. § 2000e-2(a)(1)). The Court explained that Title VII's "because of" language "incorporates the 'simple' and 'traditional' standard of but-for causation." *Id.* at 656–57 (citation omitted). "[S]ex is necessarily a but-for cause" of discrimination on the basis of transgender status "because it is impossible" to discriminate against a person for being

not resolved that request. Whether as a matter of issue preclusion, *Lewis v. Seneff*, 654 F. Supp. 2d 1349, 1359 (M.D. Fla. 2009), improper claim splitting, *Bongiovanni*, No. 3:22-cv-237-MMH-MCR, 2022 WL 1642158, at *8-10 (M.D. Fla. May 24, 2022), or deferring to the *ACP* court's reasoning "as a matter of 'good sense and wise judicial practice,'" *id.* at *14 (citation omitted), CMA should not be permitted to treat "an adverse judicial decision [as] little more than an invitation to take a mulligan[.]" *Entek GRB, LLC v. Stull Ranches, LLC*, 840 F.3d 1239, 1240 (10th Cir. 2016) (Gorsuch, J.). Nothing in the Rule, which only makes CMA members' alleged injuries more speculative due to its provisions protecting religious freedom, *see infra* at 30, has any bearing on the *ACP* court's reasoning.

[7] The terms "gender identity" and "transgender status" "are often used interchangeably." 89 Fed. Reg. at 37,556. *See Bostock*, 590 U.S. at 686 n.6 (Alito, J., dissenting).

transgender "without discriminating against that individual based on sex." *Id*. at 660, 661 (emphasis omitted). If an employer fires a transgender woman but retains an otherwise identical cisgender woman, "the employer intentionally penalizes a person identified as male at birth for traits or actions that it tolerates in an employee identified as female at birth." *Id*. Thus, "the individual employee's sex plays an unmistakable and impermissible role in the discharge decision." *Id.* That is so even if "sex" in Title VII "refer[s] only to biological distinctions between male and female." *Id*. at 655.

Bostock's reasoning applies with equal force to § 1557. The statute incorporates Title IX's prohibition on discrimination "on the basis of sex," 20 U.S.C. 1681(a), which employs a causation standard indistinguishable from Title VII's "because of . . . sex" language, 42 U.S.C. § 2000e-2(a)(1); *see also Bostock,* 590 U.S. at 650 (using the phrase "on the basis of" interchangeably with Title VII's "because of" language). Courts consistently look to interpretations of Title VII to inform Title IX because both statutes prohibit discrimination on the basis of sex using nearly identical language. *E.g., GP by and through JP v. Lee Cnty Sch. Bd.*, 737 F. App'x 910, 916 n.5 (11th Cir. 2018). Indeed, other courts have concluded that the rationale of *Bostock* applies to § 1557. *E.g., Kadel v. Folwell*, 100 F.4th 122, 164 (4th Cir. 2024); *Doe v. Snyder*, 28 F.4th 103, 144 (9th Cir. 2022). That is because if a medical provider refuses to treat the broken bone of a transgender man because he presents as a man but was assigned female at birth, but would treat the broken bone of a similarly situated cisgender man, the provider is discriminating on the basis of sex. Indeed, Plaintiffs admit that there are circumstances in which discrimination on the basis of sex includes gender identity

discrimination. ECF No. 12 at 16 (admitting that where a doctor denies a transgender woman "an orchiectomy to treat testicular cancer" impermissible discrimination "may be afoot"). That admission undermines any claim that § 92.101(a)(2)(iv) is invalid in all of its applications.

Plaintiffs lean heavily on their view that sex is binary and "biological." ECF No. 12 at 9, 14. But, as in *Bostock*, nothing in the Rule turns on whether "sex" is defined to "refer only to biological distinctions between male and female." 590 U.S. at 655; *see also id.* at 660 (concluding that "it is impossible to discriminate against a person for being . . . transgender without discriminating against that individual based on sex"). Rather, as HHS explained in the preamble, the agency "determined it is not necessary define 'sex' in this rule." 89 Fed. Reg. at 37,575. Even if "sex" refers to biological distinctions between male and female, including "'gender identity' in § 92.101(a)(2) is consistent with the Supreme Court's reasoning in *Bostock*." *Id*. at 37,574.

Plaintiffs devote much of their briefing to *Adams v. School Board of St. John's County*, 57 F.4th 791 (11th Cir. 2022), ECF No. 12 at 8-13, but nothing in *Adams* provides a reason to enjoin HHS from enforcing § 92.101(a)(2)(iv). In *Adams*, the Eleventh Circuit held that a school's restroom policy prohibiting a transgender male student from using the boys' restroom did not violate Title IX. *See Adams*, 57 F.4th at 815. *Adams* did not hold that discrimination on the basis of sex excludes discrimination on the basis of gender identity, as would be necessary to find it irreconcilable with § 92.101(a)(2)(iv). The court explained that "[w]hile *Bostock* held that 'discrimination based on . . . transgender status necessarily entails discrimination based on sex,' . . .

that statement is not in question in this appeal." *Id.* at 808-09 (quoting *Bostock*, 590 U.S. at 669). But that statement is what the Rule provides at § 92.101(a)(2)(iv).[8]

Plaintiffs' reliance on *Eknes-Tucker v. Governor of Ala.*, 80 F.4th 1205 (11th Cir. 2023), which addressed an Equal Protection Cause claim, is also misplaced. ECF No. 12 at 15-18. "Given the similarity in language prohibiting sex discrimination in Titles VII and IX," *Doe*, 28 F.4th at 114, *Eknes-Tucker* provides no basis to conclude that § 92.101(a)(2)(iv) is invalid in all of its applications.

B. Section 92.206(b)(3)

Plaintiffs likewise have not established that § 92.206(b)(3) is contrary to § 1557. That provision clarifies that not all practices of sex segregation or differing treatment based on sex—including practices preventing individuals from participating in a program or activity consistent with the individual's gender identity—violate § 1557. Rather, only those that result in "more than de minimis harm" violate § 1557. *Id. See* 89 Fed. Reg. at 37,593-94 & n.162; *see also, e.g., Burlington N. and Santa Fe Ry. Co. v. White*, 548 U.S. 53, 68 (2006).

Plaintiffs do not dispute that the challenged provision can be validly applied in an overwhelming number of (if not all) circumstances. Most applications would have nothing to do with gender identity discrimination. Consider Florida's operation of sex-segregated residential health care facilities. Bailey Decl. ¶ 35. There could be any

[8] The *Adams* court also made clear that the policy at issue in that case did "not depend in any way on how students act or identify[,]" 57 F.4th at 809, unlike a sweeping set of policies that would be authorized by enjoining enforcement of § 92.101(a)(2)(iv) in all applications.

number of ways that Florida could treat their male residents differently than their female residents in the provision of health care that, for example, subjects a male resident to more than de minimis harm, potentially covered by § 92.206(b)(3), without any transgender individual being involved. Florida's arguments about the scope of discrimination on the basis of sex, ECF No. 12 at 9, would have no bearing on an overwhelming number of those applications. ECF No. 12-5.

The provision's explicit reference to gender identity is no less valid. As compelled by a natural reading of the statute, it precludes providers from engaging in a practice that prevents an individual from participating in a health program or activity consistent with the individual's gender identity if it subjects the individual to more than de minimis harm. 42 C.F.R. § 92.206(b)(3).

Consider if Florida were to ban transgender individuals from participating as residents in its health facilities altogether because it considered those individuals to fail to comply with sex stereotypes given their sex assigned at birth, *Glenn v. Brumby*, 663 F.3d 1312, 1318 (11th Cir. 2018), and the ban caused an individual more than de minimis harm. Plaintiffs have not explained how the injunction they seek precluding enforcement in these circumstances could be justified. *See id*. at 1319.

Plaintiffs argue that Title IX "allows separating living facilities based on sex" and "separate bathrooms." ECF No. 12 at 12. Even if Plaintiffs are correct that § 1557 does not "*clearly* forbid separating private spaces based on sex," *id.*, the Rule expressly complies with, rather than violates, this interpretation. Section 92.206(b)(3) does not "prohibit[] a covered entity from operating sex separated programs and facilities." 89

Fed. Reg. at 37,593. And "the practice of assigning patients to dual-occupancy rooms . . . on the basis of sex is not, standing alone, a form of discrimination." 87 Fed. Reg. at 47,866. The plain language of § 92.206(b)(3), as in *Bostock*, does not purport to resolve § 1557's application to specific claims involving "bathrooms, locker rooms, or anything else of the kind." 590 U.S. at 681.[9]

C. Sections 92.206(b)(4) and 92.207(b)(4)-(5)

Plaintiffs similarly have not established that §§ 92.206(b)(4) and 92.207(b)(4)-(5), which address nondiscrimination related to gender-affirming care, are contrary to § 1557. Plaintiffs' error lies in viewing these provisions as imposing specific demands to provide or cover particular health services, like puberty blockers or gender affirming surgeries, when in fact these provisions only require covered entities to act in a nondiscriminatory manner. *See* 89 Fed. Reg. 37,607 ("We [] decline to state that any denial of gender-affirming care will necessarily be discriminatory regardless of context or rationale."). The Rule makes clear that "[n]othing in [§§ 92.206(b)(4) and

[9] In responding to comments in the preamble, HHS stated that refusing to place a transgender person "in facilities consistent with their gender identity" would "result in more than *de minimis* harm," 89 Fed. Reg. at 37,593—a conclusion that Plaintiffs do not dispute. That statement is consistent with federal court decisions. *E.g., Grimm v. Gloucester Cnty. Sch. Bd.*, 972 F.3d at 617-18 (4th Cir. 2020); *Whitaker ex rel. Whitaker v. Kenosha Unified Sch. Dist. No. 1 Bd. of Educ.*, 858 F.3d 1034, 1045-46 (7th Cir. 2017). Plaintiffs do not seek to enjoin enforcement of this preamble statement. ECF No. 12-5. While a Rule's preamble may help determine whether an agency's decision to adopt a particular approach was supported by adequate reasoning, it cannot render legally deficient otherwise legally permissible regulatory language. *See St. Francis Med. Ctr. v. Azar*, 894 F.3d 290, 297 (D.C. Cir. 2018); *Nat. Res. Def. Council v. EPA*, 559 F.3d 561, 565 (D.C. Cir. 2009). Insofar as Plaintiffs view the preamble statement as inconsistent with circuit precedent in some applications, absent a contrary "history of [] enforcement," *Reno*, 507 U.S. at 301, the Court must assume that HHS would enforce the regulatory text in good faith consistent with caselaw that is binding in a particular circuit, *Hyatt v. Hecker*, 807 F.2d 376, 379 (4th Cir. 1986) (agencies must "follow the law of the circuit whose courts have jurisdiction over the cause of action"), given that the Court must presume that HHS "will act properly and according to law," *FCC v. Schreiber*, 381 U.S. 279, 296 (1965).

92.207(b)(4)-(5)] requires the provision [or coverage] of any health service where the covered entity has a legitimate, nondiscriminatory reason for denying or limiting" the service or coverage. 45 C.F.R. § 92.206(c); *accord id*. § 92.207(c). The Rule thus establishes a framework for determining whether any particular denial of care or coverage violates § 1557. "When OCR investigates claims of discrimination based on the denial of care, [it] will consider the covered entity's rationale for such denial, any supporting information the covered entity offers for its position, and any evidence of unlawful animus, bias, or other discriminatory factors in the case." 89 Fed. Reg. 37,597. The framework set forth in the Rule is consistent with decades of precedent. *See, e.g.*, *McDonnell Douglas Corp. v. Green*, 411 U.S. 792, 802-03 (1973) (establishing same framework for analyzing Title VII discrimination claims); *Buckley v. Sec'y of Army*, 97 F.4th 784, 794 (11th Cir. 2024) (*McDonnell Douglas* framework appropriate for discrimination statutes that include "but-for causation" principles).

Consider Plaintiffs' hypothetical involving a surgeon who routinely provides orchiectomies. ECF No. 12 at 16-17. Plaintiffs argue that a surgeon who treats a transgender woman seeking an orchiectomy because of testicular cancer but not a transgender woman who seeks an orchiectomy because of gender dysphoria is not discriminating on the basis of sex. *Id*. But whether that is true will depend on the surgeon's reason(s) for denying treatment. For example, a determination that the service was "not clinically appropriate for [the] particular individual" would likely provide a legitimate, nondiscriminatory rationale for the denial. 45 C.F.R. § 92.206(c). In contrast, if the surgeon instead explained that they denied the orchiectomy because

of animus against transgender individuals for their sex-related traits, the surgeon would have engaged in impermissible sex discrimination. *Id*.; *see Glenn*, 663 F.3d at 1317; *Lange v. Houston County*, 101 F.4th 793, 798-99 (11th Cir. 2024) (holding that a health insurance provider can violate a statutory duty not to discriminate because of sex for denying coverage for gender-affirming care to a transgender employee because the employee is transgender). Plaintiffs have not established that the framework set forth in the Rule for assessing alleged legitimate, nondiscriminatory reasons for a denial of care or coverage is unlawful. *Bowers v. Bd. of Regents of Univ. Sys. of Ga.*, 509 F. App'x 906, 910 (11th Cir. 2013) (applying framework to Title IX claim).

D. Plaintiffs' Arguments about 20 U.S.C. § 1686 are Unmoored from the Provisions of the Rule They Seek to Enjoin HHS from Enforcing.

Plaintiffs argue that § 1557 incorporates 20 U.S.C. § 1686, which permits educational institutions to "maintain[] separate living facilities for the different sexes." ECF No 12 at 10-11. It is far from clear that Plaintiffs' reading of § 1557 to incorporate § 1686 is the best one, given that § 1557 only explicitly refers to the "ground prohibited" and "enforcement mechanisms provided for" under Title IX. 42 U.S.C. § 18116. *Schmitt v. Kaiser Found. Health Plan of Wash*, 965 F.3d 945, 953 (9th Cir. 2020). But Plaintiffs never explain why their alleged entitlement to an injunction against enforcement of the provisions cited in their proposed order, ECF No. 12-5, turns on whether Congress incorporated § 1686 in § 1557. Even if Plaintiffs are correct that § 1686 governs the application of § 1557's bar on sex discrimination, nothing in the challenged Rule precludes the agency or courts from applying § 1686 when addressing

particular cases. Relatedly, the Rule does not forbid what § 1686 permits. Insofar as this argument is related to Plaintiffs' request to enjoin enforcement of § 92.206(b)(3), again, that provision only requires that sex separation not "subject[] any individual to more than de minimis harm." 45 C.F.R. § 92.206(b)(3). Insofar as this argument is related to Plaintiffs' request to enjoin enforcement of § 92.101(a)(2)(iv), a determination that § 1686 governs § 1557 in some contexts would not mean that § 1557 never prohibits discrimination on the basis of gender identity. *See supra* at 12-15.

E. No Motion to Enjoin or Stay Any Application of the Rule to Plaintiffs' Particular Policies is Properly Before the Court.

Plaintiffs' heavy reliance on *Adams* and *Eknes-Tucker* to support their motion to enjoin portions of the Rule in all of their applications is misplaced. In addition to the reasons discussed *supra* at 14-15, both of those cases addressed various antidiscrimination provisions "as applied to a particular factual scenario," *Eknes-Tucker*, 80 F.4th at 1229, *i.e.*, one where a school district employed a particular bathroom policy, *Adams*, 57 F.4th at 811-17, and another where a state employed a particular policy restricting minors from accessing specific medical treatments, *Eknes-Tucker*, 80 F.4th at 1230. "That is not the scenario presented here." *Id.* at 1229. Rather, Plaintiffs here seek to enjoin HHS from enforcing general rules as applied to all plausible factual scenarios they might encompass. Plaintiffs' "hypothetical examples are not the stuff of ripe APA challenges." *Ass'n of Priv. Sector Colleges & Univs. v. Duncan*, 110 F. Supp. 3d 176, 196 (D.D.C. 2015), *aff'd*, 640 F. App'x 5 (D.C. Cir. 2016). *See Nat'l Ass'n of Regul. Util. Comm'rs v. FERC*, 964 F.3d 1177, 1185 (D.C. Cir. 2020).

Any request for an order enjoining HHS from enforcing the Rule to preclude particular policies would be inconsistent with the APA. Plaintiffs invoke judicial review under 5 U.S.C. § 702. Compl. ¶ 31. That provision requires Plaintiffs to "direct [their] attack against some particular 'agency action[,]'" *Lujan v. National Wildlife Federation*, 497 U.S. 871, 890 (1990), as opposed to "an abstract decision apart from [the] specific agency action" that they challenge, *Biden v. Texas*, 597 U.S. 785, 809 (2022). Plaintiffs cannot invoke the APA to have the Court review an agency decision about whether their particular policies violate the Rule before the agency analyzes any legitimate, nondiscriminatory justifications for each policy, as the Rule requires, and generates a reviewable agency action. *Supra* at 17-18; *infra* at 27-29. "It is a tautology that [a plaintiff] may not challenge [an agency's] regulations as applied until [the agency] applies the regulations[.]" *Dunn-McCampbell Royalty Int., Inc. v. Nat'l Park Serv.*, 112 F.3d 1283, 1288 (5th Cir. 1997); *see also Reno*, 507 U.S. at 300-01 (challenging application of a newly promulgated Rule would be impossible); *GeorgiaCarry.Org, Inc. v. Georgia*, 687 F.3d 1244, 1255 n.20 (11th Cir. 2012); *Nat'l Wildlife Fed. v. EPA*, 945 F. Supp. 2d 39, 44-47 (D.D.C. 2013).[10]

[10] Pre-enforcement review of any application of the Rule would also be inconsistent with § 1557 itself. As described above, *supra* at 4-5, § 1557 incorporates the administrative enforcement mechanisms of Title IX, including its detailed judicial review provision, permitting an Article III court to determine whether any application of the Rule is consistent with § 1557 and the Rule. 20 U.S.C. § 1683. Permitting pre-enforcement injunctions against hypothetical applications of the Rule would undermine the comprehensive review process established by Congress. *See Thunder Basin,* 510 U.S. at 207-18; *Florida*, 2024 WL 2803298, at *3-6.

F. 42 C.F.R. § 438.3(d)(4)

Florida also has not established that 42 C.F.R. § 438.3(d)(4), which requires contracts between states and managed care plans to include provisions that prohibit discrimination on the basis of gender identity, is unlawful.[11] Florida appears to claim that HHS lacked statutory authority to promulgate regulations prohibiting discrimination in enrollment as part of HHS's oversight of the Medicaid and CHIP programs and requiring contract terms in managed care plans that prohibit discrimination in enrollment by those plans. Florida is incorrect.

Medicaid and CHIP are joint federal-state programs that enable states to extend medical coverage to certain low-income individuals under Title XIX (Medicaid) and Title XXI (CHIP) of the Social Security Act. 42 U.S.C § 1396, *et. seq.*; *id.* § 1397aa, *et. seq.* To participate in either, each state must create a specific plan that fulfills the conditions specified in 42 U.S.C. § 1396a(a) or 42 U.S.C. §§ 1397aa-1397bb and submit the plan to HHS for approval. *Id.* § 1396a(b); *id.* § 1397ff(a)-(c); 42 C.F.R. § 457.150(a)-(c). Upon approval, states administer their plans, and the federal government provides funding to help defray costs.[12]

[11] CMA does not allege any injury to its members from this provision. *See* Compl. ¶¶ 185-215 (alleging harm only from the "OCR Rules"). Accordingly, CMA lacks standing to obtain injunctive relief against this provision. *See Mack v. USAA Casualty Insurance Co.*, 994 F.3d 1353, 1356 (11th Cir. 2021) ("[S]tanding is not dispensed in gross." (quoting *Lewis v. Casey*, 518 U.S. 343, 358 n.6 (1996)).

[12] CMS discussed the authorities for regulating managed care programs in detail in a final rule promulgated in 2016. *Medicaid and Children's Health Insurance Program (CHIP) Programs; Medicaid Managed Care, CHIP Delivered in Managed Care, and Revisions Related to Third Party Liability*, 81 Fed. Reg. 27,498, 27,500-01 (May 6, 2016).

The challenged provision does not "impose[] effects-based liability on contractors," as Florida claims. ECF No. 12 at 20. Rather, it establishes a condition of federal funding, and it is beyond dispute that HHS—through CMS—may establish requirements for state Medicaid and CHIP plans by regulation, including for the proper and efficient operation of state Medicaid plans, 42 U.SC. § 1396a(a)(4), to ensure that such plans operate in the "best interests of recipients[,]" *id.* § 1396a(a)(19), and to provide for the "effective and efficient" provision of child health assistance, *id.* § 1397aa(a). *See* 42 U.S.C. § 1302(a). That is precisely what HHS did here. *See* 89 Fed. Reg. at 37,668. Florida largely ignores HHS's authority to regulate and approve state plans, and it conspicuously avoids any reference to HHS's authority under § 1396a(a)(19). *See* ECF No. 12 at 19-20. Nor does Florida cite any authority to support its argument that HHS lacked authority to impose the particular requirements in § 438.3(d)(4) as a condition of federal funding. *See, e.g.*, *W. Virginia v. Thompson*, 475 F.3d 204, 209-14 (4th Cir. 2007) (deferring to CMS's interpretation of the Medicaid statute even in the absence of notice-and-comment rulemaking). *Compare Adams*, 57 F.4th at 815 (addressing notice requirements in the context of a private suit for damages under § 1983).

Moreover, to the extent Florida's argument is that HHS lacked authority to promulgate rules prohibiting policies or practices that have discriminatory effects, ECF No. 12 at 19-20, Florida's claim comes too late. CMS regulations have proscribed such policies and practices with respect to race, color, and national origin since 2002, *see Medicaid Program; Medicaid Managed Care*: New Provisions, 67 Fed. Reg. 40,989,

41,098 (June 14, 2002), and discrimination based on sex was added in 2016, *see* 81 Fed. Reg. at 27,856. In all that time, Florida has never challenged CMS's authority to prohibit discriminatory effects, and the statute of limitations for questioning that authority has now passed. *See* 28 U.S.C. § 2401(a).

In any event, Florida's challenge to § 438.3(d)(4) is not properly before this Court. *See Thunder Basin Coal Co. v. Reich*, 510 U.S. 200, 208 (1994). If CMS were to disallow federal financial participation on the basis of failure to comply with § 438.3(d)(4), Florida would be entitled to notice and, upon request, to receive a reconsideration of the disallowance and appeal to the Departmental Appeals Board, and could then seek judicial review if dissatisfied. 42 U.S.C. §§ 1316(e), 1397gg(e)(2); 42 C.F.R. § 430.42. Similarly, were CMS to seek to withhold or defer federal financial participation on Florida's payments to its managed care plans, there are procedural protections in place and a right to seek further review in the court of appeals. 42 U.S.C. §§ 1316(a)(3), 1396c; 42 C.F.R. §§ 430.35 through 430.40. In all events, Congress's "intent to allocate initial review of Florida's claims to CMS is 'fairly discernable in [42 U.S.C. § 1316]," and therefore the Court lacks subject-matter jurisdiction over the claim. *Florida*, 2024 WL 2803298, at *6.

G. The Rule Does Not Violate the Spending Clause.

Section § 92.101(a)(2)(iv) is not impermissibly ambiguous under *Pennhurst State Sch. & Hosp. v. Halderman*, 541 U.S. 1, 18 (1981). ECF No. 12 at 11-12. Even assuming

Penhurst requires a clear statement,[13] there is no Spending Clause problem because the relevant provision in the Rule merely explains the scope of § 1557's unambiguous prohibition on sex discrimination, based on the statutory language's plain meaning. *Bostock*, 590 U.S. at 674. In *Bostock*, the Supreme Court explained that Title VII's "message" on this score was "simple." *Id*. at 644. "Given the similarity in language prohibiting sex discrimination in Titles VII and IX," *Doe*, 28 F.4th at 114, the same clear statement exists in Title IX and § 1557; *see also Tovar v. Essentia Health*, 342 F. Supp. 3d 947, 953 (D. Minn. 2018).[14] "[S]o long as a spending condition has a clear and actionable prohibition of discrimination, it does not matter that the manner of that discrimination can vary widely." *Benning v. Georgia*, 391 F.3d 1299, 1306 (11th Cir. 2004). Moreover, the statutory provisions cited above clearly put states on notice that CMS will impose regulatory requirements for operation of programs.

[13] The *Pennhurst* analysis is most frequently invoked in the context of ascertaining the scope of liability in a private lawsuit (typically for damages). *See, e.g. Cummings v. Premier Rehab Keller, PLLC*, 596 U.S. 212, 218-219 (2022); *Adams*, 57 F.4th at 815. In those case, the *Pennhurst* analysis does not result in an unenforceable statutory or regulatory spending condition, but instead a conclusion that enforcement must be at the hands of the federal government seeking prospective compliance as a condition of continued funding rather than private individuals seeking damages for past conduct. In applying *Pennhurst*, the Supreme Court has explained that the consequence of a statute "not unambiguously confer[ring] an enforceable right upon the Act's beneficiaries" is the unavailability of a private cause of action to enforce the provision either in its entirety or in certain applications. *Suter v. Artist M.*, 503 U.S. 347, 363 (1992). A statute imposing a "generalized duty on [the] State" is not invalid, but is "to be enforced by the Secretary in the manner [of reducing or eliminating payments]." *Gonzaga Univ. v. Doe*, 536 U.S. 273, 381 (2002) (quoting *Suter*, 503 U.S. at 363).

[14] Plaintiffs seemingly argue that the Spending Clause would preclude reading § 1557 to bar separate living facilities or separate bathrooms based on sex. ECF No. 12 at 12-13. But, as explained above, the Rule does not determine whether any particular practice violates § 1557; thus, particular applications of the Rule are not at issue here.

II. Plaintiffs Cannot Establish Imminent Irreparable Injury.

Whether for a preliminary injunction, *Siegel v. LePore*, 234 F.3d 1163, 1176-77 (11th Cir. 2000), or Article III standing, *Corbett v. TSA*, 930 F.3d 1225, 1233 (11th Cir. 2019), "injunctive relief requires [a] future injury [that] 'proceed[s] with a high degree of immediacy,'" specifically, "within some fixed period of time in the future[,]" *id.* at 1233, "to reduce the possibility of deciding a case in which no injury would have occurred at all." *Lujan v. Defs of Wildlife*, 504 U.S. 555, 564 n.2 (1992). Mere fear of future injury—even if "not fanciful, irrational, or clearly unreasonable"—is insufficient. *Clapper v. Amnesty Intern. USA*, 568 U.S. 398, 416 (2013) (citation omitted). Rather, a plaintiff alleging injury due to a legal code must "assert an injury that is the result of the [code's] actual or threatened"—not merely feared—"*enforcement*, whether today or in the future." *California v. Texas*, 593 U.S. 659, 670 (2021). Consistent with the "characterization" of injunctive relief as "extraordinary[,]" *Winter*, 555 U.S. at 22, not all Article III injuries constitute irreparable harm, even if they cannot be redressed in damages, *FTC v. Standard Oil Co. of Cal.*, 449 U.S. 232, 244 (1980).

Here, Plaintiffs' allegations of possible future harm do not establish imminent injury. This Court thus lacks jurisdiction whether analyzed as a matter of standing, *Nat'l Fam. Plan. and Reprod. Health Ass'n v. Gonzales*, 468 F.3d 826, 829-31 (D.C. Cir. 2006), ripeness, *Colwell v. HHS*, 558 F.3d 1112, 1123-29 (9th Cir. 2009), or statutory preclusion of pre-enforcement jurisdiction, *Thunder Basin Coal Co. v. Reich*, 510 U.S. 200, 207-18 (1994). But for purposes of the present motion, it is most speculative that

Florida or CMA members will experience an irreparable injury "before a decision on the merits can be rendered," *Winter*, 555 U.S. at 22 (citation omitted)—which is the purpose of a preliminary injunction.

Plaintiffs' failure to show irreparable injury that will occur before the Court decides this case is premised on the combination of three points: (1) Florida and CMA members' insistence in their briefing and elsewhere that they have legitimate, nondiscriminatory bases for their policies, which is all that the Rule requires, (2) Plaintiffs' failure to show that "good-faith" reliance on a belief that policies are nondiscriminatory "would trigger" irreparable consequences, like "an immediate funding cut-off, much less the sort of retroactive penalty that was involved in *Abbott Labs [v. Gardner*, 387 U.S. 136 (1967)]," *Gonzales*, 468 F.3d at 829, and relatedly (3) the attenuated procedures required before any loss of Federal financial assistance.

First, neither Florida nor CMA members allege that their policies are "based on unlawful animus or bias, or constitute a pretext for discrimination." *E.g.*, 45 C.F.R. § 92.207(c). For example, while Florida must comply with the Rule, Florida is pre-judging that its policies are noncompliant while arguing elsewhere that it has a legitimate, nondiscriminatory reason for those polices, ECF No. 12 at 5, *see also* ECF No. 12-3 at 2 (CMA members "care for all patients with respect and without unlawful discrimination"), which is what § 1557 and the Rule requires, *see* 45 C.F.R. §§ 92.206(c), 92.207(c); 89 Fed. Reg. at 37,535.

Second, if Florida or CMA members were to stand on their good-faith representations about the bases for their policies (or even on a good-faith belief that a

provision of the Rule as applied would be invalid), they do not establish that they would suffer a "retroactive penalty" at the hands of HHS, *Gonzales*, 468 F.3d at 829, for reliance on those representations or views after the Rule's effective date. To the contrary, in § 1557, Congress sought "to obtain compliance and eliminate discrimination [and did] not wish to use punitive measures[.]" 110 Cong. Rec. S7059 (daily ed. Apr. 7, 1964).[15] Compliance at any point in any putative enforcement process would thus preclude HHS from terminating funding. 45 C.F.R. §§ 80.7(d) (no funding loss proceedings if compliance can be achieved voluntarily after OCR investigation); 80.10(f) (permitting recipient to "correct its noncompliance" to preclude future funding loss after decision by hearing examiner but before decision takes effect), 80.10(g) (recipient "shall be restored to full eligibility" as soon as "it brings itself into compliance"). In other words, Florida won't lose its funding if it first refuses to comply but then decides later that it will.

Finally, the extensive procedures, culminating in judicial review, required by § 1557 before HHS could terminate any Federal financial assistance for noncompliance make any loss of "federal financial assistance from HHS," ECF No. 12 at 20, practically impossible "before a decision on the merits can be rendered[,]" *Winter*, 555 U.S. at 22 (citation omitted). *see also Flowers Industries v. FTC*, 849 F.2d 551, 552-53 (11th Cir. 1988) (no imminent irreparable harm when agency lacked

[15]One reason that Congress precluded any funding termination decision from taking effect until after a review process by congressional committees, *supra* at 5, was to provide a "further opportunity to end the discrimination without the necessity of cutting off Federal funds[.]" 110 Cong. Rec. S7060.

power to immediately effectuate harm). "At each point in any putative enforcement process, Plaintiffs would be able to raise the same claims they now raise." *ACP*, 2022 WL 17084365, at *15. Previously, the required steps have taken extensive time.[16]

Together, all this means that Plaintiffs have not shown imminent irreparable injury. *Sch. Dist. of City of Saginaw v. HEW*, 431 F. Supp. 147, 154 (E.D. Mich. 1977) (no irreparable harm from being required to present claims following completion of Title VI proceedings). Florida claims that it "will face an untenable choice"—stop enforcing its policies "or lose federal financial assistance[,]" ECF No. 12 at 20. Even if any "choice" alone "would be sufficiently great" to justify drastic injunctive relief, *Petrol. Exploration v. PSC of Ky.*, 304 U.S. 209, 220 (1938), neither Florida nor any CMA member faces one until after they are "requested" to "correct [any charge of noncompliance], and thus hopefully achieve 'voluntary compliance[,]'" *see Cook*, 1979 U.S. Dist. LEXIS 14572, at *3. In *Cook*, for example, it took HHS's predecessor agency over two years of investigation before even a preliminary finding of noncompliance. *Id.* And "[a]t the moment it also remains speculative whether such an [investigation] may be forthcoming" at all. *See Siegel*, 234 F.3d at 1177. Moreover, informal

[16] *E.g.*, *See, e.g., Civ. Remedies Div. the Gen. Couns.*, DAB No. CR2580 (2012) (H.H.S. Aug. 2, 2012) (terminating funding in 2012 after 3 years of investigation, 2 months of ignored repeated attempts to secure voluntary compliance, and more than 2 additional years had passed); *Freeman v. Cavazos*, 939 F.2d 1527, 1528 n.1, 1530 (11th Cir. 1991) (terminating funding in 1990 after investigating for 2 years and beginning funding termination procedures in 1986); *Cook v. Ochsner Found. Hosp.*, C.A. No. 70-1969, 1979 U.S. Dist. LEXIS 14572, at *3 (E.D. La. Feb. 7, 1979) (3 years and 5 months between initiation of investigation and initiation of formal administrative adjudication proceeding); *Bd. of Pub. Instruction of Taylor Cnty, Fla. v. Finch*, 414 F.2d 1068 (5th Cir. 1969) (19 months between initiation of mandatory voluntary mediation efforts (after completion of investigation) and final order terminating funds).

cooperation with HHS during that process would not itself constitute irreparable injury. *Standard Oil*, 449 U.S. at 244; *see also Petrol. Exploration*, 304 U.S. at 220-21 (same).

The harm alleged by CMA members—who fear enforcement of § 1557 requiring conduct that would violate their "core religious beliefs[.]" Compl. ¶ 23—is even more remote and speculative. The Rule's protections for religious freedom are robust. CMA members may rely on religious freedom and conscience protections, including RFRA, without obtaining a religious exemption under §§ 92.3(c), 92.302(a), which provide that application of the Rule's provisions "to specific contexts, procedures, or health care services" shall not be required where RFRA or other protections apply, *id.* § 92.302(a). Separately, the Rule establishes a process whereby CMA members can seek assurances from OCR that federal law protecting religious freedom and conscience exempts them from any of those applications. 45 C.F.R. § 92.302(b).[17] CMA members thus face no injury at all, let alone irreparable injury, *at least* until after "the exemption [request] is finally denied." *Navy SEAL 1 v. Biden*, 574 F. Supp. 3d 1124, 1143 (M.D. Fla. 2021).

[17] CMA members can seek such assurances even before any administrative complaint is filed and "before an[y] investigation is initiated." *Id.* Where members avail themselves of this option in advance and obtain an assurance, they will face no threat of investigation or enforcement. *Id.* § 92.302(d). Even if they did not proactively seek an assurance, if any administrative complaint is filed regarding their conduct or any investigation is otherwise initiated, CMA members "may, during the pendency of that investigation, similarly notify OCR of their belief they are entitled to an exemption under the process provided at § 92.302(b)." 89 Fed. Reg. at 37,658. And a member can appeal any adverse determination by OCR regarding an exemption within HHS and can seek judicial review in the event of a final adverse decision from the agency. 45 C.F.R. § 92.302(e)-(f).

Plaintiffs' arguments to the contrary lack merit. Florida cannot invoke the "health and welfare of [its] citizens," ECF No. 12 at 21 (citation omitted), as an interest in a suit against the Federal Government. *Haaland v. Brackeen*, 599 U.S. 255, 294-95 (2023); *Florida v. HHS*, 19 F.4th 1271, 1291-93 (11th Cir. 2021). And even if it could, Florida never explains how denying patients medically necessary care because of traits or actions that it would not have questioned in members of a different sex advances those interests.

Similarly, Florida cannot show imminent irreparable injury based on interests it may have in enforcing state statutes or rules that (1) it has represented to the *Dekker v. Weida*, No. 4:22-cv-00325-RH-MAF (N.D. Fla.) court that it is not enforcing or that (2) the *Doe v. Ladapo* court has enjoined Florida from enforcing against a class. --- F. Supp. 3d ---, 2024 WL 2947123 (N.D. Fla. June 11, 2024). ECF No. 32 at 4-7.[18]

That Florida is a State does not entitle it to a special "'presumption' of irreparable harm." *See Blue-Grace Logistics LLC v. Fahey*, 340 F.R.D. 460, 466 (M.D.

[18] Florida's reliance on the Government's amicus brief in *Dekker* to suggest it faces imminent irreparable harm due to the Rule's enforcement is misplaced. ECF No. 12 at 21. In *Dekker*, the district court's findings that Florida's policies violated § 1557 occurred after a trial where plaintiffs proved that Florida's justifications for the policies were pretext for discrimination on the basis of sex. For HHS to terminate Federal financial assistance due to the same policies under the new Rule's provisions would require resource-intensive trial-type administrative proceedings that would be largely duplicative of the *Dekker* proceedings. 45 C.F.R. § 92.207(c). If Florida loses *Dekker* on appeal, presumably Florida will comply with the Eleventh Circuit's judgment and there will be no need for any administrative adjudication, let alone termination of funding. If the Eleventh Circuit reverses, Florida cannot explain why the Eleventh Circuit's opinion would not inform HHS enforcement discretion. In any event, the mere fact that Florida might need to defend itself against an administrative complaint would not itself constitute irreparable harm. *Standard Oil*, 449 U.S. at 244. And whatever harm Florida currently faces from § 1557 enforcement in cases like *Dekker* is not redressable through enjoining enforcement of the Rule in this case.

Fla. 2022) (citation omitted). Florida invokes *Abbott v. Perez*, 585 U.S. 579 (2018). But in *Abbott*, the court held that enjoining a state from enforcing a statute imposed irreparable injury, 585 U.S. at 602 n.17; here, "[Florida] has not been enjoined from establishing, enforcing, or effectuating any of its statutes," *N.M. Dep't of Game and Fish v. U.S. Dep't of the Interior*, 854 F.3d 1236, 1255 (10th Cir. 2017). The point is that the mere existence of a statute or rule on the books cannot itself be irreparable injury; the injury must derive from "actual or threatened enforcement." *California*, 593 U.S. at 670. And as explained, irreparable injury from enforcement is not imminent. Plaintiffs' evidence therefore does not connect the dots so as to demonstrate that its ostensible sovereign injury will occur before a decision on the merits. Any chilling effect on Florida's interests associated with a potentially invalid rule being on the books is insufficient. *Whole Woman's Health v. Jackson*, 595 U.S. 30, 50 (2021).

Finally, a class-wide declaratory judgment precludes a finding of imminent irreparable harm. ECF No. 32 at 1-2. It already addresses any fear of enforcement against healthcare providers. As long as that judgment remains good law, OCR will not investigate class members alleged to have engaged in the kind of gender identity discrimination addressed in that case. *Id*. Thus, there is no risk of harm to the members of Plaintiff CMA or to the healthcare facilities that Plaintiff Florida has identified. *See* Compl. ¶ 17 and ECF 12-2 (Decl. of Kevin Bailey).[19] Courts have declined to find

[19] Plaintiffs' membership in the *Neese* class may have broader implications for their ability to pursue the relief they seek in this case insofar as it is "within the subject matter of the class action." *Green v. McKaskle*, 770 F.2d 445, 447 (5th Cir. 1985); *see also, e.g.*, *Roth v. Austin*, 62 F.4th 1114, 1117-18 (8th Cir. 2023) ("[P]roper remedy is to dismiss the duplicative claims").

imminent irreparable harm in similar contexts. *See Bongiovanni*, 2022 WL 1642158, at *10; *Faust v. Vilsack*, No. 21-C-548, 2021 WL 2806204, at *3 (E.D. Wis. July 6, 2021); *see also Sanchez-Espinoza v. Reagan*, 770 F.2d 202, 208 n.8 (D.C. Cir. 1985).

III. The Equities and Public Interest Weigh Against a Preliminary Injunction.

The balance of the equities and public interest plainly weigh against the drastic relief Plaintiffs request. Plaintiffs have not made any showing of substantial, imminent, and irreparable injury of the nature that would warrant extraordinary intervention by a court of equity. Against this non-existent showing of harm weighs the significant public interest in permitting enforcement of the Rule to combat discrimination in health programs and activities receiving federal funds. It is well-established that violations of federal civil rights statutes constitute irreparable harm. *See Rogers v. Windmill Pointe Vill. Club Ass'n*, 967 F.2d 525, 528 (11th Cir. 1992); *United States v. Hayes Int'l Corp.*, 415 F.2d 1038, 1045 (5th Cir. 1969). A patient who is denied basic medical care just because a provider or insurer wants to intentionally penalize them for their sex-related traits suffers "irreparable injury." *Lange*, 101 F.4th at 801. Issuing Plaintiffs' injunction would authorize that behavior. Moreover, there is "inherent harm" in preventing HHS from enforcing statutes. *Cornish v. Dudas*, 540 F. Supp. 2d 61, 65 (D.D.C. 2008). *See Abbott*, 585 U.S. at 602 n.17.

Plaintiffs assert that "staying or enjoining enforcement of the 2024 Rules won't interfere with HHS's legitimate law-enforcement interests" and that "HHS will be able to continue enforcing Section 1557 to prevent actual intentional sex discrimination."

ECF No. 12 at 23. That is not the import of their proposed order.[20] Insofar as Plaintiffs suggest that the Court should issue an order that precludes HHS from taking enforcement actions against Florida or CMA members by citing the provisions of the Rule but leaves HHS "free to engage in the [same]" enforcement actions "that the plaintiffs say injures them" by citing the statute alone, their motion should be dismissed on standing grounds. *See Support Working Animals, Inc v. Governor of Fla*, 8 F.4th 1198, 1205 (11th Cir. 2021). An order permitting HHS to take the same enforcement actions it would take under the Rule by instead citing the statute could not plausibly redress any threat of enforcement they purport to face. *See id*.

IV. The Court Should Not Enjoin Defendants from Enforcing Any Provision of the Rule Against Nonparties or Unharmed, Unidentified CMA Members.

Any preliminary injunction or stay should be limited in scope. The Eleventh Circuit has confirmed that entry of a nationwide injunction will typically be an abuse of discretion. *See Georgia v. Pres. of the U.S.*, 46 F.4th 1283, 1306 (11th Cir. 2022).

Here, Plaintiffs fail to show that nationwide relief is necessary to redress the alleged injuries of Florida or CMA members. An order appropriately limited to enjoining Defendants from enforcing specific provisions of the Rule against Florida or CMA members insofar as they have shown individualized imminent irreparable injury from enforcement of those provisions (and otherwise persuaded the court that

[20] In the context of agency rules, a § 705 stay operates to "stay enforcement" of the stayed provisions. *Abbott Laboratories v. Gardner*, 387 U.S. 136, 156 (1967); *see also Nken v. Holder*, 556 U.S. 418, 428 (2009) (stays and injunctions have the same "practical effect").

preliminary injunctive relief is appropriate) would suffice to redress that showing of irreparable harm. Plaintiffs offer no legitimate reason consistent with Article III to extend an injunction to others. *See Gill v. Whitford*, 585 U.S. 48, 73 (2018). Nor does CMA's representation of its identified members mean that CMA may seek an injunction on behalf of nonparty CMA members that CMA has not shown face imminent irreparable harm. CMA cannot "circumvent" Rule 23's class-action "mechanisms in the name of providing injunctive relief only for nonparties' benefit" and for whom it has not shown irreparable harm. *Georgia*, 46 F.4th at 1306.[21]

CONCLUSION

Accordingly, the motion for a preliminary injunction should be denied.[22]

Dated: June 13, 2024 Respectfully submitted,

[21] Plaintiffs "lightly assume that Congress has intended to depart from [these] established [equitable] principles[,]" *see Weinberger v. Romero-Barcelo*, 456 U.S. 305, 313 (1982), when it enacted 5 U.S.C. § 705. ECF No. 12 at 24. But that provision does not change the inadvisability of a universal remedy. It was designed "to reflect existing law . . . and not to fashion new rules of intervention for District Courts." *Sampson*, 415 U.S. at 68 n.15. Its plain language requires the Court to consider relief that merely "preserve[s] status or rights pending conclusion of the review proceedings." 5 U.S.C. § 705. In tailoring any relief only "to the extent necessary to prevent irreparable injury[,]" *id.*, the statute directs courts to apply traditional equitable principles, which include tailoring relief to be no more intrusive than necessary to prevent irreparable harm to the parties. *Georgia*, 46 F.4th at 1303-04. Indeed, the House Report for the APA indicates that relief under § 705 should "normally, if not always, be limited to the parties complainant." H.R. Rep. No. 79-1980, at 43 (1946).

[22] Plaintiffs have not established that venue is proper in this district. To the extent Plaintiffs' complaint raises RFRA claims on behalf of CMA members, this Court is not a proper venue for those claims. *See* 28 U.S.C. § 1391(e); *Tucker v. U.S. Dep't of Army*, 42 F.3d 641 (5th Cir. 1994). Moreover, the RFRA claims and any (premature) as-applied challenges of individual CMA members asserted in the complaint should be severed. *See Crosby v. Austin*, No. 8:21-cv-2730-TPB-CPT, 2022WL 19236177, at *2 (M.D. Fla. Feb. 22, 2022). The Court need not address these issues in resolving the instant motion, however, because Plaintiffs' motion relies solely on their APA and Spending Clause claims to challenge provisions of the Rule in all their applications. Defendants note these issues here solely to ensure that they are not inadvertently forfeited. *See* Order, *U.S. Navy SEALs 1-26 v. Biden*, No. 4:21-cv-01236-O (N.D. Tex. May 7, 2022), ECF No. 150, at 7.

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Dkt. 35

IN THE UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
TAMPA DIVISION

STATE OF FLORIDA; FLORIDA AGENCY FOR HEALTH CARE ADMINISTRATION; FLORIDA DEPARTMENT OF MANAGEMENT SERVICES; CATHOLIC MEDICAL ASSOCIATION, on behalf of its current and future members,

Plaintiffs,

No. 8:24-cv-1080-WFJ-TGW

DEPARTMENT OF HEALTH AND HUMAN SERVICES; XAVIER BECERRA, in his official capacity as Secretary of the Department of Health and Human Services; MELANIE FONTES RAINER, in her official capacity as the Director of the Office for Civil Rights; CENTERS FOR MEDICARE AND MEDICAID SERVICES; CHIQUITA BROOKS-LASURE, in her official capacity as Administrator of the Centers for Medicare and Medicaid Services,

Defendants.

REPLY IN SUPPORT OF MOTION FOR STAY OR PRELIMINARY INJUNCTION

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INTRODUCTION

As of July 5, HHS's 2024 Rules ("Rules") will govern all entities involved in health-related activities that receive federal financial assistance, including Plaintiffs. 89 Fed. Reg. at 37,688. By their plain terms, the Rules forbid "the unremarkable—and nearly universal—practice of separating [private spaces] based on biological sex," whenever that practice conflicts with a person's gender identity. *Adams v. Sch. Bd. of St. Johns Cnty.*, 57 F.4th 791, 796 (11th Cir. 2022) (en banc); Compl. ¶ 135. And by their plain terms, the Rules say that denying "gender-transition" interventions or failing to subsidize them is discriminating based on sex, Compl. ¶¶ 136–53, and purport to preempt conflicting state law. 89 Fed. Reg. at 37,535, 37,598. The Rules are built atop a foundation that defies precedent. HHS *defined* discriminating on the basis of sex to include "[g]ender identity," 45 C.F.R. § 92.101(a)(2), even though *Adams* makes it clear—"pellucid"—that Title IX, and hence Section 1557, doesn't reach that category. Dkt. 12, at 8–12.

HHS has no answer to *Adams*. It just falls back on the classic agency playbook to avoid judicial rebuke: delay judicial relief, while it coerces compliance. That is not the law: this Court has jurisdiction, the suit is ripe, the Rules flout text and precedent and will inflict irreparable harms. Dkt. 12, at 20–23. A stay is warranted.

ARGUMENT

I. The Rules Mean What They Say

At the outset, HHS tries to obfuscate how the Rules work, and what they're about. HHS repeatedly claims that "[a]t its core, the Rule" forbids denying transgender

patients care or coverage for "a sore throat, a broken bone, or cancer—because of traits or actions that they would not have questioned in members of a different sex." Dkt. 33, at 3; *see also id.* at 10, 13, 33 ("broken bone"). But the Rules are not about addressing that extremely rare occurrence. The words "broken bone" don't appear in the Rules. The words "gender transition" and "gender affirming care," by contrast, appear over 100 times. And HHS's "equal access" rule—the "core" of the regulation—sets out a framework for prohibiting policies separating healthcare facilities based on sex and for promoting "gender transition" interventions, not for mending "broken bones."

Plaintiffs' quotations from the Rules aren't "misapprehensions," and HHS's disclaimers don't withstand scrutiny. On separate facilities, HHS claims the "equal access" rule, and specifically 45 C.F.R. § 92.206(b)(3), "does not purport to resolve § 1557's application to specific claims involving bathrooms, locker rooms, or anything else of the kind." Dkt. 33, at 1, 17 (quotation marks omitted). HHS then acknowledges, in a footnote, that the Rules say otherwise. Dkt. 33, at 17 n.9. HHS thus lacks candor in saying "the Rule does not forbid what [20 U.S.C.]§ 1686 permits." Dkt. 33, at 20.

HHS also claims that the "gender-transition" Rules don't promote a "standard of care." Dkt. 33, at 8. But "gender transition" *is* the putative "standard of care," Compl. ¶¶ 72–84, 105, and the regulatory text on its face compels access to it. HHS also says that "[n]othing in the Rule overrides a clinician's medical judgment as to whether a service is medically necessary or appropriate for any patient." Dkt. 33, at 8. That's reminiscent of the quip that the Soviet Union didn't restrict freedom of speech, only freedom *after* speech. Endocrinologists like Dr. Van Meter can have a general

policy against providing hormones for a gender transition—until HHS comes knocking. *See* Compl. ¶¶ 136–137, 195, 210–13. And HHS repeatedly says it will rely on "medical guidelines" to evaluate *individualized* medical necessity determinations, which is unnecessary unless HHS will override general judgments that, in its view, lack "medical substantiation" under relevant "guidelines." 89 Fed. Reg. at 37,613. These "guidelines" will not be Florida's rules of ethics. After all, HHS claims its Rules preempt state rules that pose an "obstacle" to gender transition—including rules reflecting the judgment of state medical boards, who are clinicians. *Id.* at 37,535, 37,598. The same is true for policies limiting coverage for "gender transition," except that here, the conflict is starker still. The United States has already said Florida's coverage limits conflict with the Rules. Dkt. 12, at 21.

HHS argues that Plaintiffs' concerns are hypothetical because covered entities may sometimes be able to prove, as an affirmative defense, that they had a legitimate, nondiscriminatory reason for denying these interventions. But guilty until proven innocent is the problem with HHS's "framework for determining whether any particular denial of [gender-transition] care or coverage violates § 1557." Dkt. 33, at 18. The "framework" relieves HHS of the need to show discrimination based on sex to establish prima facie liability and preempt conflicting state law whenever "gender transition" is involved. HHS may think Section 1557 authorizes this regime, but Plaintiffs disagree, and this dispute is not hypothetical. Plaintiffs think that "gender transition" is "experimental" and dangerous, and HHS has made clear it thinks that view is not legitimate. Compl. ¶ 10.

II. This Suit is Justiciable

Plaintiffs have standing, this Court has jurisdiction, and the suit is ripe. HHS's argument that this Court should wait out "over two years of investigation," while HHS coerces Plaintiffs, Dkt. 33, at 29–30, has no basis in justiciability principles. That's why the Sixth Circuit just rejected many of the same arguments HHS raises here. *See Tennessee v. Dep't of Educ.*, No. 22-5807, 2024 WL 2984295 (6th Cir. June 14, 2024).

A. Standing

"Government regulations that require or forbid some action by the plaintiff almost invariably satisfy both the injury in fact and causation requirements. So in those cases, standing is usually easy to establish." *Food & Drug Admin. v. All. for Hippocratic Med.*, Nos. 23-235 & 23-256, 2024 WL 2964140, at *7 (U.S. June 13, 2024) ("*FDA v. AHM*"). This is one of those cases. Plaintiffs include covered entities, and the Rules "arguably proscribe[] their conduct" and impose compliance costs. *West Virginia v. U.S. Dep't of the Treasury*, 59 F.4th 1124, 1137–38 (11th Cir. 2023). The Rules further injure Florida's sovereignty by reimagining the terms of its bargain, *id.* at 1136, and by injuring its "interest in enforcing [its] duly enacted laws without contradiction from the federal government." *Tennessee*, 2024 WL 2984295, at *10. Plaintiffs' "fear is not unfounded. It comes directly from the text of the" Rules. *Id.* at *5; *see supra* Part I. And harm is likely. *Id.* at *6. Come July 5, Plaintiffs (including CMA's doctors) must sign an assurance of compliance to continue receiving funding, modify their policies and practices, and begin trainings to conform to the "gender identity" regime. 89 Fed. Reg. at 37,684–85, 37,689; *see also* Dkt. 33, at 27 ("Florida must comply with the Rule"); 89

Fed. Reg. at 37,685 ("[A]lmost all practicing physicians [a]re likely covered by the rule."). And only one party needs to show standing is likely. *Tennessee*, 2024 WL 2984295, at *9 n.15. Thus Plaintiffs establish a "substantial likelihood of Article III standing." *Id.* at *13.[1]

B. Implied Preclusion

1557 Preclusion. In a footnote, HHS claims that Section 1557 implicitly strips district courts of jurisdiction over this pre-enforcement challenge. Dkt. 33, at 21 n.10. But "Section 1557 contains no explicit or implicit bar to judicial review." *Franciscan All., Inc. v. Burwell*, 227 F. Supp. 3d 660, 684 (N.D. Tex. 2016), so Plaintiffs may challenge rules through "actions for declaratory judgments … in a court of competent jurisdiction." 5 U.S.C. § 703. It is no wonder HHS relegated this argument to a footnote, since it has been repeatedly rejected, including most recently by the Sixth Circuit. *Tennessee*, 2024 WL 2984295, at *17.[2] Section 1557 is nothing like the Mine Act, the FTC Act, the Exchange Act, or for that matter, CHIP.

Section 1557 incorporates "[t]he enforcement mechanisms provided for and available under" laws such as Title VI and Title IX. 42 U.S.C. § 18116. But these laws

[1] The Religious Freedom Restoration Act ("RFRA") is irrelevant to CMA's standing. HHS acknowledges CMA members (indeed, all physicians) are regulated entities, and that HHS's exemption process involves costs, 89 Fed. Reg. at 37,684. Either is enough for standing.

[2] *See also Franciscan All.*, 227 F. Supp. 3d at 684 (Section 1557); *Louisiana v. EPA*, No. 2:23-CV-00692, 2024 WL 250798, at *19 (W.D. La. Jan. 23, 2024) (Title VI scheme "is not a special statutory scheme and does not vest review in courts of appeal, nor does it provide any comprehensive review process."); *Romeo Cmty. Schs. v. U.S. Dep't of Health, Educ., & Welfare*, 438 F. Supp. 1021, 1028–29 & n.8 (E.D. Mich. 1977) (Title IX does not preclude APA challenge to regulation).

don't contain "a special statutory scheme and do[] not vest review in courts of appeal, nor do[] [they] provide any comprehensive review process." *Louisiana v. EPA*, No. 2:23-CV-00692, 2024 WL 250798, at *19 (W.D. La. Jan. 23, 2024) (Title VI); *Tennessee*, 2024 WL 2984295, at *18 (Title IX). Instead, they provide that "agency action ... shall be subject to such judicial review as may otherwise be provided by law for similar action taken by such department or agency on other grounds." 20 U.S.C. § 1683. The referenced "agency action" includes rules. *See* 20 U.S.C. § 1682; *see also* 5 U.S.C. § 551(13) ("agency action" includes a "rule"). So, the "enforcement mechanisms" say courts "shall" review rules as "provided by" the APA, the opposite of a preclusive "special statutory review scheme." *Axon Enter., Inc. v. Fed. Trade Comm'n*, 598 U.S. 175, 185 (2023).

These mechanisms also don't confer "exclusive jurisdiction" on any "court of appeals." *Id*. at 185; *Thunder Basin Coal Co. v. Reich*, 510 U.S. 200, 207 (1994). The statutes provide that a sanctioned person "may obtain judicial review of such action in accordance with chapter 7 of title 5," the APA. 42 U.S.C. § 2000d-2; 20 U.S.C. § 1683. The APA itself doesn't confer jurisdiction, *Califano v. Sanders*, 430 U.S. 99, 107 (1977), so jurisdiction would still be under 1331 in district court—*i.e.*, exactly what we've filed here. *See, e.g.*, *Haven Bd. of Ed. v. Bell*, 456 U.S. 512, 518 (1982) ("Trumbull then filed suit in … District Court … contending that HEW's Title IX employment regulations were invalid and seeking declaratory and injunctive relief."). A statute that requires would-be plaintiffs to rely on federal-question jurisdiction and the APA to

challenge an agency sanction is not a special statutory review scheme channeling jurisdiction.

Social Security Act Preclusion. HHS argues the Social Security Act ("SSA") implicitly strips this Court of jurisdiction to review the new contract requirements for Medicaid contracts with managed-care organizations. Dkt. 33, at 24 (42 C.F.R. § 438.3(d)(4)). HHS specifically invokes 42 U.S.C. § 1316(e) (item disallowance) and 1316(a)(3) (plan determination). These provisions have nothing to do with reviewing managed-care-plan contracts. Contracts are reviewed by CMS under 42 C.F.R. § 438.3(a), a provision HHS doesn't mention, and CMS's decision to disapprove them is not subject to any special statutory review scheme. And in any event, channeling review through the tangential schemes HHS mentions "could foreclose all meaningful judicial review." *Axon*, 598 U.S. at 190; *see also Texas v. Brooks-LaSure*, 680 F. Supp. 3d 791, 807 (E.D. Tex. 2023) (rejecting argument that APA challenge to CMS rule was precluded by § 1316(e)). It's hard to see how Florida could tee up a challenge under them. A private managed-care entity would have to agree to a non-compliant contract with Florida to provoke HHS retaliation. That distinguishes this case from *Florida v. CMS*, No. 8:24-cv-317, 2024 WL 2803298, at *5 (M.D. Fla. May 31, 2024). A dispute about the scope of the federal government's authority under the SSA and the Spending Clause to impose disparate-impact duties through managed-care contracts is also "wholly collateral" to the agency process and has "nothing to do with the [fact-specific, reimbursement] matters" CMS adjudicates. *Axon*, 598 U.S. at 193. And this case

presents questions of law distinct from "technical considerations of agency policy." *Tennessee*, 2024 WL 2984295, at *21; *Texas*, 680 F. Supp. 3d at 807.

C. Ripeness

HHS's remaining objections sound in ripeness. Dkt. 33, at 20–21, 24. According to HHS, the suit comes too early because "[t]he Rule does not include a determination that any Plaintiffs' particular laws or policies violate § 1557." *Id.* at 3. On this view, Plaintiffs could bring APA pre-enforcement challenges only against rules that operate as a bill of attainder. This "would immunize nearly all agency rulemaking activities from the coverage of the Administrative Procedure Act." *Abbott Lab'ys v. Gardner*, 387 U.S. 136, 147 (1967). It would make the APA not "generous," *id.* at 141, but stingy. That is not the law. And HHS fails to identify any additional facts needed to rule.

Plaintiffs' challenge is ripe. The issues are "fit for judicial resolution." *Id.* at 153. HHS says its Rules are "*compelled by* the Supreme Court's reasoning in *Bostock*," Dkt. 33, at 10 (emphasis added). The Eleventh Circuit, *see Adams*, disagrees. HHS's assertion that the "justification for these Rules might vary with different circumstances," thus "overlooks the fact that both sides have approached this case as one purely of congressional intent." *Abbott Lab'ys*, 387 U.S. at 149. Plaintiffs would also suffer "hardship." *Id.* The 2024 Rules threaten Plaintiffs with the loss of billions of dollars in funds. *Tennessee*, 2024 WL 2984295, at *17. Plaintiffs "need not assume such risks while waiting for [HHS] to drop the hammer in order to have their day in court." *U.S. Army Corps of Eng'rs v. Hawkes Co.*, 578 U.S. 590, 600 (2016); *Tennessee*, 2024 WL 2984295, at *17 (same).

III. The Rules Are Invalid

A. *Adams* Controls

On the merits, HHS concedes that if "discrimination on the basis of sex excludes discrimination on the basis of gender identity" under Title IX, then the Rules are "irreconcilable with" *Adams*. Dkt. 33, at 14. *Adams* makes it "pellucid" that Title IX, and hence Section 1557, doesn't include "gender identity." *See* Dkt. 12, at 9–10. So, the Rules conflict with *Adams*. HHS argues the Court should follow *Bostock*'s but-for-causation test. That is "the dissent's theory" in *Adams*, which the majority expressly rejects. *Adams*, 57 F.4th at 814 n.7. For good reason. HHS's "dissent theory" would mean Section 1557 "would provide more protection against discrimination on the basis of transgender status under the statute . . . than it would against discrimination on the basis of sex." *Adams*, 57 F.4th at 814. At the least, none of this was "clear" on the face of the statute. *Id.* at 816. Plaintiffs are likely to succeed.

Although the Court need not reach the question because Section 1557 doesn't cover gender identity, *Adams* also means the "equal access" rule for separate facilities, 45 C.F.R. § 92.206(b)(3), is invalid. HHS's defense is that the rule may have valid applications, so the invalid applications must get a pass. This *Salerno* deference test is hard to square with HHS's argument that the APA doesn't authorize non-party relief, Dkt. 33, at 14 n.21, or the Court's duty to set aside rules in "excess of . . . authority," 5 U.S.C. § 706(2)(C), not just "entirely in excess of authority." Dkt. 33, at 14. But the Court may sidestep this question by fashioning relief as applied to Plaintiffs. And even if this test applies to party-specific claims for APA relief, and it doesn't, lawful

applications covered by other rules are "irrelevant" under *Salerno*. *City of Los Angeles, Calif. v. Patel*, 576 U.S. 409, 419 (2015); *Nat'l Mining Ass'n v. U.S. Army Corps of Eng'rs*, 145 F.3d 1399, 1407 (D.C. Cir. 1998) (the focus under *Salerno* would be on "incremental regulation"). The only putatively "valid" application HHS can come up with, "sex stereotypes," Dkt. 33, at 16, is already prohibited by a separate rule, 45 C.F.R. § 92.101(a)(2)(v).

B. The "Gender-Transition" Rules Are Unlawful

Setting aside *Adams*, the gender-transition rules are independently unlawful because they prohibit conduct that is not discriminatory. HHS argues its "framework" is "consistent with" *McDonnell Douglas*. Dkt. 33, at 18. Not so. Under *McDonnell Douglas*, a prima facie claim "falls apart because of a failure to locate a similarly situated individual." *Brewer v. Bd. of Trs. of Univ. of Ill.*, 479 F.3d 908, 921 (7th Cir. 2007). The problem with HHS's "framework" is that it doesn't require a "similarly situated individual." Dkt. 12, at 16–17. HHS doesn't defend its proxy-based reasoning either. Indeed, according to HHS, "many transgender individuals do not seek gender-affirming surgeries or other types of care." 89 Fed. Reg. at 37,682. Opposing these interventions is not discrimination, presumptively or otherwise. Dkt. 12, at 15–18.[3] So, the gender-transition rules are unlawful.

[3] HHS cites to *Lange*, a Title VII case, but *Lange* doesn't govern. Dkt. 12, at 15 n.2.

C. The Social Security Act Claim Is Timely

On the Social Security Act, HHS argued the claim is time-barred. Dkt. at 23–24. But the six-year statute of limitations "begins to run when the agency issues the final action that gives rise to the claim," *Alabama v. PCI Gaming Auth.*, 801 F.3d 1278, 1292 (11th Cir. 2015) (citing 28 U.S.C. §2401(a)), and Plaintiffs challenged the Rules the day they published. To the extent earlier rules are implicated, HHS reopened them by expanding them to "gender identity." *See Kennecott Utah Copper Corp. v. U.S. Dep't of Interior*, 88 F.3d 1191, 1227 (D.C. Cir. 1996). The suit is timely, and HHS's conclusory defense needs no reply. Plaintiffs are likely to show the Rules are invalid.

IV. The Rules Will Inflict Irreparable Harm

Harm is imminent. Effective July 5, covered entities must file an assurance of compliance with the 2024 Rules to continue receiving funds. 89 Fed. Reg. at 37,696, *to be codified at* 45 C.F.R. § 92.5; *see also Grove City Coll. v. Bell*, 465 U.S. 555, 574–75 (1984) (upholding defunding for failure to file an assurance). Plaintiffs have three options. Option 1: If Plaintiffs say they will comply, but don't mean it, they risk liability under the False Claims Act, including a penalty of $11,000 for each false claim, "plus 3 times the amount of damages which the Government sustains because of" the false claim. 31 U.S.C. § 3729(a)(1); *see, e.g.*, *United States ex. rel. Main v. Oakland City Univ.*, 426 F.3d 914, 916 (7th Cir. 2005) (university subject to False Claims Act for violating federal regulations in funding program). Option 2: If Plaintiffs refuse to file an assurance of compliance, they risk immediate termination of federal financial assistance. Just ask Grove City College. *See Grove City Coll.*, 465 U.S. 555. Option 3: If

Plaintiffs comply, they violate state standards or their religious conscience (or both), suffering injury.

Apparently, HHS thinks that, because it could subject Plaintiffs to a purgatory of informal "negotiation" and Star Chamber proceedings before dropping the hammer, Plaintiffs suffer no immediate harm from Rules purporting to preempt state law, and mandating Plaintiffs immediately assure compliance, develop policies consistent with the Rules, and train employees. Dkt. 33, at 28–30. But there's nothing to negotiate. HHS wants Plaintiffs to promote gender transitions. Plaintiffs refuse. And HHS's ability to delay judicial review to use "informal coercion" only highlights the problem with delaying equitable relief. *Tennessee*, 2024 WL 2984295, at *20. Without immediate relief, Florida "will continue to face pressure to change [its] laws to avoid legal consequences," an irreparable injury. *Id.* at *25. And covered entities will risk immediate loss of all funds.

Nor does conscience language in the rule dampen CMA's need for relief. CMA's doctors are "practicing physicians" and therefore regulated by the rule. 89 Fed. Reg. at 37. HHS has imposed a sweeping mandate on them, but only made room for conscience in narrow circumstances *if* previous statutes apply. 45 C.F.R. § 92.302. But previous conscience statutes mostly cover abortion, which is not at issue here. *See, e.g.*, 42 U.S.C. §§ 238n, 300a-7. Other provisions in them do not protect entities (like Dr. Van Meter's business), or when patients pay privately. *Id.* § 300a-7(d).

As for RFRA, the rule suggests doctors can ask HHS for an "assurance" that it will not punish them, § 92.302(b), but that does not relieve their harm. First, the rule

forces the hospitals where CMA's doctors practice to stamp out all newly-defined discrimination. But HHS is not promising to shield these doctors from the coercion it is imposing on them through hospitals. An injunction protecting CMA's doctors would stop HHS from using the rule to injure them by any means. In addition, while CMA's doctors are religious, the rule requires their physician practices to comply. But like most companies, those practices are often not set up as religious entities. For example, nothing reflects that Dr. Van Meter's company is religious. Comp., Ex. 4 ¶ 23. Therefore, RFRA would not protect those companies from the rule—and therefore would force Dr. Van Meter to make sure their companies comply—unless HHS is also forcing CMA's members to incur added costs by restructuring their businesses to be religious. This adds to the nearly $1,000 HHS admits it is imposing on CMA's members to seek an exemption. An injunction for CMA will relieve these burdens.

HHS points to other suits, but those do not dampen the need for relief. Dkt. __. *Dekker* doesn't affect Florida's interest in enforcing the spending laws at issue there. It is not a class action, and declaratory relief against the policies is limited "to the extent they categorically ban Medicaid payment for puberty blockers and cross-sex hormones for the treatment of gender dysphoria." *Dekker v. Weida*, 679 F. Supp. 3d 1271, 1299 (N.D. Fla. 2023). Florida is still enforcing the Medicaid rule against non-parties because it is not categorical—a waiver process is available. Fla. Admin. Code r. 59G-1.050(7), Compl ¶ 121; Dkt. __. *Ladapo*, recently decided, is a class action, but the judgment doesn't forbid Florida from enforcing its public health laws to restrict

procedures other than puberty blockers and hormones, so Florida may enforce the laws to prevent other interventions, such as mastectomies for minors. Dkt. __. And in any event, *Ladapo* and *Dekker* are of no relevance to Florida's Department of Management of Services ("DMS"), which has a longstanding policy limiting payment for these interventions, Compl. ¶¶ 169-72; or to the Agency for Persons with Disabilities ("APD"), which has a policy of separating dual-occupancy rooms based on sex, regardless of gender identity. Compl. ¶ 173. They, and CMA's members, need relief now.

As for *Neese v. Becerra*, 640 F. Supp. 3d 668 (N.D. Tex. 2022); *see also* Compl. ¶ 59, the classwide declaratory relief for physicians there doesn't negate a need for immediate relief for two reasons. First, Florida, AHCA, DMS, and APD are not class members, because they are not medical providers covered by the physician class. HHS ambiguously claims that APD might be a class member, Dkt. 33, at 32, but that would be wrong, as APD is an agency, not a physician. To the extent it now claims it won't enforce the Rules against APD for "the kind of gender identity discrimination addressed in that case," HHS is just engaging in "voluntary cessation," which must be disregarded. *Tennessee*, 2024 WL 2984295, at *5 n.8.

Second, as to CMA, *Neese* didn't provide injunctive relief against Defendants. 640 F. Supp. 3d at 684–85. So the judgment doesn't stop HHS from enforcing these Rules against Plaintiffs, including CMA's doctors. HHS has also appealed *Neese*, arguing that the class representatives lack standing. No. 23-10078 (5th Cir.). Argument was in January. And HHS makes no promise not to enforce the Rules as soon as it

wins that appeal; rather, it suggests the opposite. An ambiguous promise to not enforce the Rules against "the kind of gender identity discrimination addressed in that case," whatever that might entail, is thus no promise at all. And even if HHS refrains from "enforcement," the Rules still force CMA doctors to certify compliance starting July 5 or lose their funding—or their conscience. A stay is warranted.

CONCLUSION

Plaintiffs are entitled to a stay or preliminary injunction. The Court should stay the challenged Rules as to Plaintiffs, including CMA and its Members, and enjoin Defendants from enforcing the assurance-of-compliance requirement until final judgment.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on June 18, 2024, a true and correct copy of the foregoing was filed with the Court's CM/ECF system, which will provide service to all parties who have registered with CM/ECF and filed an appearance in this action. I also sent a copy by email to the following U.S. Department of Justice attorney assigned to this matter:

Liam Holland
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/s/ James R. Conde
James R. Conde

Dkt. 41

UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
TAMPA DIVISION

STATE OF FLORIDA, et al.,

Plaintiffs,

v. Case No. 8:24-cv-1080-WFJ-TGW

DEPARTMENT OF HEALTH
AND HUMAN SERVICES, et al.,

Defendants.
_____/

ORDER

Before the Court is Plaintiffs State of Florida, Florida Agency for Health Care Administration ("AHCA"), Florida Department of Management Services ("MS") (collectively, "Florida"), and Catholic Medical Association's ("CMA") Motion for Stay or Preliminary Injunction (Dkt. 12) of Final Rule. Defendants Department of Health and Human Services, Secretary of the Department of Health and Human Services (collectively "HHS"), Centers for Medicare and Medicaid Services, Administrator of the Centers for Medicare and Medicaid Services (collectively, "CMS"), and Director of the Office for Civil Rights have responded (Dkt. 33). Plaintiffs have replied (Dkt. 35). On June 21, 2024, the Court held a hearing on this matter. Upon careful consideration, and with the benefit of able argument by both sides, the Court grants Plaintiffs' Motion within the State of Florida. The subject

rules are stayed in Florida. Defendants are preliminarily enjoined within the State of Florida as follows.

BACKGROUND

The instant case is about Defendants' changed interpretation of the Affordable Care Act's ("ACA") prohibition on sex discrimination, and Defendants' attempt to enforce their new rules through the Final Rulemaking to be codified at 45 C.F.R. §§ 92.101, 92.206, 92.207 and 42 C.F.R. § 438.3(d)(4). *See* 89 Fed. Reg. 37,522 (May 6, 2024). Specifically, Defendants interpret the ACA's proscription against discrimination *on the basis of sex* to include discrimination *on the basis of gender identity*. *Id.* at 37,699 (emphasis added). They now maintain, among other things, that ACA covered providers may not "[d]eny or limit health services sought for purpose of gender transition or other gender-affirming care that the covered entity would provide to an individual for other purposes if the denial or limitation is based on an individual's sex assigned at birth, gender identity, or gender otherwise recorded." *Id.* at 37701. Plaintiffs disagree with Defendants' interpretation of the ACA. They ask the Court to enjoin Defendants from enforcing it against them.

The Final Rules considered here are broad and significant in application. As HHS has noted, "almost all practicing physicians in the United States are reached by Section 1557 [the provision at issue] because they accept some form of Federal

remuneration apart from Medicare Part B." *Nondiscrimination in Health Programs and Activities,* 81 Fed. Reg. 31,375, 31,446 (May 18, 2016).

I. The ACA and Title IX

In 2010, Congress passed the ACA seeking to improve healthcare coverage for Americans. Pub. L. No. 111-148, 124 Stat. 119. Section 1557 of the ACA furthers this goal by mandating that no individual shall, "on the ground prohibited under . . . Title IX of the Education Amendments of 1972 (20 U.S.C. 1681 et seq.) . . . be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any health program or activity, any part of which is receiving Federal financial assistance[.]" 42 U.S.C. § 18116(a). Title IX then itself provides that "[n]o person in the United States shall, *on the basis of sex*, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any education program or activity receiving Federal financial assistance[.]" 20 U.S.C. § 1681(a) (emphasis added).[1]

[1] Title IX contains a number of sex-specific exceptions to this general language. 20 U.S.C. § 1686, for instance, provides that nothing contained within Title IX "shall be construed to prohibit any educational institution receiving funds under this Act, from maintaining separate living facilities for the different sexes." Further, § 1681(a) "shall not apply to an educational institution which is controlled by a religious organization if the application of this subsection would not be consistent with the religious tenets of such organization." *Id.* at § 1681(a)(3). The ACA itself also states that, "[n]otwithstanding any other provision of [the ACA,] HHS "shall not promulgate any regulation that . . . violates the principles of informed consent and the ethical standards of health care professionals[.]" 42 U.S.C. § 18114(5).

In addition to borrowing Title IX's "on the basis of sex" language, section 1557 also incorporates Title IX and Title VI's "enforcement mechanisms[.]" 42 U.S.C. § 18116(a). This essentially means that HHS's Office for Civil Rights ("OCR") may initiate investigations to determine whether "covered entities" have failed to comply with section 1557's anti-discrimination provision. *See* 20 U.S.C. § 1682; 45 C.F.R. §§ 80.7, 92.303(a). Where compliance cannot be secured voluntarily after an adverse finding, HHS must follow an administrative process before withholding federal funding. 20 U.S.C. § 1682. "[A]ny person aggrieved" by such action may also obtain judicial review. *Id.* at § 1683.

II. HHS's Implementation of Section 1557

On May 6, 2024, HHS issued a "final rule and interpretation" regarding section 1557 (the "Rule," "Rules," or "Final Rules"). *See generally* 89 Fed. Reg. 37,522. As relevant here, the Rules provide that discrimination "on the basis of sex includes, but is not limited to, discrimination on the basis of . . . [g]ender identity[.]" 45 C.F.R. § 92.101(a)(2)(iv) (effective July 5, 2024). The Rules expand on this interpretation through 45 C.F.R. §§ 92.206, 92.207 and 42 C.F.R. § 438.3(d)(4).

At section 92.206 the Rule addresses covered entities' obligation to provide "equal access to its health programs and activities without discriminating on the basis of sex." 45 C.F.R. § 92.206(a) (effective July 5, 2024). According to HHS, this obligation specifically prohibits four things:

> (1) denying or limiting "health services, including those that have been typically or exclusively provided to, or associated with, individuals of one sex, to an individual based upon the individual's sex assigned at birth, gender identity, or gender otherwise recorded;"
>
> (2) denying or limiting, "on the basis of an individual's sex assigned at birth, gender identity, or gender otherwise recorded, a health care professional's ability to provide health services if such denial or limitation has the effect of excluding individuals from participation in, denying them the benefits of, or otherwise subjecting them to discrimination on the basis of sex under a covered health program or activity;"
>
> (3) adopting or applying "any policy or practice of treating individuals differently or separating them on the basis of sex in a manner that subjects any individual to more than de minimis harm, including by adopting a policy or engaging in a practice that prevents an individual from participating in a health program or activity consistent with the individual's gender identity;" and
>
> (4) denying or limiting "health services sought for purpose of gender transition or other gender-affirming care that the covered entity would provide to an individual for other purposes if the denial or limitation is based on an individual's sex assigned at birth, gender identity, or gender otherwise recorded."

Id. at § 92.206(b)(1)–(4). The Rule adds, "[n]othing in this section requires the provision of any health service where the covered entity has a legitimate, nondiscriminatory reason for denying or limiting that service, including where . . . the covered entity reasonably determines that such health service is not clinically appropriate for a particular individual." *Id.* at § 92.206(c). What ostensibly matters is that a "covered entity's determination must not be based on unlawful animus or bias, or constitute a pretext for discrimination." *Id.*

At section 92.207 the Rule focuses on "health insurance coverage and other health-related coverage." 45 C.F.R. § 92.207(a) (effective July 5, 2024). It provides that covered insurers must not "[h]ave or implement a categorical coverage exclusion or limitation for all health services related to gender transition or other gender-affirming care" or "[o]therwise deny or limit coverage, deny or limit coverage of a claim, or impose additional cost sharing or other limitations or restrictions on coverage, for specific health services related to gender transition or other gender affirming care[.]" *Id.* at § 92.207(b)(4)–(5). Section 92.207(c) states that "reasonable medical management techniques such as medical necessity requirements" may provide a "legitimate, nondiscriminatory reason for denying or limiting coverage of" certain health services. *Id.* at § 92.207(c).

The final change concerns 42 C.F.R. § 438.3(d)(4).[2] Unlike the previously mentioned revisions, this one addresses "standard contract requirements" for entities that deliver services under Medicaid and CHIP.[3] 42 C.F.R. § 438.3(d)(4) (effective July 9, 2024). These contracts must now affirmatively state that the contracting

[2] Although Plaintiffs' complaint addresses a number of "CMS Rules," Dkt. 1 at 46–49, Plaintiffs' Motion for Stay or Preliminary Injunction only focuses on 42 C.F.R. § 438.3(d)(4). The Court will therefore largely limit its contracts analysis to 42 C.F.R. § 438.3(d)(4).

[3] Medicaid and CHIP are joint federal-state programs that enable states to extend medical coverage to low-income individuals under Title XIX (Medicaid) and Title XXI (CHIP) of the Social Security Act. 42 U.S.C § 1396, *et. seq.*; *id.* § 1397aa, *et. seq.* To participate in either, each state must create a specific plan that fulfills the conditions specified in 42 U.S.C. § 1396a(a) or 42 U.S.C. §§ 1397aa–1397bb and submit the plan for approval. *Id.* § 1396a(b); *id.* §1397ff(a)–(c); 42 C.F.R. § 457.150(a)–(c). Upon approval, states administer and fund their plans, and the federal government provides funding to help defray costs.

entity will "not discriminate against individuals eligible to enroll on the basis of race; color; national origin; disability; or sex which includes sex characteristics, including intersex traits; pregnancy or related conditions; sexual orientation; gender identity; and sex stereotypes; and will not use any policy or practice that has the effect of discriminating" on the same grounds. *Id.* In addition, participating states must ensure that these same entities "promote the delivery of services in a culturally competent manner to all enrollees . . . regardless of sex which includes sex characteristics, including intersex traits; pregnancy or related conditions; sexual orientation; gender identity and sex stereotypes[.]" 42 C.F.R. § 438.206(c)(2) (effective July 9, 2024).

III. Florida

Florida believes that gender-change interventions are "experimental" and risk irreversible damage. Dkt. 1 at 33. It has therefore "concluded that the alleged psychological benefits of gender-change interventions are far too speculative to justify the risks, particularly in minors." *Id.*[4]

[4] In 2022, the Florida Department of Health ("DOH") released guidance to this effect. *See Treatment of Gender Dysphoria for Children and Adolescents* (Apr. 20, 2022), https://perma.cc/BB4N-2QH4. The DOH explained that "[s]ystematic reviews on hormonal treatment for young people show a trend of low-quality evidence, small sample sizes, and medium to high risk of bias. A paper published in the International Review of Psychiatry states that 80% of those seeking clinical care will lose their desire to identify with the non-birth sex." *Id.* The DOH also noted its belief that "encouraging mastectomy, ovariectomy, uterine extirpation, penile disablement, tracheal shave, the prescription of hormones which are out of line with the genetic make-up of the child, or puberty blockers, are all clinical practices which run an unacceptably high risk of doing harm." *Id.*

In line with this view, Florida has issued "standards of practice and standards of care" for licensed physicians. Fla. Admin. Code r. 64B8-9.019. The Florida Board of Medicine prohibits "[s]ex reassignment surgeries, or any other surgical procedures that alter primary or secondary sexual characteristics" as well as "[p]uberty blocking, hormone, and hormone antagonist therapies" in the treatment of minors with gender dysphoria. *Id.* The Florida Board of Osteopathic Medicine similarly prohibits such treatments. Fla. Admin. Code r. 64B15-14.014.

Florida has also passed a number of other laws and regulations that are relevant here. Rule 59G-1.050(7) provides that Florida Medicaid does not cover "puberty blockers, hormones and hormone antagonists, sex reassignment surgeries, or any other procedures that alter primary or secondary sexual characteristics" for the treatment of gender dysphoria. Fla. Admin. Code r. 59G-1.050(7). SB 254 prohibits "[s]ex-reassignment prescriptions or procedures" for "patients younger than 18 years of age," and the expenditure of state funds for the same. Fla. Stat. §§ 286.311, 456.001, 456.52. And HB 1521 mandates that covered entities must generally provide both females and males "restrooms and changing facilities for their exclusive use, respective to their sex[.]" Fla. Stat. § 553.865(2), (5), (12).

Given the foregoing, Florida asserts that compliance with the Rules will require it to violate its own laws and regulations. Florida further asserts that non-compliance will result in a significant loss of funds as well as private lawsuits.

IV. Catholic Medical Association

Like Florida, "CMA and its members hold the position that gender-transition procedures are unethical and dangerous." Dkt. 1 at 9.[5] CMA's members also have "overlapping religious objections." *Id.* They believe that the Rules interfere with their right "to the conscientious and faithful practice of medicine." *Id.*

CMA focuses on aspects of the Rules that have not been previously mentioned but which ultimately depend on Defendants' interpretation of discrimination "on the basis of sex." Among other things, the Rules will require CMA members who qualify as "covered entities" to: (1) "submit an assurance . . . that the entity's health programs and activities will be operated in compliance with section 1557" as amplified by the Final Rules; (2) "implement a written policy" that "states the covered entity does not discriminate on the basis of" healthcare for gender-identity; (3) "train relevant employees of its health programs and activities on the civil rights policies" embodied in the Rules; and (4) "provide a notice of nondiscrimination" on the basis of gender-identity "to participants, beneficiaries, enrollees, and applicants of its health programs and activities, and members of the public." 89 Fed. Reg. 37,696–98. Non-compliance may result in remedial action. *Id.*

[5] According to the Complaint, CMA is the largest association of Catholic individuals in healthcare with "2,500 members nationwide in all fields of practice." Dkt. 1 at 8. Additionally, "[m]ost CMA members provide medical care in health programs and activities that receive federal financial assistance and are subject to Section 1557." *Id.* at 9.

CMA claims that these specific requirements, and the Rules as a whole, impose a "no-win" scenario for its members to: (1) "abandon or violate their convictions on gender and incur the costs of compliance"; or (2) "maintain their positions and practices but arguably falsify their policies, notices, and assurances of compliance to HHS and then risk continuing liability"; or (3) "exit the medical field and abandon their patients." Dkt. 1 at 60. Ultimately, CMA maintains that its members' "categorical exclusion of providing, facilitating, or affirming gender transitions, and their commitment to state law, precludes CMA members from" complying with the Rules. *Id.* at 58.

CMA's approximately 2,500 members are nationwide. For reasons stated below, the undersigned believes a nationwide injunction issuing here is improvident. Thus, CMA's motion for a preliminary injunction will be denied, although its Florida members will be under this Court's order. CMA's other requested remedies must await a decision on the merits.

V. Procedural History

On May 6, 2024, Plaintiffs filed the instant lawsuit against Defendants. Plaintiffs generally assert that the Rules violate the Administrative Procedure Act ("APA"), the Spending Clause, the First Amendment's guarantee of free speech and association, and the First Amendment and Religious Freedom Restoration Act's ("RFRA") guarantees of religious freedom. *Id.* at 64–81.

Plaintiffs now move for a stay or preliminary injunction concerning 45 C.F.R. §§ 92.101, 92.206, 92.207 and 42 C.F.R. § 438.3(d)(4). *See generally* Dkt. 12. Defendants oppose such relief on the merits. *See generally* Dkt. 33. They also suggest that Plaintiffs lack standing and that Plaintiffs' claims are not ripe for review. *Id.* at 26–33.

LEGAL STANDARDS

To obtain a preliminary injunction concerning the Rules, Plaintiffs must show that: (1) they have "a substantial likelihood of success on the merits; (2) irreparable injury will be suffered unless the injunction issues; (3) the threatened injury to the movant outweighs whatever damage the proposed injunction may cause the opposing party; and (4) if issued, the injunction would not be adverse to the public interest." *Siegel v. LePore*, 234 F.3d 1163, 1176 (11th Cir. 2000) (en banc). "The first two factors are 'the most critical.'" *Swain v. Junior*, 958 F.3d 1081, 1088 (11th Cir. 2020) (quoting *Nken v. Holder*, 556 U.S. 418, 434 (2009)). Further, "the third and fourth factors [tend to] merge when, as here, the government is the opposing party." *Gonzalez v. Governor of Georgia*, 978 F.3d 1266, 1271 (11th Cir. 2020) (cleaned up) (citations omitted).

5 U.S.C. § 705 provides that, "[o]n conditions as may be required and to the extent necessary to prevent irreparable injury," a court may "issue all necessary and appropriate process to postpone the effective date of an agency action or to preserve

status or rights pending conclusion of" a review. The showing required for stay under section 705 of the APA is not materially different than that required for a preliminary injunction. *Cook Cnty., Illinois v. Wolf*, 962 F.3d 208, 221 (7th Cir. 2020); *see also Purpose Built Fams. Found., Inc. v. United States*, No. 22-60938-CIV, 2022 WL 6226946, at *2–4 (S.D. Fla. July 29, 2022).

DISCUSSION

I. Justiciability

Defendants suggest that Plaintiffs lack standing, that Plaintiffs' claims are not ripe, and that implied preclusion issues exist. The Court will address each of these contentions before turning to consider the merits.

a. Standing

"Courts have jurisdiction to hear a case only when the plaintiff has standing to sue." *Baughcum v. Jackson*, 92 F.4th 1024 (11th Cir. 2024). Standing has three requirements: (1) "the plaintiff must have suffered an injury in fact—an invasion of a legally protected interest which is (a) concrete and particularized, and (b) actual or imminent, not conjectural or hypothetical"; (2) "there must be a causal connection between the injury and the conduct complained of—the injury has to be fairly traceable to the challenged action of the defendant and not the result of the independent action of some third party not before the court"; and (3) "it must be likely, as opposed to merely speculative, that the injury will be redressed by a

favorable decision." *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 560–61 (1992) (cleaned up) (internal quotations and citations omitted). "The party invoking federal jurisdiction bears the burden of establishing these elements." *Id.* at 561. CMA's standing is not relevant here.

Florida has shown that it faces an imminent injury in fact. "Government regulations that require or forbid some action by the plaintiff almost invariably satisfy both the injury in fact and causation requirements." *Food & Drug Admin. v. All. for Hippocratic Med.*, No. 23-235, 2024 WL 2964140, at *7 (U.S. June 13, 2024). Here, among other things, the Rules force Florida to begin expending state funds on gender-transition healthcare in contravention of its own laws. *Compare* 45 C.F.R. § 92.207(a) (barring "categorical coverage exclusion or limitation for all health services related to gender transition or other gender-affirming care") *with* Fla. Stat. §§ 286.311, 456.001, 456.52 (prohibiting "[s]ex-reassignment prescriptions or procedures" for "patients younger than 18 years of age," and the expenditure of state funds for the same). This alone represents an imminent injury to Florida's sovereign "interest in enforcing [its] duly enacted laws without contradiction from the federal government." *State of Tennessee v. Dep't of Educ.*, No. 22-5807, 2024 WL 2984295, at *10 (6th Cir. June 14, 2024). And Florida "need not expose [itself] to liability to have standing to challenge the enforcement of [the Rules]." *W. Virginia by &*

through Morrisey v. U.S. Dep't of the Treasury, 59 F.4th 1124, 1137 (11th Cir. 2023) (internal quotations and citation omitted).

Having addressed injury in fact, the other questions of standing are causation and redressability. Defendants do not address these factors. *See generally* Dkt. 33. Still, it is worth noting that they are satisfied. Plaintiffs' alleged injuries are directly caused by Defendants' promulgation of the Rules and imminent (July 5, 2024) enforcement of the same. A preliminary injunction will delay this enforcement. The Florida Plaintiffs have standing.

b. Ripeness

The ripeness doctrine asks "whether there is sufficient injury to meet Article III's requirement of a case or controversy and, if so, whether the claim is sufficiently mature and the issues sufficiently defined and concrete, to permit effective decision-making by the court." *Elend v. Basham*, 471 F.3d 1199, 1211 (11th Cir. 2006) (internal quotations and citations omitted). "In cases involving pre-enforcement review, like this one, the standing and ripeness analysis tend to converge." *Baughcum*, 92 F.4th at 1036.

Florida has alleged sufficient injury to satisfy the constitutional component of ripeness for the same reason that it satisfied the injury in fact component of standing. "If, in a suit challenging the legality of government action, the plaintiff is himself an object of the action . . . there is ordinarily little question that the action or inaction

has caused him injury." *Texas v. EEOC*, 933 F.3d 433, 46 (5th Cir. 2019) (internal quotations and citations omitted). The "common-sense inquiry" called for to determine whether Florida and CMA are objects of the Rules "is easy here." *Id.* The Rules explicitly apply to "covered entities," such as the Florida Plaintiffs, and mandate assurances, notices, training, and healthcare work that they do not currently provide. *See* 89 Fed. Reg. 37,522–24, 37,696–98. Florida, moreover, is "trapped in a bind" between the Rules and Florida law, which categorically precludes gender transition procedures for minors with gender dysphoria. *Florida v. Nelson*, 576 F. Supp. 3d 1017, 1030 (M.D. Fla. 2021); *see also Texas v. United States*, 787 F.3d 733, 749 (5th Cir. 2015) (explaining that "being pressured to change state law constitutes an injury"). There is simply no question that Plaintiffs face imminent injury where Defendants have expressed no intention to forego enforcement of the Rules.

This brings the Court to the prudential component of ripeness, which focuses on "both the *fitness* of the issues for judicial decision and the *hardship* to the parties of withholding judicial review." *Harrell v. The Fla. Bar*, 608 F.3d 1241, 1258 (11th Cir. 2010) (emphasis in original). In analyzing the fitness prong, courts are generally "concerned with questions of 'finality, definiteness, and the extent to which resolution of the challenge depends upon facts that may not yet be sufficiently developed.'" *Id.* (quoting *Ernst & Young v. Depositors Econ. Prot. Corp.,* 45 F.3d

530, 535 (1st Cir.1995)). "If a claim is fit for judicial decision, that is the end of the inquiry, and the matter is ripe, given that the absence of a hardship cannot tip the balance against judicial review under those circumstances." *Club Madonna, Inc. v. City of Miami Beach*, 924 F.3d 1370, 1380 (11th Cir. 2019) (cleaned up) (internal quotations and citation omitted).

Florida's claims are fit for judicial decision. "A facial challenge presenting a purely legal argument … 'is presumptively ripe for judicial review' because that type of argument does not rely on a developed factual record." *Id.* (quoting *Harris v. Mexican Specialty Foods, Inc.*, 564 F.3d 1301, 1308 (11th Cir. 2009)); *see Susan B. Anthony List v. Driehaus*, 573 U.S. 149, 167 (2014). Here, Plaintiffs' central challenge is purely legal in nature. They argue that the Rules are facially invalid because Defendants have erroneously interpreted the Title IX and ACA proscription against discrimination on the basis of sex to include discrimination on the basis of gender identity. There is no need for trial-like factual development at this stage. "The lines are drawn, the positions taken, and the matter is ripe for judicial review." *Florida v. Weinberger*, 492 F.2d 488, 493 (5th Cir. 1974).

The Court also notes that Plaintiffs would suffer hardship without judicial review. *See Club Madonna*, 924 F.3d at 1380. "Potential litigants suffer substantial hardship if they are forced to choose between foregoing lawful activity and risking substantial legal sanctions." *Cheffer v. Reno*, 55 F.3d 1517, 1524 (11th Cir. 1995).

In the instant case, the Rules force Plaintiffs to choose between foregoing ostensibly legal healthcare policies and practices or risking private lawsuits and the withholding of federal funds that are likely unrecoverable. This is sufficient hardship. *See Texas v. Brooks-LaSure*, 680 F. Supp. 3d 791, 804 (E.D. Tex. 2023) (finding that Texas faced sufficient hardship where it had to "comply" with a CMS bulletin or "face fund disallowance"); *U.S. Army Corps of Engineers v. Hawkes Co.*, 578 U.S. 590, 600 (2016) (Plaintiffs "need not assume such risks while waiting for [Defendants] to 'drop the hammer' in order to have their day in court"). Plaintiffs' claims are ripe.

c. Implied Preclusion

The final justiciability issue to consider is implied preclusion. District courts generally "have original jurisdiction of all civil actions arising under the Constitution, laws, or treaties of the United States." 28 U.S.C. § 1331. Here the Administrative Procedure Act, 5 U.S.C. 706, assigns all legal interpretations to the courts. The prime issue here is whether the Final Rules are legally compliant with and covered by Title IX in the Eleventh Circuit. The APA mandates this task is not impliedly precluded.

In some circumstances "[a] special statutory review scheme . . . may preclude district courts from exercising jurisdiction over challenges to federal agency action." *Axon Enter., Inc. v. FTC*, 598 U.S. 175, 185 (2023). Defendants suggest that section 1557 and 42 U.S.C. § 1316 represent such schemes.

Defendants are mistaken with respect to section 1557. The threshold implied preclusion issue is whether Congress has created a "comprehensive review process . . . that oust[s] district court jurisdiction[.]" *Axon Enter.*, 598 U.S. at 186 (citing *Thunder Basin Coal Co. v. Reich*, 510 U.S. 200, 208 (1994). Congress did no such thing through section 1557. As previously mentioned, section 1557 incorporates Title IX and Title VI's "enforcement mechanisms[.]" 42 U.S.C. § 18116(a). Neither contain a special statutory review scheme that vests review in the courts of appeal or provides a comprehensive review process. They instead provide that "[a]ny department or agency action . . . shall be subject to such judicial review as may otherwise be provided by law for similar action taken by such department or agency on other grounds." 20 U.S.C. § 1683; 42 U.S.C. § 2000d-2. There is consequently no implied preclusion of Plaintiffs claims concerning 45 C.F.R. §§ 92.101, 92.206, and 92.207. *See Louisiana v. U.S. Env't Prot. Agency*, No. 2:23-CV-00692, 2024 WL 250798, at *19 (W.D. La. Jan. 23, 2024) (finding that "42 U.S.C. § 2000d-2 is not a special statutory scheme"); *Tennessee*, 2024 WL 2984295, at *18 (6th Cir. June 14, 2024) (finding that Title IX does not "implicitly preclude[] the States from brining an APA pre-enforcement challenge").

Title 42 U.S.C. § 1316's interaction with the contracts provision of 42 C.F.R. § 438.3(d)(4) creates a closer question, but not by much. Unlike section 1557, section 1316 creates a valid and comprehensive review process. *See* 42 U.S.C. §

1316(a)–(e). But here, Plaintiffs' claims are not "of the type Congress intended to be reviewed within this statutory structure." *Thunder Basin Coal Co.*, 510 U.S. at 212. Section 1316 addresses determinations concerning whether state plans "submitted to the Secretary by a State for approval under subchapter I, X, XIV, XVI, or XIX . . . conform[] to the requirements for approval under such subchapter" and general item disallowance. 42 U.S.C. § 1316(a)–(e). These matters are wholly collateral to the review of managed-care-plan contracts which are reviewed under 42 C.F.R. § 438.3(a). Additionally, Plaintiffs' claims concerning 42 C.F.R. § 438.3(d)(4) ultimately present legal APA and constitutional issues that are outside of HHS and CMS's expertise. It is unclear how Plaintiffs could seek such administrative review without "betting the farm" through immediate and wholesale defiance of the Final Rule—something courts "normally do not require plaintiffs" to do and something courts "do not consider" to be "a meaningful avenue of relief." *Enter. Fund v. Pub. Co. Acct. Oversight Bd.*, 561 U.S. 477, 490–91 (2010).

In sum, Congress' intent to allocate initial review of Plaintiffs' claims to HHS or CMS is not "fairly discernable in [42 U.S.C. § 1316 or 42 U.S.C. § 18116(a)]." *Thunder Basin*, 510 U.S. at 207. The Court has subject matter jurisdiction over Plaintiffs' claims.

II. Injunctive Factors

a. Likelihood of Success on the Merits

HHS and the Final Rule interpret Title IX, and hence section 1557, to prohibit discrimination based on "gender identity." 89 Fed. Reg. at 37,699 (45 C.F.R. § 92.101(a)(2)). The Final Rule is stillborn and a nullity if Title IX does not prohibit discrimination on the basis of "gender identity." The Eleventh Circuit has spoken on this point, clearly: Title IX does not address discrimination on the basis of gender identity. *Adams v. Sch. Bd. of St. John's Cnty.*, 57 F. 4th 791, 812–15 (11th Cir. 2022) (*en banc*). Frankly, this ends the issue—the new Rule appears to be a dead letter in the Eleventh Circuit.

The plaintiff in *Adams*, like HHS here, contended that the Title VII employment case of *Bostock v. Clayton County*, 590 U.S. 644, 659–60 (2020), means that Title IX barred discrimination on gender identity grounds.[6] The Eleventh Circuit held otherwise. In Title IX, and hence in section 1557, "because of sex" unambiguously means "biological sex" (male and female), and not "gender identity." *Adams*, 57 F.4th at 812–13. And although *Bostock*, too, proceeded on the assumption that "sex" means biological sex, *Adams* said that "the statutory context of Title IX" requires a different result. *Id.* at 813. As the *Adams* Court noted, Title IX includes many sex-specific exceptions and instructs that the prohibition must be

[6] *Bostock* held that an employer discriminates "because of sex" under Title VII of the Civil Rights Act of 1964 when he fires a male for no reason other than identifying as a woman, but "retains an otherwise identical employee" who is a female, because in that case, the individual's sex is a but-for-cause of the disparate treatment. 590 U.S. at 659.

read to permit separating living facilities based on sex, which is inconsistent with protecting "gender identity." *Id.* at 814–15 & n.7; *see* 20 U.S.C. § 1686. If Title IX were read to protect "gender identity," the Court reasoned, Title IX's carve-outs "would be rendered meaningless" whenever they came "into conflict with a transgender person's gender identity." *Adams*, 57 F.4th at 813–14. This "would provide more protection against discrimination on the basis of transgender status under the statute . . . than it would against discrimination on the basis of sex." *Id.* at 814. "That conclusion cannot comport" with the text and context of Title IX. *Id.*

A further reasoning of the Eleventh Circuit was that Title IX, unlike Title VII, was enacted under the "Spending Clause." *Adams*, 57 F.4th at 815. "A safeguard of our federalist system is the demand that Congress provide the States with a clear statement when imposing a condition on federal funding." *Id.* That "clear-statement" rule required rejecting the plaintiff's argument, because Title IX does not clearly protect gender identity. The text of Title IX says nothing about gender identity.

Notably, the federal Government's argument here about Title IX, including its argument about the spending clause, is precisely the argument it made, and flatly lost, in *Adams*. Amicus Brief of United States, Dkt. 254, No. 18-1359, *Adams*, ecf.call.uscourts.gov/n/bean/serulet/TansportRoam, last consulted June 30, 2024. Repeating the same failed argument from *Adams* will likely render the same result.

In discussing its definition of "sex" under Title IX to include gender identity,

HHS cites the reversed District Court opinion in *Adams*. *Id*. at 37573 n.110. And when incorporating *Bostock* into Title IX, HHS cites the controlling *en banc Adams* decision but notes it is contrary, using the signal "But cf." *Id*. at 37574 n.116.

In the Final Rule, HHS recognizes that "Section 1557 is best read to incorporate existing interpretations of what constitutes sex discrimination under Title IX, including regulatory interpretations *and case law*." 89 Fed. Reg. at 37,638 (emphasis added). In the Eleventh Circuit, that case law includes *Adams*.

HHS argues the Court should limit *Adams* to its facts ("transgender restroom issues") and apply *Bostock*'s reasoning to uphold the Final Rule. But *Adams* rejected applying *Bostock*.

Respect for Executive Branch interpretation of a statute was previously "especially warranted when an Executive Branch interpretation was issued roughly contemporaneously with enactment of the statute and remained consistent over time." *Loper Bright Enters. v. Raimondo*, 603 U.S. — , No. 22-1219, 2024 WL 3208360, at *9 (June 28, 2024). In contrast the Executive Branch interpretation of Title IX now conjured comes decades after the enactment of Title IX and, as seen below, the interpretation has changed repeatedly over time.

As *Loper* states, the whole point of having a written statute is "every statute's meaning is fixed at the time of enactment." *Id*. at *16. *Adams* recognizes this. Title IX, decades old, did not change meaning in 2024. HHS's attempt to alter

prospectively the meaning of Title IX shows the wisdom of *Loper's* statement that "agencies have no special competence in resolving statutory ambiguities. Courts do." *Id*. at *16. The Administrative Procedures Act, § 706, which is the present guidepost, "demand[s] that courts exercise independent judgment in construing statutes administered by agencies." *Id*. at *19; 5 U.S.C. § 706.

Eknes-Tucker v. Governor of Ala., 80 F.4th 1205 (11th Cir. 2023), also suggests that Plaintiffs will likely prevail on the merits. *Eknes-Tucker* involved a challenge to an Alabama law prohibiting gender-transition interventions in minors, particularly puberty blockers and cross-sex hormones. *Id.* at 1210, 1227. Interpreting the Equal Protection Clause, the Eleventh Circuit held that "the statute does not discriminate based on sex." *Id.*

The Alabama law prohibited drugs used for a specific medical purpose of treating gender dysphoria. *Id*. The purpose of the treatment was to end the gender dysphoria by facilitating likely gender transition or at least enabling it. Any reference to sex or difference in treatment was due to the medical purpose of the drugs coupled with biological facts about the sexes, not stereotypes. *Id.* at 1229. Only females may take supraphysiologic levels of testosterone for a gender transition, and only males can take supraphysiologic levels of estrogen for a gender transition. *Id.* at 1213, 1228. The Court said prohibiting these treatments is not discriminating on the basis of sex under Equal Protection scrutiny. "[T]he regulation of a course of treatment

that only gender nonconforming individuals can undergo" was not stereotyping "based on sex" "unless the regulation [is] a pretext for invidious discrimination against such individuals." *Id.* at 1228–30.

Like *Adams*, the *Eknes-Tucker* Court distinguished *Bostock*.[7] The Court emphasized the "different factual context" involved in *Eknes-Tucker* and *Bostock*—*Eknes-Tucker* involved a law regulating medical treatments, not a rule penalizing a transgender individual in employment for no reason other than being transgender. *Id.* at 1229. So too, here.

Eknes-Tucker held that a ban on gender-transition interventions does not intentionally discriminate "on the basis of sex." The same phrase is used in Title IX and imported into section 1557, increasing the likelihood that Plaintiff will prevail on the merits.

Section 206(b)(4) of the Rule makes it presumptively discriminatory for covered entities to "[d]eny or limit" puberty blockers, cross-sex hormones, or surgeries "sought for purpose of gender transition," so long as those entities provide the services for "other purposes." 89 Fed. Reg. at 37,701 (45 C.F.R. § 92.206(b)(4)).

[7] The Eleventh Circuit's recent decision in *Lange v. Houston County* does not govern here. 101 F.4th 793 (11th Cir. 2024). In that case, the Eleventh Circuit held that an employer violates Title VII when it denies health-insurance coverage for all gender transitions. But *Lange* (like *Bostock*) interprets Title VII, which is not a Spending Clause statute like section 1557. *Fitzpatrick v. Bitzer*, 427 U.S. 445, 458 (1976) (Brennan, J., concurring). So unlike section 1557, Title VII need not satisfy the requirement of clear and unambiguous notice. *Adams*, 57 F.4th at 815. *Adams* and *Eknes-Tucker* distinguished Title VII.

But this is insufficient to establish a prima face discrimination claim, as a patient seeking "gender transition" is not similarly situated to a patient seeking a drug or procedure to treat a different medical condition or diagnosis. *See Eknes-Tucker*, 80 F.4th at 1228; *id.* at 1233 (Brasher, J., concurring) (same); *L.W. v. Skrmetti*, 83 F.4th 460, 481–82 (6th Cir. 2023) (same in equal protection case).

To use *Bostock*'s language, HHS provides no reason to presume that a woman seeking a hysterectomy to treat cancer is "to [the doctor's mind], materially identical in all respects" to a woman seeking a hysterectomy for a gender transition. *Bostock*, 590 U.S. at 660. The diagnosis relevant to gender transition treatment—gender dysphoria—has a very different etiology and balance of risks. *See Eknes-Tucker*, 80 F.4th at 1233 (Brasher, J., concurring). Because the medical purpose is different, not similar, let alone "materially identical," intentional sex discrimination cannot be presumed. *Eknes-Tucker*, 80 F.4th at 1228; *Bostock*, 590 U.S. at 660.

One can envision many other factual scenarios showing that the Rule likely reaches well beyond "discrimination." For example, it is not actionable discrimination for a local hospital to provide an orchiectomy to a teenage boy with testicular cancer, yet refuse to even consider castrating a teenage gender dysphoric with healthy testicles. The diagnoses and medical purposes are not similarly situated.

Sections 207(b)(4) and (b)(5) prohibit a reimbursement policy or practice limiting gender-transition reimbursements if the policy or practice is "categorical"

or "results in sex discrimination." 89 Fed. Reg. at 37,701 (45 C.F.R. §§ 92.207(b)(4), (5)). HHS justifies this based on an argument that limiting coverage for a gender transition is a proxy for discriminating on the basis of gender nonconformity "because transgender individuals are the only individuals who seek transition-related care." Notice of Proposed Rule Making, 87 Fed. Reg. at 47,871. But *Eknes-Tucker* rejected that same argument: "the regulation of a course of treatment that only gender nonconforming individuals can undergo" is not discriminating "based on sex" (the same words used in Title IX) "unless the regulation [is] a pretext for invidious discrimination against such individuals." *Eknes-Tucker*, 80 F.4th at 1228–30. So *Eknes-Tucker* conflicts with these rules.

The Eleventh Circuit has concluded that limiting gender-transition treatments for minors such as pharmaceuticals or hormones is "rational." *Eknes-Tucker*, 80 F.4th at 1225. Surgery, which HHS addresses but *Eknes-Tucker* did not, would be all the more medically intrusive and "rational" to restrict.

Both *Eknes-Tucker* and the Final Rule forbid "pretext," but the Final Rule prohibits far more than "pretext," and its framework is the opposite of *Eknes-Tucker*'s. *Eknes-Tucker* requires a plaintiff to show "pretext" to establish that a state discriminated on the basis of sex. By contrast, under the Final Rule, a covered entity that bars coverage for gender-transition treatments would be presumed to discriminate based on sex, without any showing of pretext. Under the Final Rule, a

hospital's categorical denial of care ("no castration, hysterectomies, or mastectomies for gender transition") would be in violation of the Rule if the hospital provided those services for other reasons, like cancer.

The CMS contracts Rule would amend the standard contract requirements under Medicaid and CHIP to require prohibiting any policy or practice that has the "*effect of* discriminating" based on an individual's "gender identity." 89 Fed. Reg. at 37,691 (42 C.F.R. §§ 438.3(d)(4) (emphasis added), 457.1201(d)). But as explained above, section 1557 likely does not prohibit discriminating based on gender identity, and likely does not forbid the discriminatory effects that HHS defines. For additional statutory authority, HHS invokes the Social Security Act, which was also enacted under the Spending Clause and therefore likewise requires a "clear" statement of Congress. *See* 89 Fed. Reg. at 37,668.[8] But there is no clear statement. The Spending Clause failure was one of the salient points of the *Adams* opinion. 57 F.4th at 815.

In this regard, HHS defends the CMS contracts Rule by invoking its authority to adopt "methods of administration" for Medicaid that are "necessary for the proper

[8] HHS raises an affirmative defense. It argues that the claim is untimely under the Little Tucker Act's statute of limitations. 28 U.S.C. § 2401(a). This is meritless. The six-year statute of limitations "begins to run when the agency issues the final action that gives rise to the claim." *Alabama v. PCI Gaming Auth.*, 801 F.3d 1278, 1292 (11th Cir. 2015). To the extent earlier rules are implicated, HHS reopened them by vastly expanding them to gender identity medical services and contracting. *See Kennecott Utah Copper Corp. v. U.S. Dep't of Interior*, 88 F.3d 1191, 1227 (D.C. Cir. 1996). These claims accrued upon issuance of the Final Rule. *See Corner Post, Inc. v. Bd. of Governors of the Fed. Rsrv. Sys.*, 2024 WL 3237691, at *7 (July 1, 2024).

and efficient operation of the [state Medicaid] plan." 42 U.S.C. § 1396a(a)(4). But imposing these vast duties and canceling Florida law is far afield from "methods of administration."

Congress offered examples of "methods of administration," giving "more precise content" to the term. *United States v. Williams*, 553 U.S. 285, 294 (2008). It includes setting "personnel standards," providing for "medical personnel in the administration … of the plan," and transporting "beneficiaries … to and from providers." 42 U.S.C. § 1396a(a)(4). That list of routine administrative tasks looks nothing like the power to declare new civil rights guarantees for groups of people. When the SSA was enacted, States had no "clear notice" from the face of the statute that HHS could force them to adopt very costly contracts expanding treatments due to alleged disparate impacts on transgender individuals. *Adams*, 57 F.4th at 815. The contract requirement "is markedly different from" other contract requirements HHS has imposed. *Ala. Ass'n of Realtors*, 594 U.S. 758, 764 (2021); *see generally* 42 C.F.R. § 438.3. The CMS contracts Rule, like the Title IX Rule, simply rewrites the statute. That is Congress' job alone. For the foregoing reasons, Plaintiffs have established a likelihood of success on the merits.

b. Florida Faces Irreparable Harm

For many of the same reasons they establish standing and hardship, Plaintiffs also show they will suffer "irreparable harm" absent a stay. *West Virginia*, 59 F.4th

at 1149.

If the Rule is implemented, on July 5, 2024, Florida will face irreparable harm. Florida's covered entities will have to file an assurance of compliance to avoid termination of funds. They must amend their policies and begin trainings on the new rules. 45 C.F.R. §§ 92.5, 99.8, 99.9.

The Plaintiff agencies and the healthcare providers they regulate must either clearly violate Florida law, or clearly violate the new Rule. To comply with the Rule, DMS would have to alter its policy against reimbursing managed care plan members for sex-change treatments. This is not possible because DMS cannot amend its self-funded insurance plan without permission from the Florida legislature, which is not is session and which has previously barred payment of tax dollars for gender transition treatment. DMS will clearly suffer irreparable harm if the Rule is not stayed.

Other Plaintiffs would be in a similar bind. Under current law AHCA cannot use state funds for these gender change services in state Medicaid. Fla. Admin. Code r. 59G-1.050(7). HHS lawyers have previously said this present Florida AHCA law violates the Rule.[9] Even if AHCA could violate state law by expanding coverage for

[9] Brief for the United States as Amicus Curiae at 26 n.10, *Dekker v. Fla. Agency for Health Care Admin.*, No. 23-12155 (11th Cir. Dec. 4, 2023), https://perma.cc/9UYG-SVPL.

these services it cannot print money. And the Rule provides nothing for the vast added, unallotted expense.

The federal government generally enjoys immunity from suit. *West Virginia*, 59 F.4th at 1149. So these costs can never be recovered. *See*, *e.g.*, *Odebrecht Const., Inc. v. Sec., Fla. Dep't of Transp.*, 715 F.3d 1268, 1289 (11th Cir. 2013). Unrecovered monetary loss is irreparable harm. *Georgia v. President of the United States*, 46 F.4th 1283, 1302 (11th Cir. 2022).

Florida's Agency for Persons with Disabilities ("APD") also faces irreparable harm. Dkt. 12-2. APD has a policy of assigning dual-occupancy rooms in its residential living facilities on the basis of biological sex, regardless of an individual's gender identity. Presently, natal women have natal women roommates and natal males room with natal males. This makes sense given the residents APD serves. *See id*. But this would change.

The Rule would prohibit APD's room sharing policy if a biological male patient identified as a female, and refusing to lodge the natal male on the women's wing or with a female roommate would cause the natal male "more than de minimis harm." *See* § 206(b)(3) of Part 92; Dkt. 12, Ex. B; *see also* 89 Fed. Reg. at 37,593 ("A covered entity *will be* in violation of this rule if they refuse to admit a transgender person for care or refuse to place them in facilities consistent with their gender identity, because doing so would result in more than de minimis harm."

(emphasis added)). HHS earlier explained its view that "a hospital that assigns patients to dual-occupancy rooms based on sex would be prohibited from requiring a transgender woman [meaning a natal male expressing the female gender] to share a room with a cisgender man [meaning a natal male who expresses a male gender], regardless of how her sex is recorded in her insurance or medical records." NPRM, 87 Fed. Reg. at 47,866–67. HHS reiterated in its brief that "refusing to place a transgender person 'in facilities consistent with their gender identity' would result in more than de minimis harm." Dkt. 33 at 17 n.9. Absent a stay, APD may likely violate Florida law. *See* Fla. Stat. § 553.865(5), (12). APD plausibly states it would have to redesign facilities and/or hire additional staff for safety, to accommodate the preferences of gender-divergent residents. *Id*. at 9.

Florida also plausibly asserts injury in its sovereign capacity. The Final Rule injures Florida's "interest in enforcing [its] duly enacted laws without contradiction from the federal government." *Tennessee*, 2024 WL 2984295, at *10. Florida "will continue to face pressure to change their laws to avoid legal consequences." *Id.* at *25; *see also Florida v. Nelson*, 576 F. Supp. 3d 1017, 1039 (M.D. Fla. 2021); *Texas v. Becerra*, 577 F. Supp. 3d 527, 557 (N.D. Tex. 2021) ("irreparable harm exists when a federal regulation prevents a state from enforcing its duly enacted laws"). Case law has recognized this type of injury as supporting a stay. *West Virginia*, 59 F.4th at 1149.

HHS argues that a pending class action before a different court negates the need for equitable relief. *See Neese v. Becerra*, 640 F. Supp. 3d 668 (N.D. Tex. 2022). This case does not involve the Final Rule.

First, Florida, AHCA, DMS, and APD are not class members in *Neese*. Moreover, *Neese* did not provide equitable relief against Defendants. 640 F. Supp. 3d at 684–85. The judgment in *Neese*, now on appeal, does not stop HHS from enforcing the Final Rule against Plaintiffs.

Finally, the Court would note *Labrador v. Poe*, 601 U.S. — , 144 S. Ct. 921 (2024). Although arising in the context of a stay, the Supreme Court found that Idaho likely showed irreparable harm when a district judge struck down the state laws precluding puberty blockers and gender transition medical treatment for minors. *Id.*, 144 S. Ct. at 923–24 (concurrence). Here, of course, the Final Rule would similarly require repeal of substantive Florida statutes. *Labrador* suggests Florida faces irreparable harm.

c. The Balance of Harms and Public Interests Favor a Stay

The balance of harms and public interest factors "merge when, as here, the government is the opposing party." *Gonzalez v. Governor of Georgia*, 978 F.3d 1266, 1271 (11th Cir. 2020) (cleaned up). As discussed above, Plaintiffs will suffer harm and face unrecoverable, large monetary loss, legal jeopardy, and sovereign injury absent a stay.

Public Interest Requires a Lawful Rule

HHS and the public have an interest in HHS rules being legal. As noted, the Rule here appears to be contrary to the Eleventh Circuit's clear Title IX teachings in *Adams*; and *Eknes-Tucker* also teaches against the Rule indirectly. In the Eleventh Circuit, the Rule appears unlawful. "[O]ur system does not permit agencies to act unlawfully even in pursuit of desirable ends." *Ala. Ass'n of Realtors v. HHS*, 594 U.S. 758, 766 (2021); *see BST Holdings, LLC v. OSHA*, 17 F.4th 604, 618 (5th Cir. 2021) ("Any interest [the government] may claim in enforcing an unlawful [rule] is illegitimate."). In other words, the Rule invokes and relies on a Title IX that the Eleventh Circuit states does not exist.

Likewise, the reliance on the Social Security Act to impose costly new insurance/managed care contracts appears to be ultra vires to the Act. Neither is the Spending Clause requirement met, nor the stark changes permitted without a rewriting of that statute. The new Rules must be legal; and no deference on matters of legality need be shown the agency. *See Loper*, 2024 WL 3208360, at *22.

HHS's Rules Have Been Unstable, Ever-changing

A second reason why the public interest is furthered by a stay and injunction is that the Rule is ever-changing and unstable, buffeted by the prevailing political winds. The new Rule is the fourth version in the last eight years, which each version the opposite of the other. The repeated reversing of field by HHS presents large

compliance issues and costs for health care facilities and the states that regulate them; not to mention the stop-and-start effect on this sensitive area of health policy. This instability suggests that the public interest favors a preliminary pause to fully address on the merits this new, fourth version. And the instability shows little harm to HHS in keeping a steady hand rather than lurching change.

The stop/start timeline is illustrated in the case law. *See Religious Sisters of Mercy v. Becerra*, 55 F.4th 583, 589-591 (8th Cir. 2022). The first change was in 2016. Prior to 2016 the HHS rules did not require treatment and consideration of gender identity as part of healthcare nondiscrimination rules. This changed with a 2016 rule, *id.,* that stated "discrimination on the basis of sex includes discrimination on the basis of gender identity and sex stereotyping." *Id.* at 31,388; 31,467. The new rule barred providers from denying "transition-related care" based on explicit or categorical exclusions of services for purpose of gender transition. *Id.* at 31,439; 31,471. *See Religious Sisters,* 55 F.4th at 590.

After this change, though, HHS did another "180" and changed back again. *Id.* at 594; 85 Fed. Reg. 37,160 (June 19, 2020). In June 2020, HHS flatly repealed the 2016 rule, noting that it "repeal[ed] the 2016 Rule's definition of 'on the basis of sex'…" Instead, the 2020 HHS rule reverted to and relied upon the plain meaning of the term in Title IX. *Id.* at 37,178; *Religious Sisters,* 55 F.4th at 594. This change was the third rule within four years.

Now we have under review the fourth rule, as HHS has done one more about-face. Shortly after the Supreme Court issued its opinion in *Bostock,* President Biden issued an Executive Order stating that *Bostock's* reasoning meant that laws that prohibit sex discrimination, including Title IX, "prohibit discrimination on the basis of gender identity or sexual orientation," unless the laws contain sufficient indications to the contrary. *Executive Order No.* 13988, 86 FR 7023, 2021 WL 229396 (Jan. 20, 2021). The President thus ordered the head of each agency to rescind agency actions that were inconsistent with this definition he offered. Further, agencies were to promulgate new agency actions consistent with other laws including the APA, "as necessary to fully implement statutes that prohibit sex discrimination" as he defined it in the Order. *Id.* This fourth rule is the result: another 180-degree turn.

One need not be a cynic to predict that, if perchance there is a change in presidential administrations, we will have another sudden about-face by HHS and a fifth rule. This instability and repeated divergence is costly in many areas. It is entirely based upon national politics, and might support an argument that this sensitive issue of health and safety ought be left steady, or deferred to state medical regulators to decide in their public welfare role. In any event, this unstable regulatory regime does suggest there is little harm to a delay, and the public interest is here

served by a full decision on the factual merits and a preliminary stay, not to mention full development of real, hard science that was heretofore sparse in the field.

The Rule Requires Significant Alteration of Healthcare in Florida

The public has an interest in stable, orderly change in important public matters such as health care. The Final Rule would require covered entities to allow biological males who are transgender into female private spaces, including bathrooms, changing rooms, living facilities, dual-occupancy bedrooms, etc., if the natal males would otherwise suffer harm "more than de minimis." Unlike other more cautiously-worded provisions of HHS comments, HHS starkly stated, "[A] provider generally may accommodate a patient's preferences about roommate assignments. A covered entity will be in violation of this rule [Sec. 92.206] if they refuse to admit a transgender person for care or refuse to place them in facilities consistent with their gender identity because doing so would result in more than de minimis harm." 89 Fed. Reg. at 37,593. The Final Rule, moreover, allows no exceptions to this rule based on public safety or any similar rationales. That is not in the public interest, despite some minor harm that may be occasioned to gender-divergent patients by this injunction.

The Rule's commentary expressly declines to fully define the terms of "gender affirming care" or "gender identity" (other than to say it includes "transgender status") although the Rules are greatly about those subjects. 89 Fed.

Reg. 37,392; 37,596. HHS does say "gender affirming care generally refer[s] to a care designed to treat gender dysphoria that may include, but is not necessarily limited to, counseling, hormone therapy, surgery, and other related sources." 89 Fed. Reg. 37,596.

Section 92.206 of the Rule clearly mandates availability of gender transition services if similar services (hormone therapy, mastectomies, hysterectomies, etc.) are available to patients for reasons other than gender transitions. This is because "[w]hen medically necessary treatments are categorically excluded when sought by transgender enrollees for purposes of gender-affirming care, but the same treatments are covered for cisgender enrollees, such exclusions may deny transgender individuals access to coverage based on their sex." *Id.* at 37,671.

The Rule also seeks to make providers speak correctly about the subject to HHS's satisfaction, in addition to verbal assurance of compliance. The HHS commentary notes that in assessing a provider's good faith to avoid compliance sanctions the HHS will consider "whether that covered entity demonstrated a willingness to refer or provide accurate information about gender-affirming care, or is otherwise engaging in good faith efforts to ensure patients are receiving medically necessary care." *Id.* at 37,598. HHS commented that the Rule clarifies "that while providers may exercise clinical judgment when determining if a particular service is appropriate for an individual patient, they may not refuse gender-affirming care

based on a belief that such care is never clinically appropriate." *Id.* at 37,597. This is contrary to the public interest, if public interest may be defined as the laws of Florida passed by the citizens' elected representatives.

Public Interest Supports Merits-Based Consideration of HHS's "Care" Regimen

HHS's brief, notably, does not argue that encouraging gender-transition treatments serves the public interest. This is a litigation strategy as both the Rule and HHS's clear public stance are entirely to the contrary. Given the uncertain benefit, the evidence of public health harms, and HHS's failure to defend the public health benefit of gender-transition treatments in its brief, the Court concludes that encouraging widespread access of "gender affirming care" is an issue that the public interest requires to be developed thoroughly on the merits. And such an examination brings no harm to HHS.

The Final Rule compels the State to make gender-transition services available in the Medicaid managed care plans, and compels all covered entities to not preclude gender-transition treatments when such services (like mastectomies for cancer, testosterone for hypogonadism, etc.) are provided for other medical reasons. Covered entities may not categorially refuse to perform gender transition. No hospital in Florida could have a categorical exclusion for gender-transition surgeries even for minors, if similar procedures were done for non-gender purposes.

If a hospital's outreach program sponsored a women-only support or counseling group, that group would have to admit a natal male who identified as female, if refusing to admit the natal male would cause that person more than de minimis harm. And no contractor such as the Florida Medicaid multi-billion-dollar managed care plans could omit a full panoply of gender transition coverage (surgery, hormone formulary, etc.) if those services were provided for non-transition maladies. This presents a *very* expensive regimen paid for by the taxpayers but unfunded by the Rule.

An honest appraisal of the Rule shows it imposes the availability of gender transition medicine upon all covered entities, wanted or unwanted. The public interest requires a merits-based analysis of this.

Although the task here is to undertake a "facial review" of the new Rules, some issues of "public interest and balanced harms" requires the further discussion. HHS's basis for a "gender affirming care" regimen appear to be long on ipse dixit[10] and short on real, hard science. *See generally* HHS Office of Population Affairs, G*ender-Affirming Care and Young People,* opa.hhs.gov/site/default/files/2022-03/gender-affirming-care-young-people-March-2022, last consulted June 29, 2024. In this March 2022 HHS "fact sheet" the HHS advocated the panoply of "gender

[10] **Ipse dixit**. L. He himself said it; a bare assertion resting on the authority of an individual. Black's Law Dictionary (5th ed. 1979).

affirming care" including counseling, pharmaceuticals, and stating that surgeries are "typically used in adult or case-by-case in adolescence." This "fact sheet" was immediately followed up by the Department of Justice Assistant Attorney General Kristin Clarke's letter of March 31, 2022, sent to State's Attorneys General, which fairly reads as a veiled threat to bring federal enforcement actions and litigation in pursuit of this trans-care agenda.[11]

At times the HHS position about "gender affirming care" seems to be political. It is no surprise to any observer that politics on both sides of this issue are prevalent. Concerning the parties here, HHS's Assistant Secretary Levine previously urged the medical/advocacy group World Professional Association for Transgender Health ("WPATH") to drop proposed age limits for minor transgender surgery. The age limits in the proposed WPATH guidelines were 15 for mastectomies, 16 for breast augmentation or facial surgeries, and 17 for hysterectomies. Levine's staff informed WPATH that Levine was "confident, based on the rhetoric she is hearing in D.C., and from what we have already seen, that these specific lists of ages, under 18, will result in devastating legislation for trans care. [Levine] wonder[s] if the specific ages can be taken out." Levine's staff went on to tell WPATH that Levine "was very concerned that having ages (mainly for surgery) will affect access to care for trans

[11] The letter may be found at ECF No. 193-3, *Dekker v. Weida*, No. 4:22-cv-325-RH-MAF (N.D. Fla. 2023).

youth and maybe adults, too…" Levine's staff asked WPATH to remove the age limitations in the guidance for gender transition.[12] The WPATH has removed age limitations for minors on its guidance for transition surgeries.

It is in the public interest to address these issues with the benefit of a full record, substantively on the merits. The record now is sparse due to this "facial review"; further, the undersigned has no training in science or medicine. Despite this, several points are worth making.

A notable point about the Rule is that while it imposes significant "gender affirming care" and "transition treatment" requirements upon Florida, the HHS discounts, and in the commentary declares as "not germane to the proposed regulatory text," any uncertainty and lack of clarity concerning the safety and efficacy of the gender treatments HHS imposes. 89 Fed. Reg. 37672. HHS's boldness here is noteworthy and one might say brash, given that "[t]here are no large-scale population studies of gender dysphoria." American Psychiatric Association, *Diagnostic and Statistical Manual of Mental Disorders* (5th ed. 2022 Text Revision)

[12]A. Ghorayshi, *Biden Officials Pushed to Remove Agent Limits for Trans Surgery, Documents Show* (N.Y. Times June 25, 2024), https://www.nytimes.com/2024/06/25/health/transgender-minors-surgeries.html. In response to this article the administration was reported to have stated that it opposed gender-affirming surgery for minors. Rabin, Rosenbluth, Weiland, *Biden Administration Opposes Surgery for Transgender Minors,* (N.Y. Times June 28, 20240, https://www.nytimes.com/2024/06/28/health/transgender-surgery-biden.html?pvid+kwDIVPqfjXyF_P9pkx7qMxSW&smid=url-share. This latter statement contrasts with the HHS "fact sheet" which states the "gender-affirming surgeries" are "typically used in adulthood or case-by-case- in adolescence. *Gender Affirming Care*, *supra* at 39-40, opa.hhs.gov.

("DSM-5") at 515. The Rule radically changes the law in Florida, as a matter of medicine and expense, concerning the treatment of gender dysphoria in minors. Yet the predominant psychiatric disorder "guidebook," DSM-5, tells us that "[n]o general population studies exist of adolescent or adult outcomes of childhood gender variance." *Id.* at 516.

After counseling, the starting point for physical intervention in the "gender affirming care" regimen for minors is puberty blockers, often followed by cross-sex hormones, meaning supra-physical doses of testosterone for transitioning natal females, and estrogen for transitioning natal males. The Food and Drug Administration has *never* approved any of these drugs as "safe and effective" for these treatments. The reason why is that studies about these pharmaceuticals in this application lack full, hard scientific rigor. The entire gender-transition drug regimen, is "off label." Off label drug use generally is not illegal and not infrequent, but before an entire formulary and medical practice in Florida is involuntarily devoted to off-label drugs, perhaps a pause to study these merits is in order.

When the FDA regulates a drug "on-label," that assurance means the FDA has conducted or supervised sufficient testing to determine that the drug is safe for its intended use. *See Food & Drug Admin. v. Brown & Williamson Tobacco Corp.* 529 U.S. 120, 142 (2000). This has not occurred with puberty blockers or cross-sex hormones used for gender dysphoria or transition. The FDA in 2022 required a

warning label on one GnRH agonist used as an off-label transition puberty blocker; this drug may cause or correlate to the brain disorder pseudotumor cerebri (idiopathic intercranial hypertension) in minor females. The Food and Drug Administration, *Risk of Pseudotumor Cerebri Added to Labeling for Gonadotropin-Releasing Hormone Agonists* (2022), https://publications.aap.org/aapnews/news/20636/Risk-of-pseudotumor-cerebri-added-to-labeling-for?autologincheck=redirected (last consulted Jul. 1, 2024).

Off-label use of drugs bypasses the consumer safety and efficacy purpose of the FDA approval process and is nearly impossible to track. New or novel off label use, such as would be imposed by the Rule, is unlikely to be supported by strong, hard scientific evidence, because such use has not undergone extensive clinical phase trials that would ordinarily be required for such use. *See generally* Gail A. Van Norman, *Off-Label Use vs Off-Label Marketing of Drugs: Part 1: Off-Label Use—Patient Harms and Prescriber Responsibilities,* 8 J. Am. Coll. Cardiol Basic Trans. Science 224–233 (Feb. 8, 2023), https://www.jacc.org/doi/full/10.1016/j.jacbts.2022.12.011 (last visited Jul. 1, 2024).

HHS's present view on "gender affirming care" is far from shared by other medical authorities. And the science seems to be trending the other way. *See also*

Labrador v. Poe, supra (reinstating most of the Idaho law barring transition medicine for minors).

If the British National Health Service ("NHS") were subject to the HHS Rule, the NHS would be in violation, as the NHS has stopped new, non-experimental prescriptions for puberty blockers for minor gender transition throughout the U.K., and indefinitely in England. Department of Health and Social Care, *New Restrictions on Puberty Blockers* (2024), https://www.gov.uk/government/news/new-restrictions-on-puberty-blockers?ref=world-weary.com (last consulted Jun. 29, 2024). This bar comes on the heels of a peer-reviewed survey entitled the "Cass Report," which reported on the scarce evidence showing puberty suppression was safe and effective for gender transition and further considering the scarce evidence and questionable safety and efficacy of cross-sex hormone treatment. Hilary Cass, *Independent Review of Gender Identity Services for Children and Young People* (2024), https://cass.independent-review.uk/home/publications/final-report/ (last consulted Jun. 29, 2024). Other authorities expressing doubts about the efficacy of

such treatments include Sweden,[13] Finland,[14] France,[15] and Australia/New Zealand.[16]

The reason for these concerns appears that, despite statements to the contrary, the science behind these programs is reasonably disputed, and does not appear to be yet proven to anywhere near a medical certainty. One example is a recent survey that the undersigned asked all counsel to comment upon: Jonas F. Ludvigsson *et al.*, *A Systematic Review of Hormone Treatment for Children with Gender Dysphoria and*

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[13] Sweden's National Board of Health and Welfare determined that "the risks of puberty blockers and gender-affirming treatment are likely to outweigh the expected benefits of these treatments," and determined that "[t]reatment with GnRH analogues, gender-affirming hormones, and mastectomy can be administered" only "in exceptional cases." Exhibit DX8 at 3, *Dekker v. Weida*, No. 4:22-cv-325-RH-MAF (N.D. Fla. 2023) (ECF No. 193-8); National Board of Health and Welfare, *Care of Children and Adolescents with Gender Dysphoria, Summary of National Guidelines December 2022* (2022), https://www.socialstyrelsen.se/globalassets/sharepoint-dokument/artikelkatalog/kunskapsstod/2023-1-8330.pdf (last visited June 26, 2022).

[14] Finland's Council for Choices in Healthcare urged extreme caution when providing gender transitioning services to children. It says that "[t]he reliability of the existing studies with no control groups is highly uncertain, and because of this uncertainty, no decisions should be made that can permanently alter a still-maturing minor's mental and physical development." Exhibit DX9 at 7, *Dekker v. Weida*, No. 4:22-cv-325-RH-MAF (N.D. Fla. 2023) (ECF No. 193-9); Council for Choices in Healthcare in Finland, *Medical Treatment Methods for Dysphoria Related to Gender Variance in Minors* (2020), https://segm.org/sites/default/files/Finnish_Guidelines_2020_Minors_Unofficial%20Translation.pdf (last visited June 26, 2022).

[15] [The French National Academy of Medicine] concludes that "great medical caution" must be taken "given the vulnerability, particularly psychological, of this population [of younger people presenting with gender dysphoria] and the many undesirable effects, and even serious complications, that some of the available therapies can cause." Exhibit DX13 at 1, *Dekker v. Weida*, No. 4:22-cv-325-RH-MAF (N.D. Fla. 2023) (ECF No. 193-13); French National Academy of Medicine, *Medicine and Gender Transidentity in Children and Adolescents* (2022), https://www.academie-medecine.fr/la-medecine-face-a-la-transidentite-de-genre-chez-les-enfants-et-les-adolescents/?lang=en (last visited June 26, 2022).

[16] The Royal Australian and New Zealand College of Psychiatrists has said that there's a "paucity of evidence" on the outcomes of those presenting with gender dysphoria. Exhibit DX14 at 1, *Dekker v. Weida*, No. 4:22-cv-325-RH-MAF (N.D. Fla. 2023) (ECF No. 193-14).

Recommendations for Research, 112 Acta Paediatrica (Apr. 17, 2023), https://onlinelibrary.wiley.com/doi/10.1111/apa.16791 (last visited Jul. 1, 2024) ("Ludvigsson"). *See* Dkt. 38. Defendants dispute the value of the study, but its findings are worthy of a merits-based inquiry and full record.

Ludvigsson surveyed the major databases and identified nearly 10,000 potentially germane studies. After screening, 24 were found to be timely (within the last decade) and appropriate for further analysis. Dkt. 38 at 3. Eight address the use of puberty blockers, three addressed the use of cross-sex hormones, and the remainder addressed both. The results[17] appear to show how sparse the *actual hard*

[17] Ludvigsson concluded there was insufficient evidence to assess the therapeutic effects of hormone treatments on children with gender dysphoria. Ludvigsson at 2280. Studies that examined mental health outcomes suggested an improvement in global function and self-reported quality of life for children receiving puberty blockers, but no change in suicidal ideation, depression, or anxiety. *Id*. at 2286 & tbl. 2. Notably, the studies showed no change in children's experience of gender dysphoria following hormone treatment. *Id*. Other studies showed, albeit with low certainty, that puberty blockers slow bone densification in growing children, with mixed data on whether later CHST accelerates densification sufficiently to fully compensate. *Id*. at 2286–88 & tbl. 3. Ludvigsson emphasized that study weaknesses limit the conclusions that can reliably be drawn. None of the twenty-four studies were randomized controlled trials, the gold-standard in evidence-based clinical practice. *Id*. at 2287; *see*, *e.g.*, NIH, *Clinical Research: Benefits, Risks, and Safety*, https://www.nia.nih.gov/health/clinical-trials-and-studies/clinical-research-benefits-risks-and-safety ("The gold standard for testing interventions in people is called a randomized controlled trial"); E. Hariton & J.J. Locascio, *Randomized controlled trials—the gold standard for effectiveness research*, 125 BJOG 1635 (Dec. 2018), https://doi.org/10.1111/1471-0528.15199. Data related to mental health outcomes was such poor quality that the certainty of the evidence could not be assessed. *Id*. at 2282, 2286 tbl.2. The studies' short time frames (generally less than four years) and methodologies did not permit assessment of long-term outcomes or separation of psychological treatment effects. *Id*. at 2282, 2288. And analyses were performed at a group-level when assessing an individual over time would be more appropriate. *Id*. at 2288.

Ludvigsson's analysis is consistent with other independent, systematic reviews, which have similarly concluded that the evidence of benefit of medical gender transition in minors weak, while the evidence of harm is clear. *See id*. at 2290; Expert Report of Stephen B. Levine 51–52 (Feb. 23, 2022), HHS-OS-2022-0012-68192/attachment_12 at 165–66,

evidence is that lies behind the "gender affirming care" regimen that HHS embraces and for which the Final Rule compels availability in Florida.

One recent study (2024) of puberty suppression for gender dysphoria concluded:

> "In mammals, the neuropsychological impacts of puberty blockers are complex and often sex specific….There is no evidence that cognitive effects are fully reversible following discontinuation of treatment. No human studies have systematically explored the impact of these treatments on neuropsychological function with an adequate baseline and follow up. There is some evidence of a detrimental impact of pubertal suppression on IQ in children."[18]

The public interest favors a merits-based inquiry to address these matters.

III. The Court denies the Catholic Medical Association's Petition

The Catholic Medical Association is a group of some 2500 health professionals across the nation practicing the healing arts. CMA petitioned here for an injunction, which is denied. Without need to opine on CMA's representational standing, the Court simply believes that a nationwide injunction to cover all CMA members is improvident in this case for jurisprudential reasons. The CMA may

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https://www.regulations.gov/comment/HHS-OS-2022-0012-68192 at attachment 12 (last consulted Jul. 1, 2024). Even proponents acknowledge the health risks associated with gender transition in minors and the limited data addressing its safety and efficacy. These scientific assessments have led other countries to restrict, not expand, minors' access to medical gender transition.

[18]S. Baxendale, *The Impact of Suppressing Puberty on Neuropsychological function: A Review*, 113 Acta Paediatrica, (Feb. 9, 2024), https://onlinelibrary.wiley.com/doi/full/10.1111/apa.17150 (last visited Jul. 1, 2024).

remain in the case for the merits determination, and its Florida members will certainly be covered by this injunction.

First, the Court does not know who the CMA members are. Generally judges prefer to adjudicate disputes between the parties presenting before them. Although the Court has the power under Fed. R. Civ. P. 65 to enter such an injunction, how that rule intersects, if at all, with possible class action status under Rule 23 is now unclear. Also, a judge must not issue an injunction if he or she cannot enforce it. If, perchance, a CMA member in Oregon were told by her hospital administrator to follow the Final Rule in its entirety based upon Ninth Circuit precedent, enforcement of the undersigned's injunction could be problematic.

Much of this present injunction is based on the likely illegality of the Final Rule under the two specific Eleventh Circuit holdings discussed above. Those rulings do not bind outside of the Eleventh Circuit.

Several Supreme Court justices have recently criticized the modern spate of nationwide or universal injunctions from District Courts. *See, e.g., Labrador v. Poe*, 144 S. Ct. at 921, 925. The Eleventh Circuit has counseled similarly. *Georgia v. President*, 46 F.4th at 1304. Those admonitions seem condign: A nationwide injunction issuing from a District Court ought to be the rare exception, not routine.

CONCLUSION

Accordingly, it is hereby **ORDERED** and **ADJUDGED:**

(1) Plaintiffs' Motion for Stay and Preliminary Injunction (Dkt. 12) is **GRANTED** within Florida only.

(2) Pending trial on the merits, the Final Rule entitled "Nondiscrimination in Health Programs and Activities," Final Rule, 89 Fed. Reg. 37,522 (May 6, 2024) is stayed in part, in Florida. The effective date of 45 C.F.R. §§92101(a)(2)(iv), 92.206(b), 92.207(b)(3)-(5), 42 C.F.R. § 438.3(d)(4) is postponed pending the disposition of the complaint on the merits. 5 U.S.C. § 705. For the duration of this Order, an assurance of compliance with Part 92, *see* 45 C.F.R. § 92.5, shall not be construed to assure compliance with any provisions stayed by this Order.

(3) Defendants are preliminarily enjoined from instituting or pursuing any enforcement proceedings under Section 1557, 42 U.S.C. § 18116(a), based on the interpretation of discrimination "on the basis of sex" to be codified at 45 C.F.R. § 92.101(a)(2)(iv), 92.206(b), or 92.207(b)(3)-(5).

(4) This Order runs throughout the State of Florida, applying to all Plaintiffs, including the State of Florida, the Florida Agency for Health Care Administration, the Florida Department of Management Services, and their agents, agencies, contractors, and instrumentalities. Further, all

covered entities within Florida are covered by this stay and injunction.

(5) The Court waives any bond requirement found at Fed. R. Civ. P. 65(e). *City of Atlanta v. Metropolitan Atlanta Transp. Auth.*, 636 F.2d 1084, 1094 (5th Cir. Unit B 1981).

DONE AND ORDERED at Tampa, Florida, July 3, 2024.

/s/ William F. Jung
WILLIAM F. JUNG
UNITED STATES DISTRICT JUDGE

Dkt. 46

IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF FLORIDA

STATE OF FLORIDA, et al. Plaintiffs, v. **DEPARTMENT OF HEALTH AND HUMAN SERVICES**, et al., Defendants.	Case No. 8:24-CV-1080-WFJ-TGW

NOTICE OF APPEAL

Please take notice that Defendants hereby appeal to the United States Court of Appeals for the Eleventh Circuit from this Court's Order dated July 3, 2024, ECF No. 41.

Dated: August 30, 2024

Respectfully submitted,

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Counsel for Defendants

Dkt. 52

IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF FLORIDA
TAMPA DIVISION

State of Florida, et al., Plaintiffs, v. **Department of Health and Human Services**, et al., Defendants.	**Case No.** 8:24-cv-1080-WFJ-TGW

PLAINTIFF CATHOLIC MEDICAL ASSOCIATION'S NOTICE OF CROSS-APPEAL

Pursuant to Federal Rule of Appellate Procedure 4(a)(3), Plaintiff Catholic Medical Association hereby cross-appeals to the United States Court of Appeals for the Eleventh Circuit from this Court's July 3, 2024 Order (Dkt. 41) "den[ying] the Catholic Medical Association's petition" for a preliminary injunction, *id.* at 47–48.

Respectfully submitted this 11th day of September, 2024.

/s/ Julie Marie Blake

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**Lead Counsel for Plaintiff Catholic Medical Association*

CERTIFICATE OF SERVICE

I hereby certify that on September 11, 2024, I electronically filed the foregoing with the Clerk of the Court for the United States District Court Middle District of Florida by using the CM/ECF system. I certify that all participants in the case are registered CM/ECF users and that service will be accomplished by the CM/ECF system.

/s/ Julie Marie Blake
JULIE MARIE BLAKE

Dkt. 60

IN THE UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
TAMPA DIVISION

STATE OF FLORIDA; FLORIDA AGENCY FOR HEALTH CARE ADMINISTRATION; FLORIDA DEPARTMENT OF MANAGEMENT SERVICES; CATHOLIC MEDICAL ASSOCIATION, on behalf of its current and future members,

Plaintiffs,

v. No. 8:24-cv-1080-WFJ-TGW

DEPARTMENT OF HEALTH AND HUMAN SERVICES; XAVIER BECERRA, in his official capacity as Secretary of the Department of Health and Human Services; MELANIE FONTES RAINER, in her official capacity as the Director of the Office for Civil Rights; CENTERS FOR MEDICARE AND MEDICAID SERVICES; CHIQUITA BROOKS-LASURE, in her official capacity as Administrator of the Centers for Medicare and Medicaid Services,

Defendants.

PLAINTIFFS' RESPONSE TO THE COURT'S ORDER

Pursuant to the Court's November 12, 2024, Order, Plaintiffs respectfully submit the following update:

On January 20, 2024, President-elect Trump is scheduled to begin his term in office. U.S. Const. amend. XX, § 1. The incoming administration is unlikely to share the current administration's peculiar enthusiasm for promoting "gender transition" drugs and procedures or requiring that males be allowed into female private spaces. It may move to repeal the regulations challenged here. But that will take time. A final rule repealing the challenged regulations could take years. And even when the regulations are repealed, a district court may still vacate the repeal rule and reinstate the current regulations. To continue assuring compliance without risk of liability under the False Claims Act, Plaintiffs will need the stay and preliminary injunction to remain in place for the foreseeable future.

HHS's brief on appeal is currently due on January 2, 2025. Plaintiff Catholic Medical Association (CMA) has cross-appealed. It's too early to say what HHS will decide to do with these appeals after January 20, 2025. In light of this uncertainty, Florida Plaintiffs don't oppose temporarily staying the district court proceedings until February 15, 2024, to allow the incoming administration time to evaluate this litigation in light of changed priorities, as long as the stay and preliminary injunction remain in place. Given that this Court denied injunctive relief to CMA, CMA's position is that this case should proceed to final judgment.

Plaintiffs also plan to move for leave to amend the complaint to challenge the rule's intrusive disparate-impact requirements for "limited English proficient" populations. Plaintiffs, however, are willing to defer amending the complaint until the new administration can evaluate its position on those requirements.

Respectfully submitted,

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** Lead Counsel*
Counsel for Plaintiff Catholic Medical Association

CERTIFICATE OF SERVICE

I hereby certify that on November 15, 2024, a true and correct copy of the foregoing was filed with the Court's CM/ECF system, which will provide service to all parties who have registered with CM/ECF and filed an appearance in this action.

/s/ James R. Conde
James R. Conde

Dkt. 61

IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF FLORIDA

STATE OF FLORIDA, *et al.* Plaintiffs, v. **DEPARTMENT OF HEALTH AND HUMAN SERVICES**, *et al.* Defendants.	Case No. 8:24-cv-01080-WFJ-TGW

STATUS REPORT

In September, this Court granted in part Defendants' motion to stay proceedings pending final resolution of their appeal of this Court's preliminary injunction, ECF No. 47. ECF No. 50. Opening briefs in that and in related appeals are due as follows:

- *State of Tennessee v. Becerra*, No. 24-60462 (5th Cir.): November 21, 2024
- *State of Texas v. Becerra*, No. 24-40568 (5th Cir.): November 27, 2024
- *State of Florida v. HHS*, No. 24-12826 (11th Cir.): January 2, 2025

The Fifth Circuit has not decided the appeal of the Final Judgment in *Neese v. Becerra*, No. 2:21-cv-00163-Z (N.D. Tex. Nov. 22, 2022), No. 23-10078 (5th Cir.), which precludes HHS from enforcing Section 1557 (including the Rule) against CMA members and Florida DDCs to prohibit discrimination on account of gender identity.

The stay of district court proceedings in this case should remain in effect. Circumstances have not changed such that the reasons for imposing the stay, ECF No. 47, no longer exist. *See Whitman-Walker Clinic, Inc. v. HHS*, Civ. A. No. 20-1630, 2021 WL 4033072, at *4 (D.D.C. Sept. 3, 2021). The Eleventh Circuit's ruling on Defendants' appeal of the preliminary injunction will have a "substantial" if not a "controlling effect" on Plaintiffs' claims, irrespective of any district court proceedings that take place in the interim. *See Miccosukee Tribe of Indians of Fla. v. S. Fla. Water Mgmt. Dist.*, 559 F.3d 1191, 1198 (11th Cir. 2009). Pressing on with such proceedings would therefore be an inefficient, if not wholly wasteful, use of the parties' and the Court's time and resources. *Id*.

At this time, Defendants cannot speculate about possible future actions by policymakers after the upcoming change in Presidential administration.

Dated: November 15, 2024

Respectfully submitted,

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Dkt. 70

UNITED STATES COURT OF APPEALS
FOR THE ELEVENTH CIRCUIT

ELBERT PARR TUTTLE COURT OF APPEALS BUILDING
56 Forsyth Street, N.W.
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David J. Smith
Clerk of Court

For rules and forms visit
www.ca11.uscourts.gov

April 03, 2025

MEMORANDUM TO COUNSEL OR PARTIES

Appeal Number: 24-12826-JJ
Case Style: State of Florida, et al v. Department of Health and Human Services, et al
District Court Docket No: 8:24-cv-01080-WFJ-TGW

The enclosed copy of this Court's Order of Dismissal is issued as the mandate of this court. See 11th Cir. R. 41-4. Counsel and pro se parties are advised that pursuant to 11th Cir. R. 27-2, "a motion to reconsider, vacate, or modify an order must be filed within 21 days of the entry of such order. No additional time shall be allowed for mailing."

Any pending motions are now rendered moot in light of the attached order.

Clerk's Office Phone Numbers

General Information:	404-335-6100	Attorney Admissions:	404-335-6122
Case Administration:	404-335-6135	Capital Cases:	404-335-6200
CM/ECF Help Desk:	404-335-6125	Cases Set for Oral Argument:	404-335-6141

Enclosure(s)

DIS-4 Multi-purpose dismissal letter

In the

United States Court of Appeals

For the Eleventh Circuit

No. 24-12826

STATE OF FLORIDA,
FLORIDA AGENCY FOR HEALTH CARE ADMINISTRATION,
FLORIDA DEPARTMENT OF MANAGEMENT SERVICES,

Plaintiffs-Appellees,

CATHOLIC MEDICAL ASSOCIATION,
on behalf of its current and future members,

Plaintiff-Appellee
Cross-Appellant,

versus

DEPARTMENT OF HEALTH AND HUMAN SERVICES,
SECRETARY, DEPARTMENT OF HEALTH AND HUMAN SERVICES,
in his official capacity,
DIRECTOR, OFFICE FOR CIVIL RIGHTS,
in her official capacity,

CENTERS FOR MEDICARE AND MEDICAID SERVICES, ADMINISTRATOR, CENTERS FOR MEDICARE AND MEDICAID SERVICES, et al.,

Defendants-Appellants
Cross-Appellees.

Appeal from the United States District Court
for the Middle District of Florida
D.C. Docket No. 8:24-cv-01080-WFJ-TGW

Before ROSENBAUM, BRASHER, and ABUDU, Circuit Judges.

BY THE COURT:

Appellants' "Unopposed Motion to Dismiss Appeal" is GRANTED.

Cross-Appellant Catholic Medical Association's "Response to Unopposed Motion to Dismiss Appeal," which the Court construes as a motion to voluntarily dismiss the cross-appeal, is GRANTED.

The Clerk's Office is directed to close the file on this matter. Each party shall bear their own respective costs.

Dkt. 73

IN THE UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
TAMPA DIVISION

STATE OF FLORIDA; FLORIDA AGENCY FOR HEALTH CARE ADMINISTRATION; FLORIDA DEPARTMENT OF MANAGEMENT SERVICES; CATHOLIC MEDICAL ASSOCIATION, on behalf of its current and future members,

Plaintiffs,

v. No. 8:24-cv-1080-WFJ-TGW

DEPARTMENT OF HEALTH AND HUMAN SERVICES; ROBERT F. KENNEDY, JR., in his official capacity as Secretary of the Department of Health and Human Services; ANTHONY ARCHEVAL, in his official capacity as the Acting Director of the Office for Civil Rights; CENTERS FOR MEDICARE AND MEDICAID SERVICES; STEPHANIE CARLTON, in her official capacity as Acting Administrator of the Centers for Medicare and Medicaid Services,[1]

Defendants.

PLAINTIFFS' MOTION TO REOPEN AND TO CLARIFY

[1] Caption updated pursuant to Federal Rule Civil Procedure 25(d).

Plaintiffs respectfully move to reopen this case, set a deadline to file motions to govern, and clarify the effect, if any, of the Court's April 9, 2025, full closure order. ECF 71. Defendants (HHS) state that they "would like to review the motion before taking a position and anticipate filing a response within the time permitted under Local Rule 3.01(c)." In support of this motion, Plaintiffs state as follows:

BACKGROUND

1. On May 6, 2024, HHS published a final rule entitled "Nondiscrimination in Health Programs and Activities." 89 Fed. Reg. 37,522 (May 6, 2024). That final rule purports to implement Section 1557 of the Affordable Care Act ("ACA"). 42 U.S.C. § 18116(a).

2. On May 6, 2024, the same day the final rule was published, Plaintiffs filed the Complaint in this case. ECF 1.

3. On May 15, 2024, Plaintiffs sought a stay of the effective date of the final rule and a preliminary injunction, given the rule's effective date of July 5, 2024. ECF 12.

4. On July 3, 2024, the Court granted Plaintiffs' motion for a stay and preliminary injunction "within the State of Florida" "[p]ending trial on the merits." ECF 41, at 1, 49–50. The Court, however, denied preliminary injunctive relief to the Catholic Medical Association and its members residing outside of Florida. *Id.* at 47–48.

5. On August 30, 2024, HHS filed an interlocutory appeal of this Court's July 3, 2024, order. ECF 46. On September 11, 2024, Plaintiff Catholic Medical Association filed a cross-appeal. ECF 52.

6. While the interlocutory appeal was pending, the Court stayed proceedings and directed the Clerk to administratively close the case, while noting that "[a]ny party may reopen at any time by filing a motion." ECF 62.

7. Following a change in agency leadership, HHS moved to dismiss its interlocutory appeal, and Catholic Medical Association filed a response thereto. On April 3, 2025, the Court of Appeals granted HHS's motion and construed the response of the Catholic Medical Association as a request to voluntarily dismiss its cross-appeal, which the Court also granted. ECF 70.

8. On April 9, 2025, following the dismissal of the interlocutory appeals, this Court directed the clerk to "lift the stay and convert the administrative closure into a full closure." ECF 71.

ARGUMENT

Fully closing this civil action is not an appropriate disposition at this stage. This action has just progressed beyond the preliminary injunction stage. "Preliminary injunctions, however, do not conclusively resolve legal disputes. In awarding preliminary injunctions, courts determine if a plaintiff is *likely* to succeed on the merits—along with the risk of irreparable harm, the balance of equities, and the public

interest." *Lackey v. Stinnie*, 145 S. Ct. 659, 667 (2025). With no final judgment on the merits, or even an answer to the Complaint, fully closing the case is premature.

Plaintiffs recognize that this Court has broad discretion to administer its docket. This Court may well decide to stay proceedings should such a stay be appropriate under the circumstances, and the parties may have different views on how to proceed. But the Court should allow the parties an opportunity to be heard on that question by entertaining motions to govern, rather than ordering full closure. Plaintiffs therefore respectfully request that, in reopening the case, the Court set a deadline for the parties to file motions to govern.[2]

Plaintiffs also respectfully request that this Court's order clarify the effect, if any, of its full closure order. Despite the full closure order, this Court has not dissolved the July 3 Order awarding a stay and preliminary injunction, and the Order continues to apply "pending trial on the merits," ECF 49, at 49. Plaintiffs thus continue to operate their affairs within the State of Florida on the assumption that this Court's July 3 Order remains operative and continues to stay the effective date of the final rule and to restrain HHS's enforcement actions pending further order from the Court. Further, Plaintiffs do not interpret the "full closure" order as a final judgment terminating proceedings that triggers the deadline for Plaintiffs to file a notice of appeal. Nevertheless, out of an abundance of caution, Plaintiffs respectfully request that the

[2] In a related action brought by other states, HHS has agreed to proceed directly to summary judgment briefing. *See State of Tennessee et al. v. Kennedy*, 24-cv-00161-LG-BWR, ECF No. 60.

Court clarify (1) that the July 3, 2024 Order remains in place notwithstanding the April 9, 2025 full closure order, and (2) that there is, to date, no final appealable judgment.

CONCLUSION

The Court should (1) reopen the case and set a deadline to file motions to govern, (2) clarify that the July 3, 2024 Order remains operative notwithstanding the April 9, 2025 full closure order, and (3) clarify that there is, to date, no final appealable judgment.

Respectfully submitted,

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LOCAL RULE 3.01(G) CERTIFICATION

I hereby certify that Plaintiffs conferred with the opposing party, via email and telephone, and Defendant HHS states that they "would like to review the motion before taking a position and anticipate filing a response within the time permitted under Local Rule 3.01(c)."

/s/ James R. Conde
James R. Conde

CERTIFICATE OF SERVICE

I hereby certify that on May 2, 2025, a true and correct copy of the foregoing was filed with the Court's CM/ECF system, which will provide service to all parties who have registered with CM/ECF and filed an appearance in this action.

/s/ James R. Conde
James R. Conde

Dkt. 75

IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF FLORIDA

STATE OF FLORIDA, *et al.* Plaintiffs, v. **DEPARTMENT OF HEALTH AND HUMAN SERVICES**, *et al.* Defendants.	Case No. 8:24-cv-01080-WFJ-TGW

DEFENDANTS' STATUS REPORT AND RESPONSE TO PLAINTIFFS' MOTION TO REOPEN

On January 20, 2021, Donald J. Trump was inaugurated as the forty-seventh President of the United States. On the same day, the President issued an Executive Order titled "Defending Women From Gender Ideology Extremism and Restoring Biological Truth to the Federal Government." Exec. Order No. 14,168, 90 Fed. Reg. 8615 (Jan. 30, 2025) ("*Defending Women*"). On January 28, 2025, the President issued an Executive Order titled "Protecting Children from Chemical and Surgical Mutilation." Exec. Order No. 14,187, 90 Fed. Reg. 8771 (Feb. 3, 2025) ("*Protecting Children*"). *Defending Women* provides that "[i]t is the policy of the United States to recognize two sexes, male and female." 90 Fed. Reg. at 8615. And "'[s]ex' shall refer to an individual's immutable biological classification as either male or female." *Id.* *Protecting Children* provides that "it is the policy of the United States that it will not fund, sponsor, promote, assist, or support the so-called 'transition' of a child from one sex to another[.]" 90 Fed. Reg. at 8771. In line with the President's executive orders, the Secretary of Health and Human Services has promulgated "guidance expanding on the sex-based distinctions set forth in" *Defending Women*. *See Defending Women* § 3(a); https://womenshealth.gov/article/sex-based-definitions.

Defendants are committed to implementing the President's executive orders and are considering the appropriate means for doing so. But Plaintiffs have nevertheless returned to this Court seeking to press forward with their claims for prospective equitable relief. The Court should not enter Plaintiffs' requested order. In particular, the Court should not reopen the case or require the parties to file motions to govern future proceedings. Rather, insofar as this Court's Order lifting the stay and

converting the administrative closure into a full closure, ECF No. 71, has caused confusion and uncertainty on the part of Plaintiffs, the Court could instead simply vacate that Order and direct the parties to confer about what further district court proceedings, if any, are necessary at this time.

BACKGROUND

In September, this Court granted in part Defendants' motion to stay proceedings pending final resolution of their appeal of this Court's preliminary injunction, ECF No. 47. ECF No. 50. And after the November 2024 election, the Court contemplated "the likelihood of mootness given a pending change in administration." ECF No. 58. Ultimately, exercising its broad powers to manage its docket, the Court issued an order administratively closing the case in December 2024. ECF No. 62.

After the change in Presidential administrations, the President issued the *Defending Women* and *Protecting Children* Executive Orders. Thereafter, Defendants voluntarily dismissed their appeal of this Court's preliminary injunction and Plaintiff Catholic Medical Association dismissed its cross-appeal. ECF No. 70. Several days later, this Court issued an order directing the Clerk "to lift the stay and convert the administrative closure into a full closure." ECF No. 71.

On May 2, 2025, Plaintiffs filed a motion "to reopen and clarify." ECF No. 73. Specifically, Plaintiffs seek an order directing the Clerk "to reopen the case" and directing the parties to file "motions to govern future proceedings in this civil action[.]" ECF No. 73-1. The order they request would also include entry on the docket of statements about the continued effectiveness of this Court's preliminary injunction and

whether a final judgment has been entered. *Id.* On May 5, 2025, the Court issued an order taking Plaintiffs' motion to reopen under advisement and directing HHS to file a status update response within thirty days. ECF No. 74.

ARGUMENT

I. The Court Should Consider Vacating Its April 9 Order.

Plaintiffs argue that the Court's April 9 Order, ECF No. 71, has caused them confusion about whether the Court intended to enter final judgment and whether the Court intended to dissolve the preliminary injunction. *See* ECF No. 73 at 4-5. The parties do not dispute that this Court has not entered final judgment and that this Court's preliminary injunction has therefore not been dissolved. Entry of an order, declaratory in nature, reflecting that shared understanding by the parties is therefore unnecessary. *See Guerra v. Sutton*, 783 F.2d 1371, 1376 (9th Cir. 1986) (declaratory relief inappropriate where defendants "readily concede" issue and so the "legal relations between the parties are not uncertain or in need of clarification"); *Chancey v. Biden*, No. 1:22-cv-110-MW/GRJ, 2022 WL 20087120, at *2 (N.D. Fla. Aug. 25, 2022) (clarifying issues that "[n]obody disputes . . . serves no purpose").

Insofar as this Court's April 9 Order has caused confusion on the part of Plaintiffs, the Court could simply vacate it. A district court has the power to rescind its orders at any point prior to final judgment in a civil case. *Dietz v. Bouldin*, 579 U.S. 40, 46 (2016) (citing *Marconi Wireless Tel. Co. of Am. v. United States*, 320 U.S. 1, 47-48 (1943)). Likewise, a district court has inherent authority to manage its docket and

courtroom with a view toward the efficient and expedient resolution of cases. *Id.* (citing *Landis v. N. Am. Co.*, 299 U.S. 248, 254 (1936)). Thus, the Court has ample inherent authority to vacate its order dated April 9, 2025, ECF No. 71. Doing so would make clear for Plaintiffs that the Court did not enter final judgment or dissolve the preliminary injunction. It would also make clear that the stay of proceedings remains in place. The Court's April 9 Order directed the Clerk to lift the stay of proceedings, but no party had moved the Court to lift that stay or provided a basis for doing so. *See* ECF No. 62. Nor could the April 9 Order's reference to the stay be understood as intended to resume active district court proceedings, given that it was paired with a directive that the Clerk convert the administrative closure into a full closure. ECF No. 71. Thus, vacatur of the Court's April 9 Order would more effectively redress any confusion that the order has caused Plaintiffs or with respect to the stay of proceedings in this case.

II. The Court Should Deny Plaintiffs' Request for an Order Reopening the Case or Requiring the Parties to File Motions to Govern Further Proceedings.

Because vacatur of the Court's April 9 Order would fully address any confusion Plaintiffs complain of, there is no need to go further and "reopen the case" or direct the parties to "file motions to govern further proceedings" at this time, as Plaintiffs also request. Indeed, their motion points to no change in circumstance that necessitates altering the administrative closure that had long been in place, much less any pressing need to resume merits proceedings while the agency implements the President's Executive Orders.

As this Court predicted, *see* ECF No. 58, those Executive Orders have already had justiciability implications for this action. For example, this Court's preliminary injunction restraining Defendants from taking certain enforcement actions rested on its "envision[ing] of many . . . factual scenarios" for which an enforcement action would be unlawful, such as enforcement against a local hospital refusing "to even consider castrating a teenage gender dysphoria with healthy testicles." *Florida*, 739 F. Supp. 3d at 1107. But especially after *Protecting Children*, Plaintiffs and their members face no credible threat of any such enforcement action by Defendants, even setting aside the several injunctions and stays of enforcement issued by this Court and others.[1]

Defendants' ongoing implementation of the President's Executive Orders may also implicate Article III's adverseness requirement. Courts do not "give advisory opinions about issues as to which there are not adverse parties." *Princeton Univ. v. Schmid*, 455 U.S. 100, 102 (1982); *see also United States v. Windsor*, 570 U.S. 744, 759-63 (2013) (describing required "sharp adversarial presentation of the issues"). Defendants are committed to implementing the President's Executive Orders, which reflect policies not unaligned with those of Plaintiffs. *Compare Defending Women* §§ 3(f), 4(d), 5; *Protecting Children* § 1, *with* ECF No. 12 at 1, 5. And entry of final declaratory, injunctive, or other equitable relief against the Executive Branch is inappropriate

[1] *Cf. Neese v. Becerra*, 123 F.4th 751, 753-54 (5th Cir. 2024); *see Neese v. Becerra*, 127 F.4th 601, 602 (5th Cir. 2025) (Duncan, J., concurring) ("None of this may matter . . . in light of actions already taken by the new Administration."); *Protecting Children* § 5(a)(iv), 90 Fed. Reg. at 8,772 (directing HHS Secretary to "take all appropriate actions to end the chemical and surgical mutilation of children, including" under Section 1557).

"where it appears that a challenged" Executive Branch policy "is at the moment adjudication is sought, undergoing significant modification so that its ultimate form cannot be confidently predicted." *A.L. Mechling Barge Lines, Inc v. United States*, 368 U.S. 324, 331 (1961).[2]

Thus, rather than order that the case be reopened, or that motions to govern further proceedings be submitted, the Court should direct the parties to confer about what further proceedings, if any, are necessary at this time.

Dated: June 4, 2025

Respectfully submitted,

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Acting Assistant Attorney General

MICHELLE R. BENNETT
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Counsel for Defendants

[2] That this case arises under the Administrative Procedure Act ("APA") is immaterial because the APA carries forward these principles. 5 U.S.C. §702(1); *Saavedra Bruno v. Albright*, 197 F.3d 1153, 1158 & n.1 (D.C. Cir. 1999).

Dkt. 77

IN THE UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
TAMPA DIVISION

STATE OF FLORIDA; FLORIDA AGENCY FOR HEALTH CARE ADMINISTRATION; FLORIDA DEPARTMENT OF MANAGEMENT SERVICES; CATHOLIC MEDICAL ASSOCIATION, on behalf of its current and future members,

Plaintiffs,

v. No. 8:24-cv-1080-WFJ-TGW

DEPARTMENT OF HEALTH AND HUMAN SERVICES; ROBERT F. KENNEDY, JR., in his official capacity as Secretary of the Department of Health and Human Services; ANTHONY ARCHEVAL, in his official capacity as the Acting Director of the Office for Civil Rights; CENTERS FOR MEDICARE AND MEDICAID SERVICES; STEPHANIE CARLTON, in her official capacity as Acting Administrator of the Centers for Medicare and Medicaid Services,

Defendants.

PLAINTIFFS' NOTICE OF APPEAL

Plaintiffs State of Florida, Florida Agency for Health Care Administration, Florida Department of Management Services, and Catholic Medical Association appeal to the United States Court of Appeals for the Eleventh Circuit from the District Court's "full closure" order, ECF No. 71, entered in this action on the 9th day of April 2025, and the Order Denying Motion for Reconsideration/Clarification and stating

that "there is no case or controversy pending," ECF No. 76, entered in this action on the 5th day of June 2025.

Respectfully submitted,

JAMES UTHMEIER
ATTORNEY GENERAL

JOHN GUARD
CHIEF DEPUTY ATTORNEY GENERAL

JEFFREY DESOUSA
ACTING SOLICITOR GENERAL

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CERTIFICATE OF SERVICE

I hereby certify that on June 6, 2025, a true and correct copy of the foregoing was filed with the Court's CM/ECF system, which will provide service to all parties who have registered with CM/ECF and filed an appearance in this action.

/s/ James R. Conde
James R. Conde

Dkt. 84

NOT FOR PUBLICATION

In the

United States Court of Appeals

For the Eleventh Circuit

No. 25-11927
Non-Argument Calendar

STATE OF FLORIDA,
FLORIDA AGENCY FOR HEALTH CARE ADMINISTRATION,
FLORIDA DEPARTMENT OF MANAGEMENT SERVICES,
CATHOLIC MEDICAL ASSOCIATION,
on behalf of its current and future members,

Plaintiffs-Appellants,

versus

DEPARTMENT OF HEALTH AND HUMAN SERVICES,
SECRETARY, DEPARTMENT OF HEALTH AND HUMAN SERVICES,
in his official capacity,
DIRECTOR, OFFICE FOR CIVIL RIGHTS,
in her official capacity,
CENTERS FOR MEDICARE AND MEDICAID SERVICES,
ADMINISTRATOR, CENTERS FOR MEDICARE AND MEDICAID SERVICES,

Defendants-Appellees.

Appeal from the United States District Court
for the Middle District of Florida
D.C. Docket No. 8:24-cv-01080-WFJ-TGW

Before JILL PRYOR, LAGOA, and KIDD, Circuit Judges.

PER CURIAM:

The Catholic Medical Association, the State of Florida, the Florida Agency for Health Care Administration, and the Florida Department of Management Services filed this action against the U.S. Department of Health and Human Services and various federal health officials. On June 6, 2025, the plaintiffs filed a notice of appeal designating two endorsed orders, which created this appeal.

In the first endorsed order, on April 9, 2025, the district court lifted a stay that was in place while a previous appeal was pending and converted the administrative closure of the case to a "full closure." The plaintiffs filed a motion requesting that the court reopen the case and clarify the effect of the April 9 order. On June 5, 2025, in the second endorsed order, the court denied the plaintiffs' motion to reopen the case, saying "[t]here is no case or controversy presently pending." The next day, the plaintiffs filed their notice of appeal from the April 9 and June 5 orders. On June 9, 2025, the district court entered an endorsed order directing the clerk to "dismiss this case without prejudice as moot and not capable of

repetition within any reasonable time frame." The plaintiffs then filed a second notice of appeal, designating the June 9 order.[1]

A jurisdictional question asked the parties to address whether the plaintiffs' June 6 appeal was taken from a final, appealable order. The plaintiffs respond that, construed together, the April 9 and June 5 orders constituted a final judgment dismissing the case for lack of jurisdiction. Alternatively, they argue that the June 6 notice of appeal relates forward to the June 9 order such that this Court has jurisdiction over this appeal even if the April 9 and June 5 orders were not final. The defendants respond that the April 9 and June 5 orders dismissed the case as moot, ending the litigation on the merits and producing a final judgment.

Upon review of the record, particularly the plain text of the district court's endorsed orders, we conclude that there was not a final, appealable order at the time the plaintiffs' filed this first appeal. First, while the April 9 order converted the administrative closure to a "full closure," it was not final and appealable because it did not resolve any of the claims between the parties. *See CSX Transp., Inc. v. City of Garden City*, 235 F.3d 1325, 1327 (11th Cir. 2000) (providing that final decisions end the litigation on the merits and leave the court with nothing to do but execute the final judgment); *Supreme Fuels Trading FZE v. Sargeant*, 689 F.3d 1244, 1245-46 (11th Cir. 2012) (providing that an order that disposes of fewer than all claims against all parties to an action is generally not final or

[1] This notice of appeal resulted in appeal number 25-12095, which is currently pending.

immediately appealable). The June 5 order also did not dispose of any claims. *See Sargeant*, 689 F.3d at 1245-46. The district court's entry of the June 9 order dismissing the pending claims indicated that the court intended for the June 9 order—rather than the June 5 order—to end the litigation on the merits and serve as the final action in the case. *See CSX Transp., Inc.*, 235 F.3d at 1327; *Sargeant*, 689 F.3d at 1245-46. Thus, neither the April 9 nor June 5 orders was final or immediately appealable. *See* 28 U.S.C. §§ 1291, 1292.

Second, we disagree that the June 6 notice of appeal relates forward to the June 9 order such that the second notice of appeal was unnecessary. The June 6 notice of appeal was premature as to the June 9 order, and the June 9 final order did not retroactively validate this appeal from the interlocutory orders. *See Bogle v. Orange Cnty. Bd. of Cnty. Comm'rs*, 162 F.3d 653, 661 (11th Cir. 1998) (explaining that a notice of appeal must designate an existing judgment or order); *Robinson v. Tanner*, 798 F.2d 1378, 1385 (11th Cir. 1986) (providing that when a notice of appeal is filed from a non-final interlocutory order, a subsequent final judgment generally does not validate the premature notice of appeal).

Accordingly, this appeal is DISMISSED. All pending motions are DENIED as moot. This ruling does not affect the plaintiffs' separate appeal pending in appeal number 25-12095.

UNITED STATES COURT OF APPEALS
FOR THE ELEVENTH CIRCUIT

ELBERT PARR TUTTLE COURT OF APPEALS BUILDING
56 Forsyth Street, N.W.
Atlanta, Georgia 30303

David J. Smith
Clerk of Court

For rules and forms visit
www.ca11.uscourts.gov

October 02, 2025

MEMORANDUM TO COUNSEL OR PARTIES

Appeal Number: 25-11927-FF
Case Style: State of Florida, et al v. Department of Health and Human Services, et al
District Court Docket No: 8:24-cv-01080-WFJ-TGW

Opinion Issued
Enclosed is a copy of the Court's decision issued today in this case. Judgment has been entered today pursuant to FRAP 36. The Court's mandate will issue at a later date pursuant to FRAP 41(b).

Petitions for Rehearing
The time for filing a petition for panel rehearing or rehearing en banc is governed by 11th Cir. R. 40-2. Please see FRAP 40 and the accompanying circuit rules for information concerning petitions for rehearing. Among other things, **a petition for rehearing must include a Certificate of Interested Persons**. See 11th Cir. R. 40-3.

Costs
No costs are taxed.

Bill of Costs
If costs are taxed, please use the most recent version of the Bill of Costs form available on the Court's website at www.ca11.uscourts.gov. For more information regarding costs, see FRAP 39 and 11th Cir. R. 39-1.

Attorney's Fees
The time to file and required documentation for an application for attorney's fees and any objection to the application are governed by 11th Cir. R. 39-2 and 39-3.

Appointed Counsel
Counsel appointed under the Criminal Justice Act (CJA) must submit a voucher claiming compensation via the eVoucher system no later than 45 days after issuance of the mandate or the filing of a petition for writ of certiorari. Please contact the CJA Team at (404) 335-6167 or cja_evoucher@ca11.uscourts.gov for questions regarding CJA vouchers or the eVoucher system.

Clerk's Office Phone Numbers

General Information:	404-335-6100	Attorney Admissions:	404-335-6122
Case Administration:	404-335-6135	Capital Cases:	404-335-6200
CM/ECF Help Desk:	404-335-6125	Cases Set for Oral Argument:	404-335-6141

OPIN-1 Ntc of Issuance of Opinion

COS

CERTIFICATE OF SERVICE

I hereby certify that on December 1, 2025, I electronically filed the foregoing document with the Clerk of this Court by using the CM/ECF system, which will serve all parties automatically.

Dated: December 1, 2025

/s/ James R. Conde
James R. Conde

Lead Counsel and Counsel of Record for Plaintiffs-Appellants Florida Agency for Health Care Administration and Florida Department of Management Services