UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF MISSISSIPPI
SOUTHERN DIVISION

STATE OF TENNESSEE, STATE OF MISSISSIPPI, STATE OF ALABAMA, STATE OF GEORGIA, STATE OF INDIANA, STATE OF KANSAS, COMMONWEALTH OF KENTUCKY, STATE OF LOUISIANA, STATE OF NEBRASKA, STATE OF OHIO, STATE OF OKLAHOMA, STATE OF SOUTH CAROLINA, STATE OF SOUTH DAKOTA, COMMONWEALTH OF VIRGINIA, AND STATE OF WEST VIRGINIA,

Plaintiffs,

v.

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

Defendants.

Civil Action No. 1:24cv161 LG-BWR

COMPLAINT FOR INJUNCTIVE AND DECLARATORY RELIEF

1. "[F]rom time immemorial," the States have maintained primary responsibility for regulating the medical field through their constitutionally reserved powers to protect their citizens' health and welfare. *Dent v. West Virginia*, 129 U.S. 114, 122 (1889). But a new rule from the

U.S. Department of Health and Human Services ("HHS") seeks to supplant States' health regulations with a regime that sides with HHS's commitment to gender ideology over medical reality. *See* Dep't of Health & Human Servs., *Nondiscrimination in Health Programs and Activities*, 89 Fed. Reg. 37,522 (May 6, 2024) ("2024 Rule") (Exhibit A). Purporting to implement the Affordable Care Act's prohibition on "sex" discrimination, HHS's 2024 Rule threatens States and healthcare providers with massive penalties for failing to align their policies, coverage decisions, and even medical care with patients' subjective gender identities rather than sex. The results of HHS's 2024 Rule will be radical: Hospitals and clinics that limit rooms to members of the same sex will be guilty of unlawful discrimination. So too will a surgeon who performs mastectomies to treat breast cancer yet declines to remove healthy breast tissue from a girl who identifies as a boy. Even a nurse who discusses health problems more prevalent in males risks liability if her patient is a male who identifies as a woman. States, for their part, must use taxpayer funds to pay for unproven and costly gender-transition interventions through Medicaid and state health plans—even for children, who may suffer irreversible harms. Courts have twice struck down similar HHS efforts to govern the Nation's health providers by administrative fiat. Plaintiffs now ask this Court to enjoin and invalidate the 2024 Rule's unlawful attempt to do the same.

INTRODUCTION

2. HHS's 2024 Rule is the latest effort by the Biden Administration to enshrine sweeping gender-identity mandates without congressional consent.

3. When Congress adopted the Affordable Care Act in 2010, it included a nondiscrimination provision known as Section 1557. *See* 42 U.S.C. § 18116. That provision in turn incorporates other longstanding civil rights laws to protect patients from unlawful

discrimination in the healthcare industry. Relevant here is Section 1557's incorporation of Title IX of the Educational Amendments Act, 20 U.S.C. § 1681 *et seq.*

4. Congress passed Title IX in 1972 to remedy historic and persistent mistreatment of women in education. The relevant portion of the statute prohibits recipients of federal educational funding from engaging in discrimination "on the basis of sex." *Id.* § 1681(a).

5. Federal courts across the country have recognized that the ordinary public meaning of "sex" at the time of Title IX's enactment referred to the biological distinction between male and female. *E.g.*, *Adams ex rel. Kasper v. Sch. Bd. of St. Johns Cnty.*, 57 F.4th 791, 817 (11th Cir. 2022) (en banc); *Neese v. Becerra*, 640 F. Supp. 3d 668, 683 (N.D. Tex. 2022); *Franciscan All., Inc. v. Burwell*, 227 F. Supp. 3d 660, 687-88 (N.D. Tex. 2016) (*Franciscan Alliance I*); *Texas v. United States*, 201 F. Supp. 3d 810, 832-33 (N.D. Tex. 2016). Accordingly, Title IX consistently treats "sex" as binary. For example, § 1681(a)(2) delays Title IX's application to an institution in the process of "changing from being an institution which admits only students of *one* sex" to being "an institution which admits students of *both* sexes." 20 U.S.C. § 1681(a)(2) (emphasis added). Other similar provisions appear throughout the statute.

6. Despite this clear meaning of "sex," the 2024 Rule reinterprets Section 1557 and Title IX to encompass protections for "gender identity" and other "sex characteristics" that appear nowhere in the text of either law. The upshot is a regime requiring providers to engage in—and health insurers to cover—so-called "gender-affirming care."

7. To reach this result, HHS relies heavily on the Supreme Court's decision in *Bostock v. Clayton County*, 590 U.S. 644 (2020), regarding Title VII's prohibition on discrimination "because of sex." But *Bostock* did not address Section 1557 or Title IX. Indeed, *Bostock* expressly

declined to "prejudge" any issues pertaining to bathrooms, healthcare, insurance, "or anything else of the kind" under any other nondiscrimination law. *Id*. at 681.

8. This is not the first time HHS has distorted the meaning of Section 1557. HHS in 2016 promulgated a similar rule that attempted to expand Section 1557's protections against sex discrimination to include "gender identity." A federal district court enjoined that attempt, noting that such a reading "conflict[ed] with Title IX, [Section 1557's] incorporated statute." *Franciscan All., Inc. v. Azar*, 414 F. Supp. 3d 928, 941-45 (N.D. Tex. 2019). A few years later, a federal district court enjoined HHS's similar 2021 guidance, finding HHS's conclusion that "denial of … care solely on the basis of a patient's sex assigned at birth or gender identity likely violates Section 1557" to be "arbitrary and capricious." *Texas v. EEOC*, 633 F. Supp. 3d 824, 838, 847 (N.D. Tex. 2022).

9. Like HHS's prior gender-identity mandates, the 2024 Rule represents a radical affront to the physician-patient relationship and States' sovereign interests.

10. Under the guise of "nondiscrimination," the 2024 Rule seeks to dictate the details of providers' medical practices and facilities as well as impose a new national standard of care for addressing gender dysphoria. Under the 2024 Rule, healthcare professionals must preference HHS's commitment to gender ideology over both the biological reality that the sexes are different in ways that affect health risks and their assessment of the proper approach to and scope of medical treatment. Even inquiring into a person's medical history and biological sex characteristics could be enough to trigger a discrimination claim and HHS investigation—even though understanding those issues is often critical to assessing and providing appropriate medical care.

11. More than that, the 2024 rule will force many doctors to provide controversial and potentially harmful medical intervention—like sterilizing hormones and sex-change surgeries—

on adults and children alike. So long as a doctor provides medication or surgeries to treat certain physical maladies, the doctor cannot refuse to provide HHS's list of gender-dysphoria-related interventions. Doing so, in HHS's view, would be "sex" discrimination—no matter that the procedures are different, that the conditions being treated are different, or whether providing interventions to individuals with gender dysphoria under those circumstances contradicts a doctor's reasonable medical judgment.

12. By setting out this mandate, the 2024 Rule overrides Plaintiff States' limitations on providing gender-dysphoria interventions to minors, which the States have permissibly adopted to further their longstanding and sovereign interests "'in protecting the integrity and ethics of the medical profession,' and 'preserving and promoting the welfare of the child.'" *L.W. ex rel. Williams v. Skrmetti*, 83 F.4th 460, 473 (6th Cir. 2023) (citations omitted).

13. Tennessee, for example, has "ban[ned] certain medical treatment for minors with gender dysphoria," including "'surgically removing, modifying, altering, or entering into tissues, cavities, or organs' and 'prescribing, administering, or dispensing any puberty blocker or hormone'" for the purpose of either "enabling a minor to identify with, or live as, a purported identity inconsistent with the minor's sex" or "treating purported discomfort or distress from a discordance between the minor's sex and asserted identity." *Id.* (citations omitted). Mississippi likewise prohibits the provision of certain "gender transition procedures" for minors, including "gender reassignment surger[ies]" and the "prescri[ption] or "administ[ration]" of "puberty-blocking drugs [or] … cross-sex hormones." Miss. Code Ann. § 41-141-3(d), (f)(1); *see id.* § 41-141-5. Many other States maintain similar laws. *See infra* pp. 37-40.

14. Yet the 2024 Rule would expose healthcare providers—including those employed by the States—to enforcement actions, the loss of patients who rely on federal financial assistance,

and civil liability simply for complying with state law. Indeed, at least one Mississippi pediatric clinic has already filed a pre-enforcement challenge seeking to shield its medical practice and its patients from HHS's unlawful new gender-identity mandate. *See McComb Children's Clinic, Ltd. v. Becerra*, 5:24-cv-48-KS-LGI (S.D. Miss.).

15. The 2024 Rule does not stop there. It goes on to require that States use taxpayer funds to *pay for* controversial sex-transition procedures under any state-operated plan that receives federal funding. This includes state Medicaid programs, Children's Health Insurance Programs, and health plans for state employees. In doing so, the 2024 Rule purports to outlaw as impermissible "sex discrimination" the choice by policymakers in Tennessee, Mississippi, and other States to exclude insurance coverage for risky and costly gender-transition surgeries, among other things.

16. In addition, the 2024 Rule subjects States to private suits by employees and patients for failing to follow these gender-identity mandates, even though neither Congress nor the States intended to waive the States' sovereign immunity in these areas.

17. Worse still, the 2024 Rule unlawfully coerces States' compliance by threatening to strip billions of dollars in federal funding that assists their most vulnerable populations. The Plaintiff States could not have foreseen that the Affordable Care Act's nondiscrimination provision would be wielded in such a way when they accepted these federal dollars from HHS and built extensive health programs—with annual budgets in the billions—in reliance on that funding.

18. With the 2024 Rule set to take effect on July 5, 2024, the Plaintiff States also face imminent, unrecoverable compliance expenses and the risk of liability in private suits. These compliance costs and efforts will be substantial—as the 2024 Rule itself acknowledges.

19. Tennessee and tens of thousands of other commenters opposed HHS's approach for these and other reasons. *See, e.g.*, Tenn. Comment Letter (Exhibit B). Yet in adopting the 2024 Rule, HHS failed to respond to many commenters' critiques—let alone with adequate explanations or supporting evidence. But basic administrative law principles make clear that agencies must offer well-reasoned decision-making to support their regulations, not dodge important aspects of the problem or draw arbitrary lines for political reasons. Nor has Congress vested HHS with authority—let alone using clear language—to resolve these highly controversial and localized issues.

20. Because HHS overreaches in its attempt to expand federal antidiscrimination law far beyond what the statutory text, the Administrative Procedure Act ("APA"), judicial precedent, and the U.S. Constitution permit, the 2024 Rule should be vacated and set aside.

21. Plaintiffs—the States of Tennessee, Mississippi, Alabama, Georgia, Indiana, Kansas, Kentucky, Louisiana, Nebraska, Ohio, Oklahoma, South Carolina, South Dakota, Virginia, and West Virginia—accordingly bring this suit to seek preliminary and permanent relief. They ask this Court to stay the 2024 Rule's effective date and preliminarily enjoin enforcement pending judicial review. Plaintiffs further request that the Court ultimately declare unlawful, vacate, and set aside the 2024 Rule.

PARTIES

I. Plaintiffs

22. Plaintiff State of Tennessee is a sovereign State with the authority and responsibility to protect its public fisc, as well as the health, safety, and welfare of its citizens. From "time immemorial," States have regulated the practice of medicine within their borders, *L.W.*, 83 F.4th at 475 (quoting *Dent*, 129 U.S. at 121-24), and Tennessee has the sovereign

authority to promulgate standards of care for licensed physicians, to determine what medical procedures are reasonable for purposes of Medicaid coverage, and to decide what medical services should be covered by its employee health insurance policies. Tennessee, through its state-level agencies and political subdivisions, oversees and operates "health program[s] and activit[ies]" that "receiv[e] Federal financial assistance" subject to Section 1557 and the 2024 Rule. 42 U.S.C. § 18116(a). That includes Tennessee's Medicaid and Children's Health Insurance Program ("CHIP") programs, which provide health insurance coverage for nearly 1.5 million Tennesseans with the help of a combined $10.3 billion in federal funding. Tennessee also has medical facilities that provide hormonal treatment for minors for various physical conditions, but not for the purpose of "gender transition" or treating gender dysphoria. Jonathan Skrmetti, the Attorney General and Reporter of Tennessee, is authorized by statute to try and direct "all civil litigated matters … in which the state … may be interested." Tenn. Code Ann. § 8-6-109(b)(1).

23. Plaintiff State of Mississippi is a sovereign State with the authority and responsibility to protect its public fisc, as well as the health, safety, and welfare of its citizens. Mississippi has the sovereign authority to promulgate standards of care for licensed physicians, to determine what medical procedures are reasonable for purposes of Medicaid coverage, and to decide what medical services should be covered by its employee health insurance policies. Mississippi, through its state-level agencies and political subdivisions, oversees and operates "health program[s] and activit[ies]" that "receiv[e] Federal financial assistance" subject to Section 1557 and the 2024 Rule. 42 U.S.C. § 18116(a). That includes Mississippi's Medicaid and CHIP programs, which are expected to provide health insurance coverage for nearly 752,000 Mississippians with the help of an approximate combined $6.3 billion in federal funding in State Fiscal Year 2024. Lynn Fitch, the Attorney General of Mississippi, is authorized to sue on the

State's behalf. Miss. Const. art. VI, § 173; Miss. Code Ann. § 7-5-1; *see Gandy v. Reserve Life Ins. Co.*, 279 So. 2d 648, 649 (Miss. 1973).

24. Plaintiff State of Alabama is a sovereign State with the authority and responsibility to protect its public fisc, as well as the health, safety, and welfare of its citizens. Alabama has the sovereign authority to promulgate standards of care for licensed physicians, to determine what medical procedures are reasonable for purposes of Medicaid coverage, and to decide what medical services should be covered by its employee health insurance policies. Alabama, through its state-level agencies and political subdivisions, oversees and operates "health program[s] and activit[ies]" that "receiv[e] Federal financial assistance" subject to Section 1557 and the 2024 Rule. 42 U.S.C. § 18116(a). That includes Alabama's Medicaid and CHIP programs, which provide health insurance coverage for nearly 1.07 million residents with the help of a combined $6.9 billion in federal funding. Steve Marshall, the Attorney General of Alabama, is authorized by statute to "institute and prosecute, in the name of the state, all civil actions and other proceedings necessary to protect the rights and interests of the state." Ala. Code § 36-15-12.

25. Plaintiff State of Georgia is a sovereign State with the authority and responsibility to protect its public fisc, as well as the health, safety, and welfare of its citizens. Georgia has the sovereign authority to promulgate standards of care for licensed physicians, to determine what medical procedures are reasonable for purposes of Medicaid coverage, and to decide what medical services should be covered by its employee health insurance policies. Georgia, through its state-level agencies and political subdivisions, oversees and operates "health program[s] and activit[ies]" that "receiv[e] Federal financial assistance" subject to Section 1557 and the 2024 Rule. 42 U.S.C. § 18116(a). That includes Georgia's Medicaid and CHIP programs, Georgia Medicaid and Peachcare for Kids, which provide health insurance coverage for approximately 2.3

million (as of April 2024) residents with the help of approximately a combined $12.8 billion in federal funding in SFY 2023. That includes more than $12.2 billion for Georgia's Medicaid program and $543 million for the CHIP program.

26. Plaintiff State of Indiana is a sovereign State with the authority and responsibility to protect its public fisc, as well as the health, safety, and welfare of its citizens. Indiana has the sovereign authority to promulgate standards of care for licensed physicians, to determine what medical procedures are reasonable for purposes of Medicaid coverage, and to decide what medical services should be covered by its employee health insurance policies. Indiana, through its state-level agencies and political subdivisions, oversees and operates "health program[s] and activit[ies]" that "receiv[e] Federal financial assistance" subject to Section 1557 and the 2024 Rule. 42 U.S.C. § 18116(a). Indiana's Medicaid programs provide health insurance coverage for approximately 1,990,822 residents with the help of a combined $13.1 billion in federal funding. Indiana's CHIP program, which falls under the Hoosier Healthwise program, provides health insurance for approximately 137,681 children up to age 19 with the help of a combined amount of nearly $218 million in federal funding.

27. Plaintiff Commonwealth of Kentucky is a sovereign State with the authority and responsibility to protect its public fisc, as well as the health, safety, and welfare of its citizens. Kentucky has the sovereign authority to promulgate standards of care for licensed physicians, to determine what medical procedures are reasonable for purposes of Medicaid coverage, and to decide what medical services should be covered by its employee health insurance policies. Kentucky, through its state-level agencies and political subdivisions, oversees and operates "health program[s] and activit[ies]" that "receiv[e] Federal financial assistance" subject to Section 1557 and the 2024 Rule. 42 U.S.C. § 18116(a). That includes the Kentucky Children's Health Insurance

Program ("KCHIP"), which provides health insurance coverage for nearly 1.8 million residents. Kentucky received approximately $12.3 billion in HHS funding for State Fiscal Year 2022, including more than $12.1 billion for its Medicaid program and $350 million for total CHIP funding.

28. Plaintiff State of Ohio is a sovereign State with the authority and responsibility to protect its public fisc, as well as the health, safety, and welfare of its citizens. Ohio has the sovereign authority to promulgate standards of care for licensed physicians, to determine what medical procedures are reasonable for purposes of Medicaid coverage, and to decide what medical services should be covered by its employee health insurance policies. Ohio, through its state-level agencies and political subdivisions, oversees and operates "health program[s] and activit[ies]" that "receiv[e] Federal financial assistance" subject to Section 1557 and the 2024 Rule. 42 U.S.C. § 18116(a). That includes Ohio's Medicaid and CHIP programs, which provide health insurance coverage for approximately 3.8 million residents. *See* Ohio Dep't of Medicaid, *Who We Served—Annual* (2023), available at https://tinyurl.com/3p2zn5n9. The Ohio Department of Medicaid received approximately $24.5 billion in HHS funding for State Fiscal Year 2022-2023.

29. Plaintiff Commonwealth of Virginia is a sovereign State with the authority and responsibility to protect its public fisc, as well as the health, safety, and welfare of its citizens. Virginia has the sovereign authority to promulgate standards of care for licensed physicians, to determine what medical procedures are reasonable for purposes of Medicaid coverage, and to decide what medical services should be covered by its employee health insurance policies. Virginia, through its state-level agencies and political subdivisions, oversees and operates "health program[s] and activit[ies]" that "receiv[e] Federal financial assistance" subject to Section 1557 and the 2024 Rule. 42 U.S.C. § 18116(a). That includes Virginia's Medicaid and CHIP programs,

run by the Virginia Department of Medical Assistance Services, which provide health insurance coverage for approximately 2 million residents with the help of a combined $17.2 billion in federal funding.

30. Plaintiff State of West Virginia is a sovereign State with the authority and responsibility to protect its public fisc, as well as the health, safety, and welfare of its citizens. West Virginia has the sovereign authority to promulgate standards of care for licensed physicians, to determine what medical procedures are reasonable for purposes of Medicaid coverage, and to decide what medical services should be covered by its employee health insurance policies. West Virginia, through its state-level agencies and political subdivisions, oversees and operates "health program[s] and activit[ies]" that "receiv[e] Federal financial assistance" subject to Section 1557 and the 2024 Rule. 42 U.S.C. § 18116(a). That includes West Virginia's Medicaid and CHIP ("WVCHIP") programs, which provide health insurance coverage for nearly 530,000 residents with the help of roughly $4 billion in federal funding.

31. Plaintiff States of Kansas, Louisiana, Nebraska, Oklahoma, South Carolina, and South Dakota are likewise sovereign States with the authority and responsibility to protect their public fisc, as well as the health, safety, and welfare of their citizens. They also have the sovereign authority to promulgate standards of care for licensed physicians, to determine what medical procedures are reasonable for purposes of Medicaid coverage, and to decide what medical services should be covered by their employee health insurance policies. Through their state-level agencies and political subdivisions, these States oversee and operate "health program[s] and activit[ies]" that "receiv[e] Federal financial assistance" subject to Section 1557 and the 2024 Rule. 42 U.S.C. § 18116(a). Combined, these States receive many billions of dollars in federal funding from HHS, including funds to operate their respective Medicaid and CHIP programs.

II. Defendants

32. Defendant U.S. Department of Health and Human Services is an executive agency of the federal government charged with promulgating regulations under Section 1557 and with enforcing Section 1557 and related agency regulations and rules.

33. Defendant Xavier Becerra is the Secretary of the U.S. Department of Health and Human Services and is responsible for the agency's administration, including the effectuation of Section 1557 via rulemaking. 42 U.S.C. § 18116(c). He is sued in his official capacity only.

34. Defendant Melanie Fontes Rainer is the Director of the Office for Civil Rights within HHS and is responsible for bringing enforcement actions under Section 1557. She is sued in her official capacity only.

35. Defendant Centers for Medicare and Medicaid Services ("CMS") is an agency within HHS that participated in the promulgation of the 2024 Rule and will implement amendments to the CMS regulations.

36. Defendant Chiquita Brooks-LaSure is the Administrator of CMS. She is sued in her official capacity only.

37. Collectively, Defendants are referred to as "HHS."

JURISDICTION AND VENUE

38. This Court has federal-question jurisdiction under 28 U.S.C. § 1331 because the Plaintiff States challenge HHS's actions under the Administrative Procedure Act's provision for judicial review of agency action, 5 U.S.C. § 702, and other federal laws.

39. This Court has jurisdiction under 28 U.S.C. § 1346 because this case involves claims against agencies and employees of the federal government.

40. An actual controversy exists between the parties within the meaning of 28 U.S.C. § 2201(a).

41. This Court has the authority to grant Plaintiff States the relief they request under the APA, 5 U.S.C. §§ 705-06; the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02; the Constitution; and the Court's inherent equitable powers.

42. Venue is proper under 28 U.S.C. § 1391(e)(1) because Defendants are agencies of the United States and officers thereof sued in their official capacities, and Plaintiff State of Mississippi is a resident of every judicial district and division within its sovereign territory, including this judicial district and division. *See, e.g.*, *Texas v. Garland*, 2023 WL 4851893, at *3 (N.D. Tex. July 28, 2023) (noting 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)).

43. The Southern Division of the Southern District of Mississippi is a proper division for this action because a substantial part of the events giving rise to this action occurred in this division, the Mississippi Attorney General maintains a physical office in this division, and no Defendant resides in the State of Mississippi.

44. The 2024 Rule purposely regulates medical providers and health insurance plans across the country, including those located in the Plaintiff States. Therefore, this Court has personal jurisdiction over the HHS Secretary, OCR Director, and CMS Administrator for purposes of this action because their immunity has been abrogated by 5 U.S.C. § 702, and they have "submit[ted]" to such jurisdiction "through contact with and" regulatory "activity directed at" Plaintiff States and their respective medical providers and health plans. *J. McIntyre Mach., Ltd. v. Nicastro*, 564 U.S. 873, 881 (2011).

FACTUAL BACKGROUND

I. The Affordable Care Act's Prohibition on Sex Discrimination.

45. In 2010, Congress approved, and President Obama signed into law, the Patient Protection and Affordable Care Act ("ACA"). Pub. L. 111-148 (March 23, 2010). As relevant here, the ACA prohibits those receiving federal health funding from engaging in discrimination on the basis of several specified characteristics, including sex.

A. The ACA's Incorporation of Title IX.

46. Section 1557 of the ACA provides that an "individual shall not, on the ground[s] prohibited under" four existing federal civil rights laws—Title VI of the Civil Rights Act of 1964 (42 U.S.C. § 2000d, *et seq*.) (race, color, national origin); Title IX of the Education Amendments of 1972 (20 U.S.C. § 1681, *et seq*.) (sex); the Age Discrimination Act of 1975 (42 U.S.C. § 6101, *et seq*.) (age); and Section 504 of the Rehabilitation Act (29 U.S.C. § 794) (disability)—"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 …, 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).

47. Section 1557 does not create any new bases of prohibited discrimination. By referencing Title IX and three other well-established federal nondiscrimination provisions, "Congress incorporated the legal standards that define discrimination under each one." *Doe v. BlueCross BlueShield of Tennessee, Inc.*, 926 F.3d 235, 239 (6th Cir. 2019).

48. Section 1557 does not reference sexual orientation or gender identity.

49. Section 1557's sole basis for prohibiting sex discrimination is its cross-reference to "the ground prohibited under … title IX (20 U.S.C. § 1681 et seq.)." 42 U.S.C. § 18116(a).

50. Title IX states 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).

51. "Reputable dictionary definitions of 'sex' from the time of Title IX's enactment [in 1972] show that when Congress prohibited discrimination on the basis of 'sex' … it meant biological sex, i.e., discrimination between males and females." *Adams*, 57 F.4th at 812 (collecting definitions).

52. Title IX's text and structure confirm its biological-binary understanding of sex. Title IX expressly states that it does not prohibit covered entities from "maintaining separate living facilities for the different sexes," i.e., for males and females. 20 U.S.C. § 1686. And many of Title IX's exclusions specifically preserve male-only or female-only spaces. *See, e.g.*, *id.* § 1681(a)(6) (college fraternity and sorority membership practices and sex-segregated voluntary service organizations like the Girl Scouts, Boy Scouts, and Camp Fire Girls); § 1681(a)(7) (boy or girl conferences); § 1681(a)(9) (scholarships for single-sex beauty pageants). Senator Bayh explained at the time of Title IX's enactment that "differential treatment by sex" was permissible in certain instances, such as "where personal privacy must be preserved." 118 Cong. Rec. 5807 (1972) (Statement of Sen. Bayh).

53. Indeed, Title IX consistently treats sex as a binary, using phrases such as "one sex," "the other sex," and "both sexes." *See* 20 U.S.C. § 1681(a)(2) (delaying Title IX's application to an institution in the process of "changing from being an institution which admits only students of *one sex* to being an institution which admits students of *both sexes*") (emphasis added); *id.* § 1681(a)(5) (excepting a public undergraduate institution with a historic "policy of admitting only

students of *one sex*") (emphasis added); *id.* § 1681(a)(6) (excepting certain organizations whose membership "has traditionally been limited to persons of *one sex*") (emphasis added); *id.* § 1681(a)(8) (excepting from Title IX's coverage "father-son or mother-daughter activities" so long as similar opportunities provided for "*one sex*" are provided for "*the other sex*") (emphasis added); *id.* § 1681(a)(9) (excepting scholarships associated with participation in a beauty pageant "limited to individuals of *one sex* only"); *id.* § 1681(b) (clarifying that Title IX does not require "preferential or disparate treatment to the members of *one sex*") (emphasis added).

54. This treatment of "sex" as a male-female binary reflects Title IX's linguistic context. "The phrase 'gender identity' did not exist" in 1972 "outside of some esoteric psychological publications." Ryan T. Anderson, Ph.D, & Melody Wood, *Gender Identity Policies in Schools: What Congress, the Courts, and the Trump Administration Should Do*, at 9, The Heritage Found. (2017). And the word "gender" had itself "been coined only recently in contradistinction to sex." *Id.* Indeed, "psychiatric literature" at the time "conflated sexual orientation with gender identity." *Adams ex rel. Kasper v. Sch. Bd. of St. Johns Cnty.*, 3 F.4th 1299, 1336 (11th Cir. 2021) (Pryor, C.J., dissenting) (citing Jack Drescher, *Transsexualism, Gender Identity Disorder and the DSM*, 14 J. Gay & Lesbian Mental Health 109, 111 (2010)), *rev'd on reh'g on banc*, 57 F.4th 791. "Even the early users of the term 'gender identity' recognized the distinction between 'sex' and 'gender identity.'" *Franciscan Alliance I*, 227 F. Supp. 3d at 688 (noting that the psychoanalyst who coined term "gender identity" believed "sex was biological but gender was social").

55. The original post-enactment regulations implementing Title IX, *see* C.F.R. pt. 86 (1975) (now codified at 34 C.F.R. pt. 106), likewise treat sex as binary, referring multiple times to "one sex," especially versus "the other sex"; using the phrase "both sexes"; referencing "boys and

girls" and "male and female teams"; and preserving certain sex-segregated spaces. *See, e.g.*, 34 C.F.R. §§ 106.33, 106.34(a)(3), 106.36(c), 106.37(a)(3), 106.41, 106.51(a)(4), 106.58(a), 106.60(b), 106.61.

56. In the decades after Title IX's enactment, the Department of Education consistently interpreted "sex" as a biological-binary classification—male and female—consistent with the statutory text, structure, and purpose and with the statute's implementing regulations.

57. Thus, it is unsurprising that when the ACA was enacted in 2010, "no federal court or agency had interpreted Title IX sex discrimination to include gender identity." *Franciscan Alliance I*, 227 F. Supp. 3d at 688.

58. Section 1557 specifically excludes from the scope of its nondiscrimination rule "transsexualism" and any "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 that "transsexualism" and "gender identity disorders not resulting from physical impairments" are not a "disability" under section 794).

B. The ACA's Application to States and Other HHS Funding Recipients.

59. Section 1557 applies to what HHS calls "covered entities," including 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 certain pharmacies and health insurance issuers.

60. An entity "any part of which" participates in HHS financial assistance programs is subject in all respects of its health programs and activities to Section 1557. 42 U.S.C. § 18116(a). That means that any hospital or doctor's 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.

61. 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).

62. If HHS finds a covered entity in noncompliance with Section 1557, the agency may require the entity to take remedial action or lose its federal funding.

63. Section 1557 also allows members of the public to sue covered entities to require compliance and seek damages through a private right of action. *See Cummings v. Premier Rehab Keller, PLLC*, 596 U.S. 212, 218 (2022).

C. The ACA's Reservation of States' and Providers' Authority.

64. The ACA maintains the States' power to regulate the medical field, as well as providers' power to practice medicine consistent with their ethical and evidence-based obligations to patients.

65. To begin, the ACA sets out a specific "[r]ule of construction regarding health care providers." 42 U.S.C. § 18122. That rule specifies that "the development, recognition, or implementation of any guideline or other standard under any Federal health care provision"—including any provision of the ACA—"shall not be construed to establish the standard of care or duty of care owed by a health care provider to a patient in any medical malpractice or medical product liability action or claim." *Id.* § 18122(1), (2)(A). Nor, the provision goes on, shall any implementation of the ACA "be construed to preempt any State or common law governing medical professional … actions or claims." *Id.* § 18122(3).

66. The ACA sets further limits on HHS's ability to promulgate regulations interfering with healthcare entities' and professionals' provision of medical care. Relevant here, a statutory section entitled "[a]ccess to therapies" states that "[n]otwithstanding any other provision" of the ACA, the agency "shall not promulgate any regulation" that, *inter alia*: "impede[s] timely access

to health care services"; "interferes with communications regarding a full range of treatment options between the patient and the provider"; "restricts the ability of health care professionals to provide full disclosure of all relevant information to patients making health care decisions"; or "violates the principles of informed consent and the ethical standards of health care professionals." 42 U.S.C. § 18114(2)-(5).

II. Background of Gender-Transition Medical Interventions

A. Sex, Gender Identity, and Gender Dysphoria.

67. Over the past several years, debates over the clash between sex and gender identity have divided policymakers, medical professionals, and the public.

68. As the Supreme Court has observed, and as Tennessee, Mississippi, and other Plaintiff States' laws set out, sex "is an immutable characteristic." *Frontiero v. Richardson*, 411 U.S. 677, 686 (1973) (plurality opinion). It refers to "male or female according to their reproductive organs and functions assigned by the chromosomal complement." Comment of Ethics & Public Policy Center, at 12, HHS-OS-2022-0012-74097 ("EPPC Comment") (citing Institute of Medicine, *Exploring the Biological Contributions to Human Health: Does Sex Matter?* 1 (2001), https://doi.org/10.17226/10028)); *see, e.g.*, Tenn. Code Ann. § 1-3-105(c) (defining "sex" as "a person's immutable biological sex as determined by anatomy and genetics existing at the time of birth and evidence of a person's biological sex"); Miss. Code Ann. § 41-141-3(a) (defining "sex" as "the biological indication of male and female in the context of reproductive potential or capacity" as determined "at birth, without regard to an individual's psychological, chosen, or subjective experience of gender"); Ala. Code § 26-26-3 (defining "sex" as "[t]he biological state of being male or female, based on the individual's sex organs, chromosomes, and endogenous hormone profiles"); Kan. Stat. Ann. § 77-207(a) (defining "sex" as an "individual's

biological sex, either male or female, at birth," and further defining "male" and "female" based on their differing biological reproductive systems).

69. The "enduring" physical differences between men and women result in different health risks and conditions that necessitate distinct treatments based on biological reality. *United States v. Virginia*, 518 U.S. 515, 533 (1996). Indeed, in the medical field, sex is critical. Women have ovaries, and thus face risks of ovarian cancer, while men do not, so do not; the opposite goes for testicular cancer. *See, e.g.*, Nat'l Cancer Institute, *Reproductive System*, https://perma.cc/A9LT-PZEX. The same reality applies to many other sex-related or sex-correlated risks and conditions in areas ranging across mental health, autoimmune diseases, pain processing, and musculoskeletal health. *See generally* Nat'l Inst. of Health, *Sex and Gender Influences in Health and Disease*, https://perma.cc/92ND-DV5R. Biology also affects how patients' symptoms present and their proper drug dosage, among many other things. *See id.*; I. Zucker & B. Prendergast, *Sex Differences in Pharmacokinetics Predict Adverse Drug Reactions in Women*, Biology of Sex Differences (2020), https://perma.cc/6XH6-ADX8. These biological differences, by definition, mean there are "medical procedures unique to one sex or the other." *L.W.*, 83 F.4th 460 at 484.

70. In contrast, the term "gender identity" refers to "an individual's internal sense of gender, which may be male, female, neither, or a combination of male and female." 81 Fed. Reg. 31,467. Unlike sex, gender identity is not ascertainable from observing human anatomy or chromosomes. Nor is it an immutable or stable characteristic. According to the World Professional Association for Transgender Health ("WPATH"), a prominent advocacy group that promotes so-called "gender-affirming care," a person's gender identity instead can "change … over time" and encompass "a huge variety of gender identities and expressions." WPATH,

Standards of Care for the Health of Transgender and Gender Diverse People, Version 8, 28 Int'l J. of Transgender Health S15, S41 (2022) ("WPATH 8").

71. The term "transgender" describes people who "identify as a gender" different from their sex. 87 Fed. Reg. 47,831 n.75.

72. Sometimes, persons report experiencing a "persistent sense of discomfort" caused by an incongruence between their sex and gender identity. *L.W.*, 83 F.4th at 467 (citing Am. Psych. Ass'n, *Diagnostic and Statistcal Manual*, 261 (3d ed. 1980) ("DSM-3")). Initially, the American Psychiatric Association referred to this condition as "gender identity disorder." *Id.*

73. In 2013, the American Psychological Association replaced 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) ("DSM-5").

74. Not all transgender individuals experience "dysphoria." *Id*. at 451.

75. Historically, reported rates of gender dysphoria have been very low. In 2013, the DSM-5 estimated the incidence of gender dysphoria in adults to be between 0.0002% and 0.014%. *Id*. at 454. However, these numbers have increased dramatically in recent years, particularly in adolescent populations. Recent surveys estimate that between 2-9% of high school students identify as transgender or "gender non-conforming." Expert Report of Stephen B. Levine, M.D., 35 (Feb. 23, 2022), *in* Attachments to Comments of Alliance Defending Freedom, *Factual Evidence*, HHS-OS-2022-0012-68192. Consistent with these surveys, gender clinics around the world have seen the number of referrals for gender dysphoria increase rapidly over the last decade. *Id*. at 35-36.

76. Like gender identity, gender dysphoria is not permanent. In children, gender dysphoria typically resolves over the course of puberty, so long as the child is not subjected to social transitioning. Levine, *supra*, at 40-42. And desistence has increasingly been observed among those who first manifest gender dysphoria during or after puberty. *Id*. at 42-45. "Watchful waiting" has thus long served as the "standard approach" for addressing gender dysphoria in minors. Levine, *supra*, at 17-19.

77. Many of the youth who present with gender dysphoria also present with mental health comorbidities. Levine, *supra*, at 13-14, 49.

B. Emergence of New "Gender-Transition" Protocols.

78. Physicians did not begin offering to minors "what the medical profession has come to call gender-affirming care" until the late 1990s. *L.W.*, 83 F.4th at 467.

79. Influential medical interest groups have since advocated for treating gender dysphoria in both adults and children by "affirming" their incongruence with sex through a protocol of social, chemical, and surgical transition designed to align their physical appearance and behavior with their internal sense of gender. *Id*. These groups assert that gender-transition interventions, referred to as "gender-affirming care," are medically necessary for many individuals—including minors going through puberty—even though these "treatments" can lead to infertility and other harmful side effects.

80. WPATH now publishes what it describes as "standards of care" for treating people with gender dysphoria in both children and adults. *See* WPATH 8, *supra*; *see also* WPATH, *Standards of Care for the Health of Transsexual, Transgender, and Gender-Nonconforming People*, Version 7 (2012), HHS-OS-2022-0012-4074 ("WPATH 7").

81. HHS has previously described WPATH as an "advocacy group." 85 Fed. Reg. at 37,198. So has WPATH itself. *See Boe v. Marshall*, No. 2:22-cv-184-LCB, Doc. 208, at 3 (M.D. Ala. Dec. 27, 2022). That label makes sense. Members of WPATH are required to show a commitment to "trans rights" and need not be medical professionals. Levine, *supra*, at 26-27. Contrary viewpoints "have been known to be shouted down and effectively silenced by the large number of nonprofessional adults who attend the organization's biennial meetings." *Id*. at 26. And WPATH has ardently opposed efforts to discover the bases for its "standards." *See Boe v. Marshall*, No. 2:22-cv-184-LCB, Doc. 263, at 1-3 (M.D. Ala. Mar. 27, 2023).

82. Another leading advocate for so-called "gender-affirming care" is the Endocrine Society, which has published recommendations for treating gender dysphoria in minors and adults. Those recommendations advocate for the use of both hormonal and surgical interventions as medically necessary "treatments"—all while the Society's members stand to financially benefit from the use of such treatments for gender dysphoria. Hembree, et al., *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"). Yet the Endocrine Society "makes no warranty, express or implied, regarding [its] guidelines," "nor do they establish a standard of care." *Id*. at 3895.

83. The gender-transition protocol embraced by these medical interest groups proceeds in four escalating steps: (1) social transition with mental health treatment; (2) puberty blockers (for those who have not completed puberty); (3) cross-sex hormones—*i.e.*, hormones associated with the physiological development of the opposite sex; and (4) gender-transition surgery. Jason Rafferty, et al., *Ensuring Comprehensive Care and Support for Transgender and Gender-Diverse*

Children and Adolescents 6-7, 142 Pediatrics 4 (2018); *see* WPATH 7, *supra*, at 57; WPATH 8, *supra*, at S258, App'x E (non-exhaustive list of gender-transition surgeries).

84. Many of these medical interventions carry with them irreversible, lifelong consequences, including sterilization, loss of sexual function, decreased bone density, increased risks of cardiovascular disease and cancer, negative psychological consequences, and a lifelong dependence on hormone drugs. *See infra*, ¶¶ 87-104.

85. The medical guidelines advocated by WPATH and 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).

86. WPATH's latest set of "standards" removes *all* minimum-age requirements for cross-sex hormones and all gender-transition surgeries except for phalloplasty. WPATH 8, *supra*, at S43-79. These standards moreover devote an entire chapter to self-identified "eunuchs"—individuals "assigned male at birth" who "wish to eliminate masculine physical features, masculine genitals, or genital functioning"—and the recommendation of "castration to better align their bodies with their gender identity." *Id*. at S88-89. WPATH's recommendation for the castration of "eunuchs" was based on information it learned from a "large online peer-support community" with thousands of stories that "focus on the eroticization of child castration" and "involve the sadistic sexual abuse of children." *Id*. at S88; Genevieve Gluck, *Top Trans Medical Association*

Collaborated With Castration, Child Abuse Fetishists, REDUXX (May 17, 2022), https://perma.cc/5DWF-MLRU.

C. Risks of Gender-Transition Interventions.

87. "[N]o one disputes" that the above-mentioned interventions for gender dysphoria "carry risks or that the evidence supporting their use is far from conclusive." *L.W.*, 83 F.4th at 489.

88. The FDA may approve the marketing of drugs as safe and effective to treat a certain condition based on "adequate and well-controlled investigations"—typically a double-blind, randomized, clinical trial. 21 U.S.C. § 355(d). But 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.

89. Although the FDA has approved puberty blockers to rectify a hormonal imbalance in young children caused by precocious puberty, it has *not* approved their use as treatment for gender dysphoria in either children or adults. *L.W.*, 83 F.4th at 488. So, too, for cross-sex hormones. *Id*. Thus, the use of puberty blockers and cross-sex hormones for the purpose of treating gender dysphoria is considered "off label."

90. The known risks of hormonal gender transition are significant and well known. Risks associated with puberty-blocking drugs include "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. Recently, the FDA 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).

91. While some proponents say puberty blockers act merely as a "pause button," research shows that is not the case. Nearly *all* minors who start puberty blockers progress to sterilizing cross-sex hormones, and the majority of those individuals go on to have gender-transition surgery. Levine, *supra*, at 48-49 (UK study found 98% of adolescents who used puberty blockers progressed to cross-sex hormones); de Vries et al., *Puberty suppression in adolescents with gender identity disorder: a prospective follow-up study*, 8 J. Sex Med. 8 (2011) (Dutch study found 100% of adolescents who took puberty blockers progressed to cross-sex hormones); de Vries et al., *Young Adult Psychological Outcome After Puberty Suppression and Gender Reassignment*, 134 Pediatrics 4 (2014) (follow-up study found most adolescents who received cross-sex hormones went on to have sex-reassignment surgery).

92. Conversely, without hormonal intervention, most children exhibiting gender dysphoria come to align their gender identity with their sex by the time they reach adulthood. Desistence is increasingly observed among teens and young adults who first manifest gender dysphoria during or after adolescence. Levine, *supra*, at 40-45; Paul Hruz, *Deficiencies in Scientific Evidence for Medical Management of Gender Dysphoria* 36, 87 The Lineacre Quarterly 1 (Feb. 2020), *in* Attachments to Comments of Alliance Defending Freedom, *Factual Evidence*, HHS-OS-2022-0012-68192 (noting most recent studies reported desistence in nearly 85% of children before the adoption of the "affirming" model).

93. 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).

94. Giving adolescent girls the high doses of testosterone needed for gender transition induces hyperandrogenism. According to WPATH 8, this causes "clitoral enlargement" (clitoromegaly), "vaginal atrophy" (atrophy of the lining of the vagina and uterus), "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). The Endocrine Society Guideline further advises that induced hyperandrogenism presents a "[v]ery high risk of" erythrocytosis, along with an increased risk of severe liver dysfunction, coronary artery disease, cerebrovascular disease, hypertension, and breast or uterine cancer. Endocrine Society Guideline, *supra*, at 3886-87.

95. Giving 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. WPATH 8, *supra*, at S254, App'x C, Tbl. 1. The Endocrine Society Guideline adds that this condition can also lead to a "[v]ery high risk of" thromboembolic disease and increased risk of macroprolactinoma, breast cancer, coronary artery disease, cerebrovascular disease, cholelithiasis, and hypertriglyceridemia. Endocrine Society Guideline, *supra*, at 3886.

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. The surgical removal of a person's reproductive organs, referred to as "bottom surgery," causes irreversible sterility. As WPATH acknowledges, these types of 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 groups assert that the significant physical side effects and increased health risks of medicalized gender-transition—including risks to fertility—are outweighed by the purported psychological benefits, including suicide prevention.

99. But no reliable studies demonstrate that medical gender transition lowers suicide rates, nor is there reliable evidence that medical transition improves long-term mental health relative to other treatments lacking medical risk. *See* Levine, *supra*, at 49-61; Hruz, *supra*, at 38 (citing 30-year study in Sweden that showed patients who had undergone medical gender transition had a completed suicide rate that was nineteen times higher than that of the general population). Some experts believe that this protocol may actually decrease mental wellbeing and increase suicide by, among other things, preventing desistance. *E.g.*, Levine, *supra*, at 70-71.

100. As the First and Fifth Circuits have concluded, "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); *see Kosilek v. Spencer*, 774 F.3d 63, 68-96 (1st Cir. 2014) (en banc). Recently leaked internal files from WPATH have only further demonstrated that the organization "is neither scientific nor advocating for ethical medical care." Environmental Progress, *The WPATH Files, Pseudoscientific Surgical and Hormonal Experiments on Children, Adolescents, and Vulnerable Adults* 3 (Mar. 4, 2024), https://perma.cc/4ZCW-FF23. WPATH-affiliated doctors have violated their "ethical requirement to obtain informed consent," with "members admitting that children and adolescents cannot comprehend the lifelong consequences"

of so-called "gender-affirming care." *Id*. Internal WPATH communications even revealed discussions about surgeons performing "non-binary" surgeries aimed at "creating bespoke anatomical features that do not exist in nature." *Id*. at 37, 51, 64.

101. In sum, the evidence supporting gender-transition interventions is weak, at best. HHS concluded as much in 2016 and again in 2020, when it remarked on the lack of "high quality evidence" to support the efficacy of gender-transition surgeries and other treatments. Tamara S. Jensen, et al., Decision Memo, CAG #00446N, Centers for Medicare & Medicaid Servs. (Aug. 30, 2016), https://perma.cc/R2ME-YQRA; 85 Fed. Reg. at 37,187; *see also* Endocrine Society Guideline, *supra* (acknowledging that most of its recommendations regarding gender-transition interventions are based on "low quality" or "very low quality" evidence); Levine, *supra*, at 22-33, 50-55.

102. The evidence of harm from gender-transition interventions, however, is apparent. *See* Levine, *supra*, at 56-71; The Cass Review, *Independent Review of Gender Identity Services for Children and Young People: Interim Report* 47 (Feb. 2022), HHS-OS-2022-0012-4075 (finding no consensus). Amplifying these concerns are the fact that adolescents often "lack the capacity to consent to such a significant and potentially irreversible treatment." *L.W.*, 83 F.4th at 488. With increasing frequency, detransitioners have come forward lamenting the harmful effects of these medical interventions and their regret for undergoing them. *Id*. at 487; Levine, *supra*, at 42-45.

103. Citing these concerning dynamics, "some of the same European countries that pioneered these treatments now express caution about them and have pulled back on their use." *L.W.*, 83 F.4th at 477. 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; *see* Levine, *supra*, at 31. To illustrate:

- ***Sweden:*** 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)*, Society for Evidence-Based Gender Medicine (Feb. 27, 2022), HHS-OS-2022-0012-10295, https://perma.cc/NWB6-3XEU.
- ***Finland:*** Finland's Council for Choices in Health Care has concluded that gender-transition 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:*** The United Kingdom has similarly restricted puberty blockers after finding the evidence inadequate to conclude that they are safe and effective to treat gender dysphoria. *B.P.J. by Jackson v. W. Va. State Bd. of Educ.*, 98 F.4th 542, 570 n.7 (4th Cir. 2024) (Agee, J., concurring in part and dissenting in part).

104. In July 2023, a group of respected clinicians from Finland, the UK, Sweden, Norway, Belgium, France, Switzerland, South Africa, and the United States published a letter in the *Wall Street Journal* reiterating that every systematic review to date "has found the evidence for mental-health benefits of hormonal interventions for minors to be of low or very low quality" and that there is "no reliable evidence to suggest that hormonal transition is an effective suicide-prevention measure." Kaltiala, et al., *Youth Gender Transition Is Pushed Without*

Evidence, Wall St. J. (July 14, 2023), https://perma.cc/P9GM-MHF7. Noting that "the risks are significant" and highlighting the growing international consensus that psychotherapy should be the "first line of treatment for gender-dysphoric youth," they urged American medical societies "to align their recommendations with the best available evidence—rather than exaggerating the benefits and minimizing the risks." *Id*.

D. States' Regulation of Gender-Transition Interventions.

105. Tracking the developing international consensus, more than twenty States have restricted access to gender-transition treatments for children. *L.W.*, 83 F.4th at 471 (collecting state statutes restricting the provision of gender-transition procedures for minors). Many States also have adopted limitations on the coverage of gender-transition interventions by their Medicaid and CHIP programs, as well as their state health plans.

1. Tennessee

106. In September 2022, the Tennessee public learned that Vanderbilt University Medical Center was engaged in a widespread and profit-motivated practice of prescribing hormones and conducting surgeries on children for the purpose of treating gender dysphoria. *See* Kruesi, *Social media posts spark calls to investigate Tenn.'s VUMC*, AP News (Sept. 21, 2022), https://perma.cc/K3DN-AV4Z. Vanderbilt was performing "top surgery" (i.e., double mastectomy) on gender dysphoric minors as young as 16. The founder of Vanderbilt's Transgender Health Clinic boasted that such surgeries would "make a lot of money" for Vanderbilt, as would "routine hormone treatment." Amanda Prestigiacomo, *'Huge Money Maker': Video Reveals Vanderbilt's Shocking Gender 'Care,' Threats Against Dissenting Doctors*, The Daily Wire (Sept. 20, 2022), https://perma.cc/M8YH-DLM3. Vanderbilt was giving hormone drugs to "children as young as 13." *Id*.

107. In response, and in an effort to "protect the health and welfare of minors" from unproven and risky gender-transition medical interventions, Tennessee legislators passed and Governor Lee signed SB1. *See* S.B.1, 113th Gen. Assem. (2023), codified at Tenn. Code Ann. § 68-33-101, *et seq*.

108. This law prohibits certain medical procedures on a minor "for the purpose of" either (1) "[e]nabling [the] minor to identify with, or live as, a purported identity inconsistent with the minor's sex" or (2) "[t]reating purported discomfort or distress from a discordance between the minor's sex and asserted identity." Tenn. Code Ann. § 68-33-103(a)(1). Prohibited procedures include surgery and the use of puberty blockers and cross-sex hormones. *Id*. § 68-33-102(5).

109. In adopting these restrictions, the General Assembly noted that the prohibited procedures can lead to "life-altering consequences" for minors, including "becoming irreversibly sterile, having increased risk of disease and illness, or suffering from adverse and sometimes fatal psychological consequences." *Id*. § 68-33-101(b). It also determined that the harms of these treatments "are not yet fully known" and, in any case, outweigh any potential near-term benefits because they "are experimental in nature and not supported by high-quality, long-term medical studies." *Id*. And it found that "minors lack the maturity to fully understand and appreciate the life-altering consequences of such procedures." *Id.* § 68-33-101(h).

110. Tennessee also limits access to gender-transition interventions through the State's Medicaid program, which is the "primary federal program" though which States "provide medical care to indigents at public expense." *Mem'l Hosp. v. Maricopa Cnty*., 415 U.S. 250, 262 n.19 (1974); *see* 42 U.S.C. §§ 1396-1, 1396a. State Medicaid programs are administered jointly by the States and the federal government through a "contract[ual]" relationship. *NFIB v. Sebelius*, 567 U.S. 519, 577 (2012).

111. Tennessee's Medicaid program is administered by the Division of TennCare. Like all other insurance plans, TennCare expressly excludes coverage for dozens of categories of medical services, products, and supplies—even when considered medically necessary. Tenn. Comp. R. & Regs. 1200-13-13-.10(3). Among other things, TennCare does not cover treatments for infertility, sexual dysfunction, certain organ and tissue transplants, dental services, and certain pharmaceuticals. *Id.*

112. TennCare also does not cover "sex change or transformation surgery." *Id.* 1200-13-13-.10(3)(b)(72), -(86). And subject to exceptions for procedures that address defects caused by injury, physical disease, or a congenital condition, TennCare also excludes coverage for "cosmetic surgery or surgical procedures [performed] primarily for the purpose of changing the appearance of any part of the body to improve appearance or self-esteem." *Id.* 1200-13-13-.10(b)(22).

113. Tennessee's CHIP program, referred to as "CoverKids," maintains the same exclusions as TennCare. *See id.* 1200-13-21-.06(1).

114. Tennessee also provides healthcare benefits to thousands of State employees through its state health plan ("State Plan"). The statutorily created State Insurance Committee determines the Plan's premiums, benefits package, funding method, and eligibility provisions. Tenn. Code Ann. § 8-27-202. The State Plan is funded, in part, through contributions made by state-agency employers on behalf of their employees using federal funding received from HHS. For example, the Division of TennCare annually contributes approximately $11.6 million to the State Plan on behalf of its employees, including approximately $7.3 million in HHS funds.

115. The State Plan excludes over 50 categories of medical and mental health/substance abuse services from coverage, as well as coverage for dental expenses, on-the-job injuries, and

non-behavioral mental health/substance abuse expenses. *See* State Plan Document § 12.04 (2024), https://perma.cc/F3BB-2RHR.

116. The State Plan has long excluded coverage for "[s]urgery or treatment for, or related to, sex transformations … other than psychological treatment or counseling." *Id.* at § 12.04(A)(28). It also generally excludes "[c]harges incurred in connection with cosmetic surgery directed toward preserving or improving a patient's appearance." *Id.* at § 12.04(A)(16).

2. Mississippi

117. In 2023, Mississippi legislators passed, and Governor Reeves signed, the Regulate Experimental Adolescent Procedures Act. *See* H.B.1125, 2023 Reg. Sess., codified, in part, at Miss. Code Ann. § 41-141-1, *et seq*.

118. The law prohibits certain medical procedures on a minor "for the purpose of assisting [that] individual with a gender transition," defined as "the process in which a person goes from identifying with and living as a gender that corresponds to his or her sex to identifying with and living as a gender different from his or her sex" in certain circumstances. Miss. Code Ann. § 41-141-3(d)-(f); *id.* § 41-141-5. Prohibited procedures include certain surgeries and the use of puberty blockers and cross-sex hormones. *Id.* § 41-141-3(d), (f)(1); *id.* § 41-141-5.

119. Mississippi also limits access to gender-transition interventions through the State's Medicaid and CHIP programs.

120. Mississippi's Medicaid and CHIP programs are administered through the State's Division of Medicaid within the Office of the Governor. Like all other insurance plans, these programs expressly exclude certain coverage for dozens of categories of medical services, products, and supplies—even when those services are considered medically necessary. *See* 23 Miss. Admin. Code Pt. 200, R 5.1(C).

121. Mississippi's Medicaid and CHIP programs do not cover any "operative procedure, or any portion of a procedure, performed primarily to improve physical appearance and/or treat a mental condition through change in bodily form." *Id*. at Pt. 200, R. 2.2(A)(7). Mississippi's Medicaid and CHIP programs also exclude coverage if the service is "experimental, investigational, or cosmetic in nature." *Id.* at Pt. 200. R. 5.1(B)(7).

122. In addition, the Division of Medicaid is prohibited by statute from "reimburs[ing] or provid[ing] coverage" for certain "gender transition procedures" for minors. Miss. Code Ann. § 43-13-117.7; *see id.* §§ 41-141-3 (definitions), 41-141-7 (prohibition on use of "[p]ublic funds" and other resources for provision of certain "gender transition procedures" for minors).

123. Mississippi also provides healthcare benefits to thousands of State employees through its state health plan ("Mississippi State Plan"). The State School and Employees Health Insurance Management Board determines the Plan's premiums, benefits package, funding, and eligibility provisions. *Id*. §§ 25-15-5, 25-15-303.

124. The Mississippi State Plan limits or excludes coverage for dozens of categories of medical, dental, and other services and expenses. *See* Mississippi's State and School Employees' Life and Health Insurance Plan, Plan Document, at 33-38 (Rev. Jan. 2024), https://bit.ly/3X0oPQz.

125. The Mississippi State Plan excludes coverage for "[s]ex transformations" and "[p]uberty-blocking drugs." *Id*. at 36. It also generally excludes coverage for "cosmetic services," subject to narrow exceptions. *Id*. at 33; *see also* Miss. Code Ann. § 83-9-36.1 (excluding coverage for certain "gender transition procedures" for minors from coverage in Mississippi health-benefit plans).

3. Other Plaintiff States

126. Alabama law prohibits providers from performing certain gender-dysphoria-related medical procedures on minors. *See* Alabama Vulnerable Child Compassion and Protection Act, Act 2022-289, *codified at* Ala. Code § 26-26-4; *Eknes-Tucker v. Gov. of Ala.*, 80 F.4th 1205 (11th Cir. 2023) (reversing preliminary injunction of law). Prohibited procedures include castration, vasectomy, hysterectomy, oophorectomy, orchiectomy, and penectomy, as well surgeries that artificially construct tissue with the appearance of genitalia that differs from the individual's sex, the removal of any healthy or non-diseased body part or tissue, except for a male circumcision, and the use of puberty blockers and cross-sex hormones. Ala. Code § 26-26-4. Moreover, Alabama Medicaid does not provide coverage for (i) sex-change surgeries or (ii) cross-sex hormones prescribed as transitioning treatments.

127. Georgia law prohibits providers from performing certain gender-transition medical interventions on minors, including "(1) sex reassignment surgeries, or any other surgical procedures, that are performed for the purpose of altering primary or secondary sexual characteristics; and (2) hormone replacement therapies." Ga. Code Ann. § 43-34-15.

128. Indiana law prohibits providers from knowingly performing certain "gender transition procedures" for minors. *See* Ind. Code § 25-1-22-13(a). Prohibited procedures include:

a. Genital Gender Reassignment Surgery, which includes but is not limited to: (1) penectomy, orchiectomy, vaginoplasty, clitoroplasty, or vulvoplasty for male sex patients, (2) hysterectomy, ovariectomy, phalloplasty, vaginectomy, scrotoplasty, or implantation of erection or testicular prostheses for female patients, and (3) urethral reconstruction with or without a metoidioplasty, and for a female patient. *Id.* § 25-1-22-6.

b. Non-Genital Gender Reassignment Surgery, which includes but is not limited to: (1) Mammoplasty, facial feminization surgery, liposuction, lipofilling, voice surgery, thyroid cartilage reduction, gluteal

augmentation, hair reconstruction for male patients, and (2) subcutaneous mastectomy, voice surgery, liposuction, lipofilling, or pectoral implants. *Id*. § 25-1-22-8.

c. Hormone Therapy, which includes any use of testosterone, estrogen, or progesterone given to an individual greater than would be produced endogenously by a healthy individual of that individual's age and sex. *Id*. § 25-1-22-4.

d. Puberty Blocking Drugs, which includes but is not limited to: gonadotropin releasing hormone analogues and synthetic antiandrogen drugs used to block the androgen receptors. *Id*. § 25-1-22-11.

129. Kansas' Medicaid and CHIPS programs are administered by the Kansas Department of Health and Environment ("KDHE") and the Kansas Department of Aging and Disability Services ("KDADS"). Kansas contracts with three managed-care providers ("MCOs") to provide healthcare plans to qualifying individuals: United, Sunflower, and Aetna. These MCOs provide medically necessary care to enrolled individuals, as described and covered by their respective healthcare plans. None of the MCOs that administer healthcare benefits under KanCare covers gender-transition surgeries. *See* United Healthcare Handbook (2024), https://perma.cc/X36H-U64B; Sunflower Health Plan Handbook (2024), https://perma.cc/8CX5-VF39; Aetna Better Health Handbook (2024), https://perma.cc/C6V9-2ME7. Additionally, Kansas state agencies, including KDHE and KDADS, which operate KanCare, must identify individuals by biological sex whenever they collect data on individuals "for the purpose of complying with anti-discrimination laws or for the purpose of gathering accurate public health, crime, economic or other data." Kan. Stat. Ann. § 77-207(c).

130. Kentucky law prohibits health care providers from performing certain gender-dysphoria-related medical procedures on minors. *See* Ky. Rev. Stat. § 311.372. Prohibited procedures include any surgery that would sterilize or artificially construct tissue having the

appearance of genitalia differing from the minor's sex, and the prescription or administration of drugs to delay or prevent normal puberty or to produce hormones in amounts greater than would be produced normally in a healthy minor of the same age and sex. *Id.* § 311.372(2).

131. Louisiana law prohibits providers from performing or administering certain medical interventions "that attempt to alter a minor's appearance in an attempt to validate a minor's perception of the minor's sex, if the minor's perception is inconsistent with the minor's sex." La. Stat. Ann. § 40:1098.2(A). That includes the prescription or administration of puberty-blocking drugs and cross-sex hormones, and the performance of gender-transition surgeries. *Id.*

132. Nebraska law generally prohibits (with narrow exception) providers from performing certain gender-altering medical procedures on minors. *See* Neb. Rev. Stat. § 71-7304, -7305. Prohibited procedures include surgery and the use of puberty blockers and cross-sex hormones. *Id.* § 71-7303(6)(a). Nebraska law further prohibits the use of State funds, directly or indirectly, for providing gender-altering procedures to minors. *See* Neb. Rev. Stat. § 71-7306. Additionally, Nebraska's Medicaid program excludes sex change procedures from coverage. *See* 471 Neb. Admin. Code § 18-006.01.

133. Ohio law prohibits providers from performing certain gender-transition medical services for minors. Ohio Rev. Code § 3129.02. Prohibited services include "gender reassignment" surgery and, subject to exceptions, prescribing cross-sex hormones and puberty-blocking drugs. *Id.* Additionally, Ohio's Medicaid program does not cover "gender transformation" medical services. Ohio Admin. Code Rule 5160-2-03(A)(2)(e); *see also* Ohio Rev. Code § 3129.06.

134. Oklahoma law prohibits healthcare professionals from providing "gender transition procedures" to any person under the age of 18. *See* Okla Stat. tit. 63, § 2607.1(B). That includes

(1) "surgical procedures that alter or remove physical or anatomical characteristics or features that are typical for the individual's biological sex," and (2) "puberty-blocking drugs, cross-sex hormones, or other drugs to suppress or delay normal puberty or to promote the development of feminizing or masculinizing features consistent with the opposite biological sex." *Id.* § 2607.1(A)(2)(a).

135. South Carolina law prohibits healthcare professionals from providing "gender transition procedures," including puberty-blocking drugs, cross-sex hormones, and gender-transition surgeries, to any person under the age of 18. *See* Help Not Harm Bill, H.B. 4624, 125th Leg. Sess. (S.C. 2024), *codified at* S.C. Code Ann. § 44-42-310, *et seq*. The law further prohibits the use of public funds for any such gender-transition procedures, and it expressly precludes the South Carolina Medicaid Program from reimbursing or providing coverage for the same. *Id.*

136. South Dakota law likewise prohibits healthcare professionals from performing or prescribing certain gender-transition medical interventions for minors. *See* S.D. Codified Laws § 34-24-34. Prohibited services include puberty-blocking drugs, cross-sex hormones, and gender-transition surgeries. *Id*.

III. HHS's Prior Failed Attempts to Use Section 1557 to Further Gender Ideology.

137. Since Congress enacted the ACA, HHS has twice tried and failed to use Section 1557's prohibition on sex-based discrimination as a mandate to provide and pay for gender-transition medical interventions.

A. The Obama Administration's Vacated 2016 Rule.

138. Well into President Obama's first term, federal regulators heeded the historical understanding of Title IX as limited to sex-based discrimination. In a 2010 "Dear Colleague Letter" on bullying, the Obama Department of Education acknowledged that Title IX did not cover

claims of sex discrimination by lesbian, gay, bisexual, and transgender students based on their "LGBT status" alone. U.S. Dep't of Educ., Off. for Civ. Rts., Dear Colleague Letter on Bullying, at 8 (Oct. 26, 2010) (marked "not for reliance"), https://perma.cc/3AGM-SB8P. Instead, the letter advised, any claims must overlap with allegations of "sexual harassment or gender-based harassment." *Id.*

139. Yet, a few years later, things began to shift. In 2014, the Department of Education performed an about-face by asserting that "Title IX's sex discrimination prohibition extends to claims of discrimination" based solely on "gender identity." U.S. Dep't of Educ., Off. for Civ. Rts., Questions and Answers on Title IX and Sexual Violence, at 5 (Apr. 29, 2014) (rescinded in 2017), https://perma.cc/Y7BD-XHFU.

140. In 2016, HHS followed suit with a rule that dramatically altered the agency's understanding of the scope of sex discrimination under Section 1557. Dep't of Health & Hum. Servs., Nondiscrimination in Health Programs and Activities, 81 Fed. Reg. 31,375 (May 18, 2016) ("2016 Rule"). In particular, HHS defined Section 1557's prohibition of discrimination "on the basis of sex" to include discriminating against an individual "on the basis of … gender identity." *Id*. 31,467. The 2016 Rule defined "gender identity" 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.* And HHS defined "transgender individual" as "an individual whose gender identity is different from the sex assigned to that person at birth." *Id.*

141. The 2016 Rule required covered entities—including "almost all licensed physicians"—to perform or refer patients for sex-transition procedures. *See* 81 Fed. Reg. 31,445.

And it prohibited insurers from maintaining "explicit, categorical (or automatic) exclusion[s] or limitation[s] of coverage for all health services related to gender transition." *Id.* at 31,429.

142. The U.S. District Court for the Northern District of Texas preliminarily enjoined and later vacated HHS's rule insofar as it purported to prohibit "discrimination on the basis of gender identity." *Franciscan Alliance I*, 227 F. Supp. 3d at 696. The court concluded that "HHS's expanded definition of sex discrimination" that included gender identity "exceed[ed] the grounds incorporated by Section 1557" because "the meaning of sex in Title IX unambiguously refers to 'the biological and anatomical differences between male and female students as determined at their birth.'" *Id.* at 687, 689 (citation omitted); *accord Franciscan All., Inc. v. Azar*, 414 F. Supp. 3d 928, 941-45 (N.D. Tex. 2019).

143. The vacatur of the 2016 Rule remains "in effect." *Franciscan All., Inc. v. Becerra*, 47 F.4th 368, 377 (5th Cir. 2022).

B. The Biden Administration's Vacated 2022 Guidance.

144. During President Trump's Administration, HHS issued a rule rescinding the failed 2016 Rule and returning the agency's interpretation of sex-based discrimination under Section 1557 to the plain, longstanding interpretation of Title IX. *See* Dep't of Health & Hum. Servs., Nondiscrimination in Health and Health Education Programs or Activities, Delegation of Authority, 85 Fed. Reg. 37,160 (June 19, 2020) ("2020 Rule"). In so doing, the 2020 Rule specified that "the term 'on the basis of … sex' in Section 1557 does not encompass discrimination on the basis of gender identity." 85 Fed. Reg. 37,191.

145. Upon taking office, however, President Biden announced his administration's contrary view that all laws prohibiting sex discrimination—including Title IX—would

presumptively prohibit discrimination on the basis of gender identity or sexual orientation. *See* Exec. Order No. 13,988, 86 Fed. Reg. 7023-25 (Jan. 20, 2021).

146. As the basis for this view, President Biden's Executive Order and various agency pronouncements cited the Supreme Court's decision in *Bostock*. In that case, the Supreme Court held that Title VII's prohibition of discrimination "because of sex" prevents an employer from firing an employee simply "for being homosexual or transgender." *Id.* at 651-52. The Court explained that an employer who fires a male employee "for no reason other than the fact he is attracted to men … discriminates against him for traits or actions it tolerates in his female colleague," and vice versa. *Id.* at 660.

147. The *Bostock* Court, though, "proceed[ed] on the assumption that 'sex' … refer[s] only to biological distinctions between male and female." *Id.* at 655. It also expressly declined to "prejudge" whether its decision would "sweep beyond Title VII" to other nondiscrimination laws, such as Title IX, or affect policies and conduct—like access to bathrooms—other than the termination of employees simply for being homosexual or transgender. *Id.* at 681. Post-*Bostock* guidance issued by the Department of Education's Office of the General Counsel emphasized that *Bostock* did not affect the longstanding meaning of Title IX's reference to "sex." *See* Reed D. Rubinstein, Memo. for Kimberly M. Richey, Acting Assistant Secretary of the Office for Civil Rights, re: *Bostock v. Clayton Cnty.*, 140 S. Ct. 1731 (2020) (Jan. 8, 2021), https://perma.cc/Q9YC-Q4Y2.

148. Notwithstanding these limits, in May 2021 HHS published guidance purporting to interpret Section 1557 "consistent with … *Bostock*" by reading the statute to prohibit "[d]iscrimination on the basis of sexual orientation; and discrimination on the basis of gender identity." U.S. Dep't of Health & Human Servs., 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) ("*Bostock* Notification").

149. In March 2022, HHS doubled down on this view in a second Section 1557 guidance letter. U.S. Dep't of Health & Human Servs., Office for Civil Rights, HHS Notice and Guidance on Gender Affirming Care, Civil Rights, and Patient Privacy, (Mar. 2, 2022) ("March 2022 Guidance"), https://perma.cc/R4GJ-9CB3. This guidance reaffirmed the *Bostock* Notification's "interpretation" of Section 1557. *Id.* at 1-2. HHS further explained that efforts by covered entities to restrict access to "gender affirming care" may be treated as discrimination based on an individual's "gender identity," in violation of Section 1557. *Id.*

150. Shortly after HHS published its March 2022 guidance letter, an HHS sub-agency called the Office of Population Affairs released a two-page memorandum entitled "Gender-Affirming Care and Young People." *See* Office of Population Affairs, *Gender-Affirming Care and Young People*, https://perma.cc/H3CS-94KX. In this brief document, 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*. at 1. It 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*. HHS threatened to sue anyone who disagreed with this purported "standard of care." *See* March 2022 Guidance 1-2.

151. A federal district court later vacated and set aside as unlawful the March 2022 Guidance, finding HHS's conclusion that "denial of … care solely on the basis of a patient's sex assigned at birth or gender identity likely violates Section 1557" was "arbitrary and capricious."

Texas v. EEOC, 633 F. Supp. 3d 824, 838, 847 (N.D. Tex. Oct. 1, 2022). Among other things, the court held that the March 2022 Letter 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) (incorporating "section 794 of title 29")), failure to provide cross-sex hormones or gender-transition surgeries could amount to discrimination on the basis of a disability. *Id*. at 832-38. Other federal district courts enjoined similar efforts to extend *Bostock*'s reasoning to the Title IX context. *See, e.g.*, *Tennessee v. Dep't of Educ.*, 615 F. Supp. 3d 807, 839 (E.D. Tenn. 2022); *Neese*, 640 F. Supp. 3d at 675-78.

IV. HHS's New Attempt to Distort Section 1557 Through the 2024 Rule.

A. The Proposed Rule.

152. In August 2022, HHS published a Notice of Proposed Rulemaking for Section 1557. Dep't of Health & Human Servs., *Nondiscrimination in Health Programs and Activities*, 87 Fed. Reg. 47,824 (Aug. 4, 2022) ("Proposed Rule").

153. The Proposed Rule was largely cribbed from the previously enjoined 2016 Rule. Like the 2016 Rule, the Proposed Rule interpreted Title IX's—and by implication Section 1557's—ban on sex discrimination to include "discrimination on the basis of sex stereotypes; sex characteristics, including intersex traits; pregnancy or related conditions; sexual orientation; and gender identity." *Id.* at 47858.

154. According to HHS, *Bostock's* reasoning "support[ed] the interpretation that Title IX's prohibition of discrimination 'on the basis of' sex" extends to discrimination based on a "person's sexual orientation or transgender status." *Id.* at 47859.

155. The Proposed Rule broadly defined a "covered entity" as States and any other "recipient[s] of Federal financial assistance," HHS itself, and "an entity established under Title I

of the ACA." *Id.* at 47,912. Like the 2016 Rule, the Proposed Rule explicitly applied to health insurance issuers and administrators. *Id.* at 47,918.

156. The Proposed Rule stated that it would be unlawful for a covered entity to "deny[] or limit[] 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." *Id*. at 47,867.

157. In HHS's telling, this mandate meant that if a medical provider prescribes testosterone to treat a boy's hormone deficiency, the provider could not categorically refuse to prescribe testosterone to treat a gender dysphoric girl who identifies as a boy. In the same way, if a provider performs vaginoplasties to treat congenital defects or trauma to a woman's vagina, that provider could not refuse to perform a "vaginoplasty" on a gender dysphoric male who desires to have his genitals removed and replaced with repurposed tissue intended to replicate the appearance of a vagina. Similar logic would apply across a range of distinct procedures.

158. HHS asserted that the Proposed Rule would 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 reasonably determines that such health service is not clinically appropriate for that individual." *Id.* at 47,867.

159. Yet at the same time, the Proposed Rule warned that "a provider's view that no gender transition or other gender-affirming care can ever 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." *Id.* In other words, HHS proposed to override state laws prohibiting the provision of gender-transition drugs and surgeries to minors for the purpose of treating gender dysphoria.

160. HHS proposed a similar mandate for health insurers. Like the 2016 Rule, the Proposed Rule "prohibit[ed] 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"—regardless of the risks and costs. *Id*. at 47,871. And the Proposed Rule went on to instruct that exclusions deeming all "gender-affirming care for transgender people" as "'experimental' would result in prohibited discrimination on the basis of sex." *Id.* at 47,874.

161. The upshot is that HHS proposed to limit the ability of providers to exercise independent medical judgment about the medical necessity and appropriateness of sex-transition procedures, and to foreclose insurers from relying on concerns about the efficacy and long-term impacts of these treatments in assessing coverage.

162. HHS further proposed to enforce Section 1557's prohibition against sex-based discrimination using the "provisions applicable to Title VI to administrative enforcement actions." *Id*. at 47,828, 47,886. Noncompliance with HHS's Section 1557 mandates can result in the "suspension or termination" of federal funding or "other action authorized by law." *Id*. at 47919.

163. Consistent with the 2016 Rule, the Proposed Rule also included a private right of action against covered entities. *Id.* at 47885.

164. HHS also proposed to amend CMS regulations relating to Medicaid, CHIP, and the Program of All-Inclusive Care for the Elderly ("PACE").

165. HHS "propos[ed] to reinstate references to sexual orientation and gender identity in the Medicaid managed care regulation … that prohibits Medicaid managed care plans from discriminating against individuals eligible to enroll and from using any policy or practice that has the effect of discriminating on the basis of … sex." 87 Fed. Reg. 47,893. And HHS proposed to

"revise the term 'sex' in the current regulation text to 'sex (including sexual orientation and gender identity).'" *Id.*

166. The Proposed Rule also sought to amend the Medicaid and CHIP regulations to require that entities that deliver services must "promote the delivery of services in a culturally competent manner to all enrollees, … and regardless of sex which includes … gender identity." *Id.* at 47910.

167. The Proposed Rule also required State Medicaid and CHIP programs to "have methods to promote access and delivery of services in a culturally competent manner to all beneficiaries … regardless of sex (including sexual orientation and gender identity)." *Id.*

168. With respect to its PACE regulations, HHS proposed to change the word "sex" to "sex (including sexual orientation and gender identity)." *Id.* at 47,894.

B. Commenters' Widespread Objections to HHS's Proposal.

169. Underlining the import of and opposition to HHS's redefinition of sex discrimination under Section 1557, the Proposed Rule generated more than 80,000 comments.[1]

170. The State of Tennessee and nineteen co-signing States submitted a public comment criticizing the Proposed Rule as unlawful. *See* Tenn. Comment Letter (Exhibit B).

171. The States explained that HHS's interpretation of "sex" to mean "gender identity" or "sexual orientation" does not comport with Title IX's text or plain meaning, and that "the Proposed Rule [is] an attempt to stretch HHS's power beyond the text of the statute Congress enacted." *Id.* at 1, 12. Further, Tennessee criticized HHS's reliance on *Bostock* as support for its interpretation of Section 1557 and Title IX because "the rule in *Bostock* extends no further than

[1] Comments on the Proposed Rule are available at https://www.regulations.gov/document/HHS-OS-2022-0012-0001/comment.

Title VII." *Id.* at 7. And, given that Title IX relies on a "biological binary of sex," the Proposed Rule ignored relevant statutory structure and historical practice. *Id.* at 8.

172. Tennessee also provided several reasons that the Proposed Rule violated Constitutional constraints. For example, the Proposed Rule encouraged regulated parties "to insert themselves into constitutionally protected family affairs," threatening families' Fourteenth Amendment Due Process rights. *Id.* Tennessee also reminded HHS of the limits on Congress's spending power, explaining that Section 1557 did not "unambiguously prohibit discrimination based on sexual orientation or 'gender identity.'" *Id.* at 12. For this reason, Tennessee explained, the Spending Clause would not allow HHS to impose a new condition on federal funds, including Medicaid funds. *Id.* at 12. Tennessee also argued that the Proposed Rule's condition on federal funding was unconstitutionally coercive. *Id.*

173. Commenters also objected to the Proposed Rule's approach of establishing national standards of medical care for gender-transition treatment. Commenters explained that it was arbitrary and capricious for HHS to fail to consider effects that innate sex differences have on health. *See* EPPC Comment, *supra*, at 14-16. And they objected to the lack of medical consensus regarding the appropriate means of treating gender dysphoria—particularly for minors—while noting the irreversible nature of certain treatments and the increased prospects of sterilization as well as other associated risks. *See, e.g.*, Comment of Florida Agency for Healthcare Administration, HHS-OS-2022-0012-69566; Comment of Society for Evidence-Based Gender Medicine, HHS-OS-2022-0012-73218; Comment of American College of Pediatricians, at 3-5, HHS-OS-2022-0012-74010; EPPC Comment, *supra*, at 24-34; ADF Comment, *supra*, at 17-27.

C. Final 2024 Rule.

174. On May 6, 2024, HHS finalized the 2024 Rule, which generally will take effect July 5, 2024. The 2024 Rule has two parts. First, HHS's Office of Civil Rights ("OCR") promulgated regulations purporting to set out funding recipients' nondiscrimination obligations under Section 1557. Second, CMS promulgated amendments to separate regulations for specific aid programs under both Section 1557 and provisions of the Social Security Act ("SSA") and the Public Health Act ("PHA").

1. OCR Regulations.

175. The OCR regulations require that covered entities "provide individuals equal access to [their] health programs and activities without discriminating on the basis of sex." 89 Fed. Reg. at 37,770.

176. HHS declared that it was "not necessary to define 'sex'" for purposes of implementing this requirement. 89 Fed. Reg. at 37,575. HHS instead defined "[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." *Id.* at 37,699.

177. HHS's interpretation of this non-discrimination obligation will have immediate and industry-altering consequences. Under the 2024 Rule, no health facility may "[a]dopt or apply any policy or practice" that "prevents an individual from participating in a health program or activity consistent with the individual's gender identity." *Id.* at 37,701. That includes the use of sex-separated "intimate space[s]." *Id.* at 37,593. So, for example, a covered entity "will be in violation" of the 2024 Rule for refusing to place a transgender person "in facilities consistent with their gender identity." *Id.* That means covered entities will be compelled to allow men who

identify as women to share a room, bathroom, and other private facilities with women, and vice versa. 87 Fed. Reg. 47,866-67.

178. The OCR Regulations will also dictate the medical treatments and decisions of providers. Even while recognizing that sex-based characteristics are relevant to providing medical care, the 2024 Rule declares that "providers may use sex-based distinctions to administer individualized care, provided those distinctions do not cause more than *de minimis* harm." 89 Fed. Reg. at 37,594. But "*de minimis* harm" is a low bar: HHS suggests that merely "experiencing … distress" is enough to cross that threshold. *Id*. at 37,593.

179. HHS specifies that no covered provider—meaning most doctors across the nation—can "[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.* at 37,700.

180. So too, a provider cannot deny "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 of limitation is based on sex assigned at birth, gender identity, or gender otherwise recorded." 89 Fed. Reg. at 37,701.

181. To translate: HHS now deems it *sex discrimination* if a doctor or other medical entity declines to provide persons with gender dysphoria any (purportedly) similar treatments as those given to persons with cancer and other physical ailments. And this mandate has no age limit—meaning it applies equally to minors for whom such interventions are unproven, risky, and life altering.

182. The mandate in OCR's Regulations extends to all so-called "gender-affirming care," which "includes hormone therapy, surgery, and other related services." *Id.* So "a

gynecological surgeon may be in violation of the rule if they accept a referral for a hysterectomy but later refuse to perform the surgery upon learning" it was sought for purposes of "gender transition." 87 Fed. Reg. at 47,867. Or it would be presumptively discriminatory for a clinic to prescribe hormone replacement therapy to treat menopause but refuse to provide the same type of therapy for a "gender transition."

183. The OCR Regulations recognize that providers might have a "legitimate, nondiscriminatory reason for denying or limiting" a service, such as where the covered entity determines that a "health service is not clinically appropriate for a particular individual." 89 Fed. Reg. at 37,701. But HHS's view of this concept is narrow. As HHS puts it, Section 1557's nondiscrimination mandate would not require a doctor to provide "a prostate exam for a transgender man who does not anatomically have a prostate." *Id.* at 37,607.

184. Otherwise, HHS will evaluate a covered entity's decision not to provide services for gender-transition purposes based on "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. HHS signals that the "medical necessity standards" and "guidelines" it will use to evaluate these decisions come from WPATH and the Endocrine Society. *See* 87 Fed. Reg. at 47,868.

185. The OCR regulations require that a provider's decision not to provide gender-transition treatments "must not be based on unlawful animus or bias[] or constitute pretext for discrimination." 89 Fed. Reg. at 37,701. This means that a provider must rationalize why a gender-transition treatment "is not clinically appropriate *for a particular individual*." *Id.* (emphasis added).

186. Thus, decisions based on the lack of evidence of efficacy and safety of medical gender-transition interventions generally—as described by the comprehensive systematic reviews that have recently come out of Europe—"may be considered evidence of pretext for discrimination." *Id.* at 37,613. Along the same lines, a provider's determination that so-called "gender-affirming care" is "experimental or cosmetic would be considered evidence of pretext." 87 Fed. Reg. 47,874.

187. HHS likewise views "categorical exclusions for gender affirming care" as suggestive of pretext, even if required by state law. *Id.* As a result, a provider who declines treatment to minors under state laws prohibiting such treatment would engage in "prohibited discrimination on the basis of sex." *Id.*

188. HHS's enforcement decisions are also informed by "consideration of … whether [a] covered entity demonstrated a willingness to refer or provide accurate information about gender-affirming care." 89 Fed. Reg. at 37,598. But any provider who deviates from the WPATH script risks being found insufficiently willing to provide "accurate information." 87 Fed. Reg. 47,784 (citing WPATH to conclude that "[c]haracterizing [gender-transition treatments] as experimental or cosmetic … is not based on current standards of medical care"). HHS requires providers to parrot controversial positions of gender-transition advocates, even when doing so would give patients a false sense of certainty about the efficacy of these treatments.

189. The OCR regulations also apply to entities involved in federally funded health insurance and health-related coverage administered by HHS, such as Medicaid and CHIP. Such entities may not discriminate in healthcare coverage, in insurance benefit design, or in marketing practices. *See* 89 Fed. Reg. at 37,701. And HHS specifically prohibits limits or restrictions on

coverage or claims, including cost sharing, "based upon [an] individual's sex assigned at birth, gender identity, or gender otherwise recorded." *Id.*

190. HHS also prohibits covered entities from denying or limiting "coverage," denying or limiting "coverage of a claim," or imposing "additional cost sharing or other limitations or restrictions on coverage, for specific health services related to gender transition or gender-affirming care if such denial, limitation, or restriction *results* in discrimination on the basis of sex." *Id.* (emphasis added). Thus, even facially neutral insurance policies that tend to screen out services used by transgender individuals may be found discriminatory, even if those policies are not motivated by sex or gender identity.

191. HHS purports to provide a safe harbor for insurers. "Nothing in [the rule] 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.* But categorical exclusions of coverage for gender-transition interventions, including surgeries, would be considered unlawful sex discrimination.

192. Failing to comply with the OCR regulations puts the States' federal funding at risk, including their Medicaid funding. 45 C.F.R. §§ 80.8, 92.303.

2. CMS Regulations.

193. In addition to amending HHS's Section 1557 regulations, the 2024 Rule also amends CMS regulations relating to Medicaid, CHIP programs designed to provide healthcare for children and pregnant women, and PACE's program for providing elderly care. In addition to relying on its authority under Section 1557, CMS claimed authority to make these changes to

Medicaid under 42 U.S.C. § 1396a(a)(4), to CHIP under 42 U.S.C. § 1396aa(a) (CHIP), and to PACE under 42 U.S.C. §§ 1395eee(f), 1396u-4(f) (PACE).

194. Under CMS's revised Medicaid and CHIP regulations, contracts with entities that deliver services 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 (emphasis added). Thus, a managed care organization's facially neutral policies or practices that lack any discriminatory purpose that nonetheless have a discriminatory *effect* on transgender individuals may now violate its contract.

195. Entities that deliver services also must "promote the delivery of services in a culturally competent manner to all enrollees, … and regardless of sex which includes … gender identity." *Id.*

196. Under the 2024 Rule, States' Medicaid and CHIP programs "must 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.

197. With respect to its PACE regulations, CMS likewise revised the regulatory language's reference to "sex" to include "sex characteristics, including intersex traits; pregnancy or related conditions; sexual orientation; gender identity; and sex stereotypes." 89 Fed. Reg. at 37,669.

PLAINTIFFS' IMPENDING IRREPARABLE HARM

198. The 2024 Rule will inflict significant, irreparable harm on the Plaintiff States that only prompt judicial intervention can redress.

I. Nonrecoverable Compliance Costs.

199. *First*, Plaintiff States would suffer the "irreparable harm of nonrecoverable compliance costs." *R.J. Reynolds Vapor Co. v. FDA*, 65 F.4th 182, 194 (5th Cir. 2023) (citation omitted).

200. The 2024 Rule acknowledges as much. HHS estimates that the cost of revising relevant policies and procedures to comply with the 2024 Rule will result in a one-time cost of $65 million across all covered entities. 89 Fed. Reg. at 37,680. It predicts the initial cost of training employees on the 2024 Rule across all covered entities will be more than $927 million, with ongoing annual training estimated to cost another $309 million per year. *Id*. at 37,679, 37,680. And it estimates that required annual recordkeeping will cost millions more. *Id*. at 37,682.

201. Because TennCare's administrative rules for the State's Medicaid and CHIP programs exclude coverage for gender-transition surgeries, compliance with the 2024 Rule would require amending those rules through formal rulemaking. The rulemaking process is governed by the Tennessee Uniform Administrative Procedures Act and takes approximately nine months to complete. That process includes rule drafting, obtaining the review and approval of the offices of the Governor and Attorney General, posting for public comment, a rulemaking hearing, and a hearing before the Joint Government Operations Committee of the Tennessee legislature.

II. Derogation of Plaintiff States' Sovereignty.

202. *Second*, enforcement of the 2024 Rule would undermine Plaintiff States' sovereignty. "[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).

203. The State also "has an interest in protecting vulnerable groups … from mistakes," *Glucksberg*, 521 U.S. 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). It is also "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, 756-57 (1982) (quoting *Globe Newspaper Co. v. Superior Court*, 457 U.S. 596, 607 (1982)).

204. As discussed, Plaintiff States have adopted laws prohibiting healthcare providers from offering gender-transition treatments to minors. *See supra*, ¶¶ 107-09, 117-18, 126, 128, 130-36. Tennessee, Mississippi, and other Plaintiff States have likewise chosen not to cover certain gender-transition interventions—including sex-reassignment surgeries—through their Medicaid or state employee health programs. *See supra*, ¶¶ 112-13, 116, 121-126, 129, 132-35. Plaintiff States will be unable to enforce these duly enacted laws and longstanding policies without coming into conflict with the 2024 Rule.

205. States have "sovereign interests in enforcing their duly enacted state laws." *Tennessee*, 615 F. Supp. 3d at 841. Thus, "irreparable harm exists when a federal regulation prevents a state from enforcing its duly enacted laws." *Texas v. Becerra*, 577 F. Supp. 3d 527, 557 (N.D. Tex. 2021) (collecting cases).

III. Threatened Loss of Federal Funding and Civil Liability.

206. *Third*, enforcement of the 2024 Rule threatens to collectively strip Plaintiff States of tens of billions of dollars in federal HHS funds and to impose substantial penalties through private suits. This severe financial exposure endangers important health programs that serve some of the Plaintiff States' most vulnerable residents.

207. For example, TennCare administers Tennessee's Medicaid program, as well as CoverKids and its PACE program for the elderly. TennCare annually serves nearly 1.5 million Tennesseans, including low-income individuals, pregnant women, children, caretaker relatives of young children, older adults, and those with disabilities.

208. TennCare received approximately $10.3 billion in HHS funding for State Fiscal Year 2022-2023. That includes more than $10.2 billion for Tennessee's Medicaid program, $109.8 million for CoverKids (CHIP), and $10.8 million for the State's PACE program.

209. All are regulated by the 2024 Rule. Yet Tennessee's Medicaid and CHIP programs each categorically exclude coverage for gender-transition surgeries, which the 2024 Rule prohibits. *See* Tenn. Comp. R. & Regs. 1200-13-13-.10(a)(72), 1200-13-21-.06(1).

210. Tennessee thus faces a credible threat that HHS will enforce the 2024 Rule against it and terminate substantial federal financial assistance to noncomplying state entities. The 2024 Rule also subjects Tennessee to civil liability through Section 1557's private right of action.

211. The same goes for Mississippi and many of the other Plaintiff States. *See supra*, ¶¶ 23-31.

IV. Fiscal Costs of Covering Gender-Transition Interventions.

212. *Fourth*, the 2024 Rule's mandate that health insurers cover gender-transition drugs and surgeries will inevitably result in increased costs for each health plan.

213. According to WPATH 8, the purportedly medically necessary drug interventions for 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.

WPATH 8, *supra*, at S110.

214. According to WPATH 8, the purportedly "medically necessary" so-called "gender-affirming surgical procedures," *id*. 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 pubic bone, which is more pronounced in females);

w. "Nipple-areola tattoo;"

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

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

z. "Hair removal," including "laser epilation" (laser removal) or "electrolysis" (permanent removal by destroying hair follicles), "from the face, body and genital areas."

Id. at S258, App'x E (cleaned up). WPATH makes clear that the above list "is not intended to be exhaustive." *Id*.

215. According to one study used by HHS in its economic-impact analysis of the 2024 Rule, "the average cost of transition-related care (surgery, hormones, or both) per person needing treatment was $29,929 over 6.5 years," or approximately $4,600 per year. Aaron Belkin, *Caring for Our Transgender Troops—The Negligible Cost of Transition-Related Care*, 373 New Eng. J. Med. 1089 (2015).

216. According to the Williams Institute, 0.52% of adults and 0.74% of adolescents in Tennessee identify as transgender. *See* Williams Institute, *Transgender People*, https://perma.cc/2FNL-G3ZP (last visited May 30, 2024).

217. As of May 2024, approximately 670,000 adults were enrolled in Tennessee's Medicaid program, and approximately 824,000 minors were enrolled in Tennessee's Medicaid and CHIP programs. On top of that, roughly 115,000 adults and nearly 30,000 minors are enrolled in Tennessee's State Plan for state and higher education employees.

218. Mississippi's Medicaid and CHIP programs are expected to provide health insurance coverage for nearly 752,000 in Fiscal Year 2024. Thousands more are enrolled in Mississippi's State Plan.

219. As of May 2024, approximately 345,000 adults were enrolled in Alabama's Medicaid program, and approximately 719,000 minors were enrolled in Alabama's Medicaid and CHIP programs. Thousands more were enrolled in Alabama's State Plan.

220. As of April 2024, approximately 842,652 adults were enrolled in Georgia's Medicaid program, and approximately 1,452,001 minors were enrolled in Georgia's Medicaid and CHIP programs.

221. As of April 2024, more than 1 million adults were enrolled in Indiana's Medicaid program, and more than 800,000 minors were enrolled in Indiana's Medicaid and CHIP programs.

222. As of May 2024, approximately 1.5 million adults were enrolled in Kentucky's Medicaid program and almost 530,000 children were enrolled in Medicaid.

223. As of December 2023, approximately 3.6 million Ohioans were enrolled in the State's Medicaid program, with approximately 1.5 million children enrolled in Medicaid or CHIP.

224. As of May 2024, approximately 1,212,000 adults were enrolled in Virginia's Medicaid program, and approximately 782,000 minors were enrolled in Virginia's Medicaid and CHIP programs.

225. Covered plans of the remaining Plaintiff States collectively provide health benefits to millions more individuals.

226. Based on the demographic estimates from the Williams Institute, that means there are likely thousands of people enrolled across the Plaintiff States' covered plans who identify as transgender.

227. Thus, the 2024 Rule's gender-transition mandate will undoubtedly have a "substantial" fiscal effect on Plaintiff States. 89 Fed. Reg. at 37,683. And again, any monies the States expend as a result of the 2024 Rule could not later be recovered—even if the States ultimately prevail in their legal challenge.

V. Threat to the Health and Safety of Vulnerable Citizens.

228. *Finally*, the 2024 Rule will ultimately subject some of Tennessee's most vulnerable citizens to a gender-transition protocol that will leave them with irreversible side effects—including sterilization—and increased health risks for the rest of their lives.

229. The most recent systematic review of the available evidence, published in April 2024, only confirms prior concerns of leading national health authorities abroad and in many States at home regarding the lack of quality evidence supporting the safety and efficacy of medical gender transition, particularly for minors. *See* The Cass Review, *Independent review of gender identity services for children and young people: Final Report* (April 2024), *available at* https://cass.independent-review.uk/home/publications/final-report/.

230. This evidence review highlighted the "weak evidence" regarding the impact of puberty blockers on gender dysphoria and their still unknown effect on "cognitive and psychological development." *Id.* It further noted that the use of cross-sex hormones to treat gender dysphoria in minors "presents many unknowns" due to the "lack of long-term follow-up data," which leaves "inadequate information about the range of outcomes for this group." *Id.*

231. Clinicians are still unable to determine with any certainty which gender dysphoric youth will go on to have an enduring transgender identity. *Id.* That is alarming, given that gender dysphoria for most children naturally resolves by the time they reach adulthood if not subjected to transitioning interventions. Levine, *supra*, at 40-45.

232. Although a growing number of detransitioners have come forward to shed light on the permanent consequences they have endured because of the gender-transition protocol, public advocacy and delayed justice through private lawsuits against their medical providers cannot reverse their chemical or surgical sterilization or restore their lost adolescence.

CLAIM I
Violation of APA, 5 U.S.C. § 706(2)(A), (C)
The 2024 Rule Unlawfully Defines "on the Basis of Sex"

233. Plaintiffs incorporate by reference all preceding paragraphs.

234. HHS is a federal agency within the meaning of the APA. *See* 5 U.S.C. § 551(1).

235. The 2024 Rule is "final agency action" within the meaning of 5 U.S.C. § 704.

236. Plaintiff States lack another adequate remedy in court, and no rule requires that they appeal to a superior agency authority before seeking judicial review.

237. The APA requires courts to set aside and vacate agency action that is "not in accordance with law" or "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right." 5 U.S.C. § 706(2)(A), (C); *see Data Mktg. P'ship, LP v. U.S. Dep't of Lab.*, 45 F.4th 846, 859 (5th Cir. 2022).

238. The 2024 Rule exceeds HHS's statutory authority because it defines discrimination "on the basis of sex" in a manner contrary to Section 1557 and Title IX.

239. The text of neither Section 1557 nor Title IX mentions "sexual orientation" or "gender identity" as protected categories. Instead, Congress expressly limited Title IX's coverage to discrimination "on the basis of sex," and the ordinary public meaning of "sex" at the time of Title IX's enactment unambiguously excludes consideration of a person's gender identity. *See Adams*, 57 F.4th at 812. If the plain meaning of Title IX was not enough, the statute's structure, history, and purpose confirm that "sex" is limited to the traditional biological binary of male and female. Indeed, it makes perfect sense to import Title IX's understanding of "sex"—and sex discrimination—into Section 1557 because, much like in the educational context where differential treatment on the basis of sex may be warranted (e.g., facilities, sports teams), healthcare also

requires different treatment based on biological realities. Men and women have different health needs based on biological sex.

240. Other structural features of the statute confirm the invalidity of HHS's reading. The ACA elsewhere references "sexual orientation," *see* 42 U.S.C. § 294e-1(b)(2), signaling that if Congress wished to prohibit LGBTQ+ discrimination in Section 1557, it knew how to do so.

241. Section 1557, moreover, 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 that "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 do not have a disorder of sex development—a physical impairment—do not have a "disability" and are excluded from "section 792 of title 29."

242. The 2024 Rule nonetheless states that "sex" discrimination prohibited by Title IX—and incorporated by Section 1557—includes discrimination based on "sexual orientation" and "gender identity." 89 Fed. Reg. 37,698-99.

243. The 2024 Rule rests on *Bostock* for this result. But *Bostock* explicitly declined to "prejudge" whether other nondiscrimination laws—like Title IX—prohibit discrimination based on sexual orientation and transgender status, or whether its ruling affected common practices like maintaining sex-separated "bathrooms." 590 U.S. at 681. Thus, as many federal courts have held, "the rule in *Bostock* extends no further than Title VII." *Pelcha v. MW Bancorp, Inc.*, 988 F.3d 318, 324 (6th Cir. 2021) ("[T]he Court in Bostock was clear on the narrow reach of its decision and how it was limited only to Title VII itself."). And "it does not follow that principles announced

in the Title VII context automatically apply in the Title IX context." *Meriwether v. Hartop*, 992 F.3d 492, 510 n.4 (6th Cir. 2021).

244. Nor can *Chevron* deference save the 2024 Rule's misinterpretation of Title IX and Section 1557. For starters, HHS's reading falls outside the range of reasonable interpretations of the statutory text because it purports to resolve a policy issue of major political significance without clear congressional authority, *see West Virginia v. EPA*, 597 U.S. 697, 721-24 (2022), and fails to construe "on the basis of sex" "to avoid serious constitutional doubts," *Brawner v. Scott Cnty.*, 14 F.4th 585, 592 n.2 (6th Cir. 2021) (quoting *FCC v. Fox Tel. Stations, Inc.*, 556 U.S. 502, 516 (2009)); *see also infra* Claim III. And to the extent *Chevron* would permit HHS's interpretation, that decision should be reconsidered. *Cf. Loper Bright Enters. v. Raimondo*, No. 22-451 (U.S.) (argued Jan. 17, 2024) (presenting question "[w]hether the Court should overrule *Chevron*").

245. These problems all infect and render unlawful HHS's amendments to its OCR Regulations. They also preclude HHS's amendments to its regulations related to Medicaid, CHIP, and PACE to prohibit discrimination on the basis of gender identity under Section 1557 as well as provisions of the Social Security Act. For the reasons already discussed, Section 1557 does not warrant those changes to the CMS Regulations.

246. Neither does the Social Security Act. Section 1902(a) of the SSA, 42 U.S.C. § 1396a(a)(4)(A), requires State plans to provide "such methods of administration … as are found by the Secretary to be necessary for the proper and efficient operation of the plan." Non-discrimination rules are not "methods of administration." HHS's interpretation of Section 1902 as providing carte blanche authority to impose requirements on State Medicaid plans is inconsistent

with the statutory text and violates the "clear notice" requirements for Spending Clause legislation and the major questions doctrine.

247. Section 2101(a) of the SSA, *id*. § 1397aa, also does not authorize HHS's gender-identity mandate for CHIP. This provision does not grant HHS rulemaking authority or otherwise support HHS's interpretation of "sex" discrimination to include sexual orientation and gender identity. HHS's interpretation of this section is inconsistent with the text and statutory context, as well as the "clear notice" required by the Spending Clause and the major questions doctrine.

248. Section 1894(f)(A) and 1934(f)(A) of the SSA, 42 U.S.C. § 1395eee(f); *id*. § 1396u-4(f), similarly do not give HHS authority to impose its gender identity mandate. HHS's reading of these provisions to afford near limitless rulemaking authority is contrary to statutory text and context, as well as the "clear notice" required by the Spending Clause and the major question doctrine.

249. Because the 2024 Rule's interpretation of Section 1557 and related provisions contravenes the statutory text and bedrock canons of statutory interpretation, it is not entitled to deference and exceeds HHS's legal authority. The 2024 Rule should thus be declared unlawful and "set aside"—meaning vacated. *See* 5 U.S.C. § 706(2); *see also Career Colls. & Sch. of Tex. v. U.S. Dep't of Educ.*, 98 F.4th 220, 255 (5th Cir. 2024) (collecting authorities).

CLAIM II
Violation of APA, 5 U.S.C. § 706(2)(A), (C)
The 2024 Rule Unlawfully Regulates the Practice of Medicine

250. Plaintiffs incorporate by reference all preceding paragraphs.

251. HHS further exceeds its statutory authority because the 2024 Rule pervasively regulates the practice of medicine—a matter within the traditional authority of the States and which Congress has not authorized the agency to regulate. This arbitrary expansion of HHS's authority

harms providers within Plaintiff States—including those health professionals the States employ directly.

252. Congress does not use "muffled hints" or "obscure" language to give federal agencies "authority to regulate areas traditionally supervised by the States' police power." *Gonzales v. Oregon*, 546 U.S. 243, 274 (2006). Agencies possess that authority only when Congress grants it to them clearly.

253. "There 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. OSHA*, 595 U.S. 109, 121 (2022) (Gorsuch, J., concurring). HHS thus must point to "exceedingly clear language if it wishes to significantly alter the balance between federal and state power" in the field of medical regulation. *See U.S. Forest Serv. v. Cowpasture River Preservation Ass'n*, 590 U.S. 604, 622 (2020).

254. Applying that principle in *Gonzales*, the Supreme Court refused to read the federal Controlled Substances Act to give the U.S. Attorney General the power "to prohibit doctors from prescribing regulated drugs for use in physician-assisted suicide." 546 U.S. at 248-49, 275. Reading federal law otherwise would have allowed a federal agency "to effect a radical shift of authority from the States to the Federal Government to define general standards of medical practice in every locality"—without any clear grant of authority. *Id*. at 275.

255. These principles require invalidating the 2024 Rule, which prolifically directs (and hampers) health providers' practice of medicine and ousts States from their traditional role as regulators of the medical profession and medical ethics. Examples of HHS's improper overreach abound.

256. *First*, the 2024 Rule regulates how covered health entities run their facilities. That includes inhibiting entities from maintaining sex-separated "intimate space[s]." 89 Fed. Reg. at 37,593. According to HHS, covered entities will be guilty of sex discrimination if they "refuse to place [a transgender person] in facilities consistent with their gender identity," *i.e.*, if they maintain women's-only or men's-only spaces. *Id*. That mandate will undermine the medical treatment of those whose intimate spaces have been invaded.

257. *Second*, the 2024 Rule risks punishing doctors who decline to provide medically inappropriate care. The 2024 Rule declares that "providers may use sex-based distinctions to administer individualized care," but only if "those distinctions do not cause more than *de minimis* harm." *Id.* at 37,594. As discussed, "*de minimis* harm" is a low bar that HHS says even emotional "distress" would exceed. *Id*. at 37,593. Under the final rule, then, if a male patient seeks OBGYN services from a covered entity, and that entity declines to provide those services on the ground that they are inappropriate for a male, then the entity would face legal liability for sex discrimination if that male patient claims to have suffered "distress."

258. Likewise, the 2024 Rule risks deeming doctors guilty of sex discrimination simply for hewing to well-settled and scientifically grounded understandings about "sex" and the attendant medical consequences. The 2024 Rule pledges: "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." *Id*. at 37,575. But that pledge is hollow, and the final rule elsewhere defies that promise. The 2024 Rule is clear: "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." *Id*. at 37,576; *see id.* at 37,575 ("discrimination based on anatomical or physiological sex characteristics is inherently sex-

based"). Thus, if a doctor believes that removing cancerous breast tissue can be surgically appropriate and is willing to perform such a surgery in line with that medical judgment, the 2024 Rule requires him also to surgically remove the healthy breast tissue of a patient suffering from gender dysphoria—even if that procedure defies the doctor's medical judgment.

259. *Third*, the 2024 Rule also invades the doctor-patient relationship. HHS acknowledges that "[p]roviders 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." *Id*. at 37,595. Although HHS claims that "this rule does not prohibit or inhibit that," all the agency is willing to commit to is that such basic health-related inquiries "are not per se discriminatory." *Id*. If a patient "makes clear that further inquiries are unwelcome," however, "the inquiries may rise to the level of harassment on the basis of sex." *Id*. Suppose a doctor sees a patient seeking a life-altering and potentially dangerous gender-transition procedure, and the doctor responsibly asks the many questions needed to assess and inform the patient of the soundness of the procedure and dangers involved. If the patient declines that line of questioning but the doctor insists on doing her duty to assess and inform, the doctor risks liability for sex discrimination. Fears of that sort of liability will chill and undermine the doctor-patient relationship and resulting care.

260. *Fourth*, the 2024 Rule imposes a national standard of care for gender dysphoria without congressional authorization. The 2024 Rule mandates that nearly all doctors nationwide provide treatments pushed by an international organization recently shown to lack scientific and ethical rigor, *see* 87 Fed. Reg. at 47,834 n.139 (citing standards from WPATH). Providers are prohibited from exercising their own reasonable medical judgment about the appropriateness and safety of sex-transition procedures generally. Nor can they decline to provide sex-transition procedures based on the experimental nature of those procedures. Instead, to receive federal

funding from Medicaid, Medicare, and other programs, doctors—including employees of Plaintiff States—must perform sex-transition procedures even if those procedures are against their medical judgment and the subject of serious dispute in the medical community.

261. Making matters worse, the 2024 Rule's gender-transition-intervention mandate purports to nullify contrary state laws limiting the provision of gender-transition medical interventions to minors. The 2024 Rule openly deems preempted those 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 in minors. *See* 89 Fed. Reg. at 37,535, 37,598. These state laws permissibly reflect that the safety, efficacy, and appropriateness of "gender-transition" interventions are disputed matters on which policymakers may "reasonably exercise caution." *L.W.*, 83 F.4th at 477. Yet the 2024 Rule overrides those laws without demonstrating that this result was "the clear and manifest purpose of Congress." *Wyeth v. Levine*, 555 U.S. 555, 565 (2009) (citation omitted). General preemption principles foreclose this result.

262. In short, the 2024 Rule seeks to transform the practice of medicine across the country by dictating what treatments must be provided, how doctors must interact with patients, what doctors may say or not say, what doctors must affirm to be true or untrue, and more. But HHS's cited statutes fail to "effect" this "radical shift of authority from the States to the Federal Government" on sound medical practice. *Gonzales*, 546 U.S. at 275. And the 2024 Rule flouts the limits of Section 1554 of the ACA, which *prohibits* HHS from interfering with providers' practice of medicine. Section 1554 bars HHS from adopting any rule that "impede[s] timely access to health care services"; "interferes with communications regarding a full range of treatment options between the patient and the provider"; "restricts the ability of health care professionals to

provide full disclosure of all relevant information to patients making health care decisions"; or "violates the principles of informed consent and the ethical standards of health care professionals." 42 U.S.C. § 18114(2)-(5). As discussed, HHS's 2024 Rule breaches all these limits, and then some.

263. Because the 2024 Rule's nationalization of medical care along HHS's preferred ideological lines exceeds HHS's authority, the 2024 Rule should be declared unlawful, "set aside," and vacated. *See* 5 U.S.C. § 706(2).

CLAIM III
Violation of APA, 5 U.S.C. § 706(2)(B)
The 2024 Rule Is Contrary to the U.S. Constitution

264. Plaintiffs incorporate by reference all preceding paragraphs.

265. The APA requires courts to set aside and vacate agency action that is "contrary to constitutional right, power, privilege, or immunity." 5 U.S.C. § 706(2)(B); *see also id.* § 706(2)(A); *Data Mktg. P'ship*, 45 F.4th at 859.

266. The 2024 Rule is unconstitutional, and thus unlawful, for several reasons.

267. *Spending Clause*. Congress passed Section 1557 under the Spending Clause of the United States Constitution. "[L]egislation enacted pursuant to the spending power is much in the nature of a contract: in return for federal funds, the States agree to comply with federally imposed conditions." *Adams*, 57 F.4th at 815 (quoting *Pennhurst*, 451 U.S. at 17). That framework means that "if Congress intends to impose a condition on the grant of federal moneys [under its Spending Clause authority], it must do so unambiguously." *Id.* (citation omitted). This "clear-statement rule" applies with special strength when a federal-funding condition "encroache[s] upon a traditional state power," such as the regulation of health care. *Kentucky v. Yellen*, 54 F.4th 325, 354 (6th Cir. 2022); *see also L.W.*, 83 F.4th at 473-74.

268. Nowhere in Section 1557, Title IX, the Social Security Act, or anywhere else has Congress permitted HHS to regulate "nondiscrimination" based on gender identity—let alone issue rules that contain the 2024 Rule's sweeping gender-identity mandates. *See supra* Claims I-II. Nor can HHS's 2024 Rule itself provide notice to satisfy the Spending Clause clear-statement rule. As the Fifth Circuit has held, the "needed clarity" to satisfy the Spending Clause "cannot be … provided" by "regulations clarifying an ambiguous statute." *Tex. Educ. Agency v. U.S. Dep't of Educ.*, 992 F.3d 350, 361 (5th Cir. 2021). Instead, it "must come directly from the statute." *Id.*

269. Independently, Congress is forbidden under the Spending Clause from wielding the Federal purse as "a 'weapon[] of coercion, destroying or impairing the autonomy of the states." *See NFIB*, 567 U.S. at 579 (quoting *Steward Machine Co. v. Davis*, 301 U.S. 548, 586 (1937)). Thus, Congress exceeds its Spending Clause authority when it offers a financial inducement that is "so coercive as to pass the point at which 'pressure turns to compulsion.'" *South Dakota v. Dole*, 483 U.S. 203, 211 (1987) (citation omitted).

270. HHS's 2024 Rule conditions hundreds of billions of dollars in federal funding for Plaintiff States—amounts representing large portions of their overall budgets, *see supra*, ¶¶ 22-31—on States' ceding their longstanding power to regulate permissible medical procedures and performing controversial treatments causing proven, life-long harms. Just as in *NFIB*, linking States' Medicaid funding to their following HHS's controversial federal mandate for gender-transition interventions is an unlawful "gun to the head" of States that violates the Spending Clause's anti-coercion limit. 567 U.S. at 581. That the "States, not the Federal Government, are the traditional source of authority over safety, health, and public welfare" further compounds the federalism harms inflicted by HHS's coercive regime. *Kentucky v. Biden*, 23 F.4th 585, 609 (6th Cir. 2022) (citation omitted).

271. *Nondelegation Doctrine*. To the extent HHS asserts authority to define new practices that violate Section 1557, it transgresses "the Constitution's rule vesting federal legislative power in Congress," not agencies acting by "pen-and-phone regulations." *West Virginia*, 597 U.S. 737, 753 (Gorsuch, J., concurring). Reading "sex" as a term capacious enough to encompass a controversial gender-identity mandate, among other novel ideas, would shift "unfettered" lawmaking power to the Department in a manner the nondelegation doctrine does not tolerate. *See Tiger Lily, LLC v. U. S. Dep't of Hous. & Urban Dev*., 5 F.4th 666, 672 (6th Cir. 2021).

272. Moreover, to the extent that HHS predicates its new regulations on the "medical necessity standards" and "guidelines" issued by WPATH and the Endocrine Society, they violate the private nondelegation doctrine. *See Carter v. Carter Coal Co*., 298 U.S. 238, 311 (1936). Handing off regulatory authority to private parties is "legislative delegation in its most obnoxious form; for it is not even delegation to an official or an official body, presumptively disinterested, but to private persons whose interests may be and often are adverse to the interests of others in the same business"—or the public welfare. *Id*.; *see also Dep't of Transp. v. Ass'n of Am. Railroads*, 575 U.S. 43, 60-64 (2015) (Alito, J., concurring).

273. *Eleventh Amendment*. The Eleventh Amendment provides that the "Judicial power of the United States shall not be construed to extend to any suit in law or equity, commenced or prosecuted against one of the United States by Citizens of another State, or by Citizens or Subjects of any Foreign States." U.S. Const. amend. XI. As a result of this limit, there are only two circumstances in which an individual may bring a suit against a State in federal court. *First*, a State may waive its sovereign immunity by consenting to being sued. *See College Sav. Bank v. Fla. Prepaid Postsecondary Educ. Expense Bd.*, 527 U.S. 666, 670 (1999). *Second*, Congress may

abrogate a state's sovereign immunity through legislation enacted pursuant to its Section 5 enforcement power under the Fourteenth Amendment. *Id.*

274. Neither scenario applies here. As discussed, the statute does not condition—let alone do so clearly—States' HHS funding on their following the 2024 Rule's gender-identity mandates. *See supra* Claim I. Nor could HHS's attempt to apply 1557 to gender-identity discrimination pass Section 5 muster, including because gender identity is not a suspect characteristic and HHS has offered no evidence that the ACA was passed in response to a documented history of discrimination against transgender individuals. *See City of Boerne v. Flores*, 521 U.S. 507, 529-36 (1997). The 2024 Rule thus cannot constitutionally subject States to private suits for money damages.

275. Because the 2024 Rule is unconstitutional in the ways described above, it should be declared unlawful, "set aside," and vacated. 5 U.S.C. § 706(2)(B).

CLAIM IV
Violation of APA, 5 U.S.C. § 706(2)(A)
The 2024 Rule Is Arbitrary and Capricious

276. Plaintiffs incorporate by reference all preceding paragraphs.

277. The APA requires courts to set aside agency action that is "arbitrary, capricious," or an "abuse of discretion." 5 U.S.C. § 706(2)(A).

278. A federal agency acts in an "arbitrary and capricious" manner when it (1) attempts to regulate based "on factors … Congress has not intended it to consider"; (2) "entirely fail[s] to consider an important aspect of the [regulatory] problem"; (3) "offers an explanation for" its conduct "that runs counter to the evidence before" it; or (4) reaches a determination that "is so implausible … it could not be ascribed to a difference in view or … agency expertise." *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983).

279. The 2024 Rule's gender-identity mandates are arbitrary and capricious.

280. *First*, HHS failed to offer a "reasoned explanation" of the 2024 Rule's departure from the historic understanding of "sex" as used in Title IX. *Encino Motorcars, LLC v. Navarro*, 579 U.S. 211, 221 (2016). If anything, HHS's history of shifting positions on the meaning of "sex" demonstrates that HHS's purported *Bostock*-based justifications for the 2024 Rule are nothing more than "contrived reasons" offered to support a predetermined result. *Dep't of Commerce v. New York*, 139 S. Ct. 2551, 2576 (2019).

281. *Second*, the 2024 Rule never defines "sex." But without defining sex, HHS cannot reasonably explain what it means to discriminate "on the basis of" sex. HHS failed to adequately consider that in medical practice, as in education, differences between the sexes are a biological reality. HHS's 2020 Rule previously conceded as much: It explained that preferencing ideology over science "risk[s] masking clinically relevant, and sometimes vitally important, information"—like potential pregnancy in a transgender male. 85 Fed. Reg. at 37,189-90. But the 2024 Rule does not engage with the biological and medical realities that sex has in medical care, or the "life-and-death" risks associated with ignoring them. *Id.* at 37,190.

282. *Third*, by requiring healthcare professionals to ignore the medical and biological differences between the sexes at the risk of causing "more than *de minimis* harm," 89 Fed. Reg. at 37,593-94, the 2024 Rule will prevent healthcare professionals from using their reasonable medical judgment and will damage the doctor-patient relationship, thus undermining the provision of sound medical treatment on a wide scale.

283. *Fourth*, HHS's decision to embrace the WPATH Standards and Endocrine Society Guideline runs counter to the evidence before the agency. Commenters presented numerous studies and scholarly reviews showing that the "standards" advocated by these medical interest

groups are based on weak evidence and that there is no consensus on gender-transition interventions. The 2024 Rule instead replaces science-based medicine with ideology-driven mandates.

284. *Fifth*, HHS "entirely failed to consider an important aspect of the problem," *State Farm*, 463 U.S. at 43, namely the numerous negative side effects associated with "gender-affirming care." HHS never acknowledged, for example, that its preferred "standard of care" may render an untold number of minors and adults infertile for the rest of their lives. HHS needs to consider that disadvantage.

285. *Sixth*, HHS failed to consider whether requiring providers to "affirm" gender ideology and to use patients' preferred pronouns instead of ones that are biologically accurate will drive providers out of Medicaid and CHIP. The potential shortage of providers and its harm to Medicaid and CHIP recipients is an "important aspect of the problem" that HHS failed to consider. *State Farm*, 463 U.S. at 43.

CLAIM V
Relief Under the Declaratory Judgment Act, 28 U.S.C. § 2201, and 5 U.S.C. § 706
Claim for Declaratory Judgment Against Defendants

286. Plaintiffs incorporate by reference all preceding paragraphs.

287. The Declaratory Judgment Act provides that in the case of an "actual controversy within its jurisdiction … any court of the United States, upon the filing of an appropriate pleading, may declare the rights and other legal relations of any interested party seeking such declaration." 28 U.S.C. § 2201(a).

288. This case presents an actual controversy. The 2024 Rule governs Plaintiff States, meaning its requirements affect their legal rights. Moreover, the imminent enforcement of HHS's

2024 Rule threatens to force recipients of federal HHS funding in the Plaintiff States to choose between violating state law and abandoning consistent policies or losing their federal funding.

289. The controversy arises in this Court's jurisdiction, as it relates to questions of federal law. Venue is proper, as the State of Mississippi resides in this District. 28 U.S.C. § 1391(e).

290. As set forth throughout this Complaint, the Plaintiff States have filed an appropriate pleading to have their rights declared. The Court can resolve this controversy by declaring that Plaintiff States have a right to receive HHS funding notwithstanding their respective state laws and administrative rules prohibiting gender-transition interventions for minors and excluding gender-transition interventions from their state-sponsored health insurance plans.

PRAYER FOR RELIEF

An actual controversy exists between the parties that entitles the Plaintiff States to declaratory and injunctive relief. Plaintiffs respectfully request that this Court:

a) Enter a stay of the Final Rule's effective date under 5 U.S.C. § 705 and a preliminary injunction enjoining Defendants, and any other agency or employee of the United States, from enforcing or implementing the portions of the 2024 Rule that exceed HHS's statutory authority, violate the APA, and violate the U.S. Constitution;

b) Enter a judgment declaring, pursuant to 28 U.S.C. § 2201 and 5 U.S.C. § 706, that: (i) the Final Rule's gender-identity mandates are unlawful; (ii) the Final Rule is arbitrary and capricious; and (iii) the Plaintiff States, their political subdivisions, and their resident healthcare providers may continue receiving federal financial assistance notwithstanding any failure to adhere to the 2024 Rule's unlawful requirements;

c) Set aside and vacate the Final Rule, pursuant to 5 U.S.C. § 706, on the basis that it exceeds HHS's statutory authority and violates the APA and the U.S. Constitution;

d) Permanently enjoin Defendants and their officers, agents, servants, employees, attorneys, and any other persons who are in active concert or participation with Defendants from withholding federal financial assistance from the Plaintiff States, their political subdivisions, and their resident healthcare providers and health insurance issuers for refusing to comply with the Final Rule's unlawful requirements;

e) Grant any and all other relief the Court deems just and proper.

Date: May 30, 2024.

Respectfully submitted,

LYNN FITCH
Attorney General

/s/ *Scott G. Stewart*
SCOTT G. STEWART
Solicitor General
Bar No. 106359
JUSTIN L. MATHENY
Deputy Solicitor General
Bar No. 100754
MISSISSIPPI ATTORNEY GENERAL'S OFFICE
P.O. Box 220
Jackson, Mississippi 39205
(601) 359-3680
scott.stewart@ago.ms.gov
justin.matheny@ago.ms.gov

Counsel for Plaintiff State of Mississippi

JONATHAN SKRMETTI
Attorney General & Reporter

/s/ *Steven J. Griffin*
STEVEN J. GRIFFIN
Senior Counsel for Strategic Litigation
Bar No. 103218
WHITNEY HERMANDORFER*
Director of Strategic Litigation
HARRISON GRAY KILGORE*
Strategic Litigation Counsel and Assistant Solicitor General
OFFICE OF THE TENNESSEE ATTORNEY GENERAL
P.O. Box 20207
Nashville, Tennessee 37202
(615) 741-3491
steven.griffin@ag.tn.gov
whitney.hermandorfer@ag.tn.gov
harrison.kilgore@ag.tn.gov

*Motion for Pro Hac Vice admission under L.R. 83.1(d) forthcoming.

Counsel for Plaintiff State of Tennessee

STEVE MARSHALL
Attorney General

/s/ *A. Barrett Bowdre*
A. BARRETT BOWDRE*
Principal Deputy Solicitor General
OFFICE OF THE ATTORNEY GENERAL
STATE OF ALABAMA
501 Washington Avenue
P.O. Box 300152
Montgomery, Alabama 36130-0152
(334) 242-7300
barrett.bowdre@AlabamaAG.gov

*Motion for admission *Pro Hac Vice* under Local Rule 83.1(d) forthcoming

Counsel for Plaintiff State of Alabama

CHRISTOPHER CARR
Attorney General

/s/ *Stephen Petrany*
STEPHEN PETRANY*
Solicitor General
OFFICE OF THE ATTORNEY GENERAL OF GEORGIA
Georgia Department of Law
40 Capitol Square SW
Atlanta, Georgia 30334
(404) 458-3408
spetrany@law.ga.gov

*Motion for admission *Pro Hac Vice* under Local Rule 83.1(d) forthcoming

Counsel for Plaintiff State of Georgia

THEODORE E. ROKITA
Attorney General

/s/ *James A. Barta*
JAMES A. BARTA*
Solicitor General
INDIANA ATTORNEY GENERAL'S OFFICE
IGCS – 5th Floor
302 W. Washington St.
Indianapolis, Indiana 46204
(317) 232-0709
James.Barta@atg.in.gov

*Motion for admission *Pro Hac Vice* under Local Rule 83.1(d) forthcoming

Counsel for Plaintiff State of Indiana

KRIS W. KOBACH
Attorney General

/s/ *Jay Rodriguez*
JAY RODRIGUEZ*
Assistant Attorney General
OFFICE OF THE KANSAS ATTORNEY GENERAL
120 SW 10th Ave.
Topeka, Kansas 66612
(785) 296-4733
jay.rodriguez@ag.ks.gov

*Motion for admission *Pro Hac Vice* under Local Rule 83.1(d) forthcoming

Counsel for Plaintiff State of Kansas

RUSSELL COLEMAN
Attorney General

/s/ *Justin D. Clark*
JUSTIN D. CLARK*
Civil Chief
LINDSEY R. KEISER*
Assistant Attorney General
COMMONWEALTH OF KENTUCKY
OFFICE OF THE ATTORNEY GENERAL
700 Capital Avenue, Suite 118
Frankfort, Kentucky 40601
(502) 696-5300
justind.clark@ky.gov
lindsey.keiser@ky.gov

*Motion for admission *Pro Hac Vice* under Local Rule 83.5 forthcoming

Counsel for Plaintiff Commonwealth of Kentucky

ELIZABETH B. MURRILL
Attorney General

/s/ *J. Benjamin Aguiñaga*
J. BENJAMIN AGUIÑAGA*
Solicitor General
OFFICE OF THE LOUISIANA ATTORNEY GENERAL
1885 N. 3rd St.
Baton Rouge, Louisiana 70802
aguinagab@ag.louisiana.gov

*Motion for admission *Pro Hac Vice* under Local Rule 83.1(d) forthcoming

Counsel for Plaintiff State of Kansas

MICHAEL T. HILGERS
Attorney General

/s/ *Lincoln J. Korell*
LINCOLN J. KORELL*
Assistant Solicitor General
OFFICE OF THE ATTORNEY GENERAL OF NEBRASKA
2115 State Capitol
Lincoln, Nebraska 68509
(402) 471-2682
lincoln.korell@nebraska.gov

*Motion for admission *Pro Hac Vice* under Local Rule 83.1(d) forthcoming

Counsel for Plaintiff State of Nebraska

DAVE YOST
Attorney General

/s/ T. Elliot Gaiser
T. ELLIOT GAISER
Solicitor General
OFFICE OF THE OHIO ATTORNEY GENERAL
30 East Broad Street, 17th Floor
Columbus, Ohio 43215
(614) 466-8980
Thomas.Gaiser@ohioago.gov

*Motion for admission *Pro Hac Vice* under Local Rule 83.1(d) forthcoming

Counsel for the State of Ohio

GENTNER DRUMMOND
Attorney General

/s/ Garry M. Gaskins, II
GARRY M. GASKINS, II*
Solicitor General
OKLAHOMA OFFICE OF THE ATTORNEY GENERAL
313 NE 21st Street
Oklahoma City, Oklahoma 73105
(405) 312-2451
Garry.Gaskins@oag.ok.gov

*Motion for admission *Pro Hac Vice* under Local Rule 83.1(d) forthcoming

Counsel for the State of Ohio

ALAN WILSON
Attorney General

/s/ *Thomas T. Hydrick*
THOMAS T. HYDRICK*
Assistant Deputy Solicitor General
OFFICE OF THE ATTORNEY GENERAL OF SOUTH CAROLINA
1000 Assembly Street
Columbia, South Carolina 29201
(803) 734-4127
thomashydrick@scag.gov

*Motion for admission *Pro Hac Vice* under Local Rule 83.1(d) forthcoming

Counsel for Plaintiff State of South Carolina

MARTY J. JACKLEY
Attorney General

/s/ *Clifton Katz*
CLIFTON KATZ*
Assistant Attorney General
OFFICE OF THE ATTORNEY GENERAL
STATE OF SOUTH DAKOTA
1302 E. Hwy. 14, Suite #1
Pierre, South Dakota 57501
(605) 773-3215
clifton.katz@state.sd.us

*Motion for admission *Pro Hac Vice* under Local Rule 83.1(d) forthcoming

Counsel for Plaintiff State of South Dakota

JASON S. MIYARES
Attorney General

/s/ *Kevin M. Gallagher*
KEVIN M. GALLAGHER*
Principal Deputy Solicitor General
BRENDAN T. CHESTNUT*
Deputy Solicitor General
VIRGINIA ATTORNEY GENERAL'S OFFICE
202 North 9th Street
Richmond, Virginia 23219
(804) 786-2071
kgallagher@oag.state.va.us
bchestnut@oag.state.va.us

*Motion for admission *Pro Hac Vice* under Local Rule 83.1(d) forthcoming

Counsel for Plaintiff Commonwealth of Virginia

PATRICK MORRISEY
Attorney General

/s/ *Michael R. Williams*
MICHAEL R. WILLIAMS*
Principal Deputy Solicitor General
OFFICE OF THE ATTORNEY GENERAL OF
WEST VIRGINIA
State Capitol Complex
Building 1, Room E-26
Charleston, WV 25301
(304) 558-2021
michael.r.williams@wvago.gov

*Motion for admission *Pro Hac Vice* under Local Rule 83.1(d) forthcoming

Counsel for Plaintiff State of Virginia

Exhibit A

U.S. Dep't of Health & Human Servs., *Nondiscrimination in Health Programs and Activities*, 89 Fed. Reg. 37,522 (May 6, 2024) ("2024 Rule")

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*.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Background
A. Regulatory History
B. Overview of the Final Rule
II. Provisions of the Proposed Rule and Analysis and Responses to Public Comments
Subpart A—General Provisions
Purpose and Effective Date (§ 92.1)
Application (§ 92.2)
Treatment of the Title IX Religious Exception
Relationship to Other Laws (§ 92.3)
Definitions (§ 92.4)
Assurances Required (§ 92.5)
Remedial Action and Voluntary Action (§ 92.6)
Designation and Responsibilities of a Section 1557 Coordinator (§ 92.7)
Policies and Procedures (§ 92.8)
Training (§ 92.9)
Notice of Nondiscrimination (§ 92.10)
Notice of Availability of Language Assistance Services and Auxiliary Aids and Services (§ 92.11)
Data Collection
Subpart B—Nondiscrimination Provisions
Discrimination Prohibited (§ 92.101)
Subpart C—Specific Applications to Health Programs and Activities
Meaningful Access for Individuals With Limited English Proficiency (§ 92.201)
Effective Communication for Individuals With Disabilities (§ 92.202)
Accessibility for Buildings and Facilities (§ 92.203)
Accessibility of Information and Communication Technology for Individuals With Disabilities (§ 92.204)
Requirement To Make Reasonable Modifications (§ 92.205)
Equal Program Access on the Basis of Sex (§ 92.206)
Nondiscrimination in Health Insurance Coverage and Other Health-Related Coverage (§ 92.207)
Prohibition on Sex Discrimination Related to Marital, Parental, or Family Status (§ 92.208)
Nondiscrimination on the Basis of Association (§ 92.209)
Nondiscrimination in the Use of Patient Care Decision Support Tools (§ 92.210)
Nondiscrimination in the Delivery of Health Programs and Activities Through Telehealth Services (§ 92.211)
Subpart D—Procedures
Enforcement Mechanisms (§ 92.301)
Notification of Views Regarding Application of Federal Religious Freedom and Conscience Laws (§ 92.302)
Procedures for Health Programs and Activities Conducted by Recipients and State Exchanges (§ 92.303)
Procedures for Health Programs and Activities Administered by the Department (§ 92.304)
III. Change in Interpretation—Medicare Part B Funding Meets the Definition of Federal Financial Assistance; Responses to Public Comment
IV. CMS Amendments
A. Medicaid and Children's Health Insurance Program (CHIP)
B. Programs of All-Inclusive Care for the Elderly (PACE)
C. Insurance Exchanges and Group and Individual Health Insurance Markets
1. Comments and Responses to 45 CFR 147.104(e), 155.120(c), 155.220(j), 156.125(b), 156.200(e), and 156.1230(b)
2. Health Insurance Exchanges
a. Non-Interference With Federal Law and Nondiscrimination Standards (45 CFR 155.120)
b. Federally-Facilitated Exchange Standards of Conduct (45 CFR 155.220)
c. Essential Health Benefits Package: Prohibition on Discrimination (45 CFR 156.125)
d. QHP Issuer Participation Standards (45 CFR 156.200)
e. Direct Enrollment With the QHP Issuer in a Manner Considered To Be Through the Exchange (45 CFR 156.1230)
3. Prohibition of Discrimination—Group and Individual Health Insurance Markets Guaranteed Availability of Coverage (45 CFR 147.104)
V. Executive Order 12866 and Related Executive Orders on Regulatory Review
A. Regulatory Impact Analysis
a. Baseline Conditions
b. Costs of the Final Rule

c. Total Quantified Costs
3. Discussion of Benefits
4. Analysis of Regulatory Alternatives to the Final Rule
B. Regulatory Flexibility Act—Final Small Entity Analysis
1. Entities That Will Be Affected
a. Physicians
b. Pharmacies
c. Health Insurance Issuers
d. Local Government Entities
2. Whether the Rule Will Have a Significant Economic Impact on Covered Small Entities
C. Executive Order 12250 on Leadership and Coordination of Nondiscrimination Laws
D. Paperwork Reduction Act
1. ICRs Regarding Assurances (§ 92.5)
2. ICRs Regarding Section 1557 Coordinator (§ 92.7) and Training (§ 92.9)
3. ICRs Regarding Notice of Nondiscrimination (§ 92.10) and Notice of Availability of Language Assistance Services and Auxiliary Aids and Services (§ 92.11)
E. Assessment of Federal Regulation and Policies on Families

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.'').

rulemakings.[6] However, in light of the comments received, OCR has determined that it is reasonable to allow additional time for covered entities to comply with certain procedural requirements. The additional time will provide covered entities with the opportunity to properly designate a Section 1557 Coordinator and designee(s) (as applicable); develop and tailor to their respective organization's policies and procedures; train relevant staff; and develop their required notices. For this reason, we are adopting phased-in applicability dates for certain provisions, as reflected in the chart at the end of this section.

Comment: Some commenters requested that OCR allow for temporary safe harbors for covered entities' compliance with certain aspects of the final rule. Specifically, commenters suggested that the final rule allow for an 18-month good faith safe harbor for covered entities currently operating in accordance with the 2016 Rule language access requirements, particularly the notice and tagline requirements at former 45 CFR 92.8.

Response: OCR declines to grant safe harbors for covered entities that are or have been operating in accordance with the 2016 Rule's notice and tagline requirements. Granting such a safe harbor would fail to recognize the importance of this final rule's requirement. The Notice of Availability of Language Assistance Services and Auxiliary Aids and Services (''Notice of Availability'') at § 92.11 requires notice of auxiliary aids and services in addition to language assistance services, which we have now revised to reflect a delayed applicability date of one year from the effective date. This revised applicability date reasonably allows enough time for covered entities to come into compliance with the Notice of Availability provision.

Comment: Comments from organizational health insurance issuers generally supported the Proposed Rule's delayed applicability date for provisions that require changes to health insurance or group health plan coverage benefits or benefit design, which proposed a delayed applicability date of the first day of the first plan year beginning on or after the year following the effective date of the final rule's publication in the **Federal Register**.[7] One commenter generally requested that OCR provide flexibility for plans depending on when the rule is finalized. Another commenter specifically requested that OCR consider allowing a temporary safe harbor compliance exception for group health plans and health insurance issuers of group health insurance coverage so that plan design changes for non-calendar-year plans may be implemented the first day of the new plan year occurring on or after January 1, 2024.

Response: OCR is cognizant that health insurance issuers and group health plans develop their health insurance coverage and other health-related coverage benefit designs in advance of the plan year that the coverage is offered. Accordingly, we are including a delayed applicability date to the extent that the final rule's provisions require changes to health insurance coverage or other health-related coverage, including group health plan coverage benefit design for health insurance coverage or other health-related coverage that is newly subject to certain provisions of § 92.207 (Nondiscrimination in health insurance coverage and other health-related coverage). In such circumstances, the final rule's applicability date is the first day of the first plan year beginning on or after January 1, 2025. This delayed applicability date applies equally to health insurance issuers and group health plans that are offering calendar-year and non-calendar-year plans. For example, a newly covered group health plan eligible for the delayed applicability date that offers a non-calendar year plan effective July 1, 2024, would have until the following plan year, effective July 1, 2025, to comply with the benefit design requirements, as July 1, 2025, would be the first day of the first plan year beginning on or after January 1, 2025.

The 2020 Rule remains in effect until the effective date of this final rule. In the interim, covered entities that are subject to the 2020 Rule must continue to comply with the parts of the 2020 Rule that remain in effect. Notwithstanding the repeal of the former § 92.207 (2016 Rule), the 2020 Rule prohibits discrimination in health insurance coverage that receives Federal financial assistance. Consistent with the 2020 Rule preamble, OCR interprets and enforces section 1557 under the 2020 Rule to prohibit discrimination in benefit design in health insurance coverage and other health-related coverage that receive Federal financial assistance.[8]

As such coverage is currently prohibited from having discriminatory benefit designs, the obligation to comply with this final rule's § 92.207(b)(1) through (5) does not require a delayed applicability date. Therefore, we have revised the delayed applicability date for § 92.207(b)(1) through (5) under § 92.1(b) to reflect that the delayed applicability date is for health insurance coverage and other health-related coverage that are not already subject to this part as of the date of publication of this final rule. Because § 92.207(b)(6) (most integrated setting) describes a category of prohibited benefit design features that OCR is not explicitly enforcing under the 2020 Rule, OCR will not enforce this provision until the delayed applicability of the first day of the first plan year beginning on or after January 1, 2025. The delayed applicability date for all provisions of § 92.207 is in effect for covered health insurance coverage and other health-related coverage that are not subject to the 2020 Rule as of the date of publication of this final rule and are therefore newly subject to this final rule.

Examples of health insurance coverage or other health-related coverage subject to the 2020 Rule (and thus the benefit design provisions under § 92.207(b)(1) through (5) as of July 5, 2024) include but are not limited to Medicare Advantage plans, Medicare Part D plans, Medicaid managed care plans, and qualified health plans.[9] For complaints received prior to January 1, 2025 alleging discrimination related to benefit design, OCR will examine whether the health insurance coverage or other health-related coverage is subject to the 2020 Rule. If OCR determines the coverage was subject to

[6] The 2016 Rule's effective date was 60 days after publication of the final rule, with the exception of the provisions on health insurance and benefit design, which went into effect the first day of the first plan year following the effective date. 81 FR 31375. The 2020 Rule's effective date was 60 days after publication, with no exceptions. 85 FR 37160.

[7] The term ''group health plan'' is generally used to refer to a health benefit arrangement that is a distinct legal entity and can also be used to refer to the underlying health coverage or benefits. For ease of reference, this document uses the term ''group health plan'' when referring the plan as a distinct legal entity and uses the term ''group health plan coverage'' to refer to the underlying health coverage or benefits provided by the group health plan.

[8] *See* 85 FR 37160 (stating the rule prohibits age discrimination, ''including [in] health plan marketing and benefit design''); *id.* at 37177 (stating that HHS ''will enforce vigorously Section 1557's prohibition on discrimination on the basis of disability against all covered entities, including when discrimination is alleged to have taken place in benefit design''); *id.* at 37201 (''OCR will examine carefully any allegations of discrimination by health insurance issuers, including through benefit design.'').

[9] Qualified health plans are covered by the 2020 Rule as a program or activity administered by an entity established under title I of the ACA (*i.e.,* an Exchange), pursuant to § 92.3(a)(3). *See* 85 FR 37174. Qualified health plans are also subject to the 2020 Rule to the extent they receive Federal financial assistance. *Id.*

the 2020 Rule, the covered entity providing the coverage is responsible for complying with the specific benefit design provisions of § 92.207(b)(1) through (5) on July 5, 2024. In its review of such complaints, OCR will consider the nature of the challenged benefit design feature and whether it would have been prohibited under the 2020 Rule. For example, a Medicare Advantage plan that imposes additional cost-sharing for health services related to a particular disease but not for other diseases would be investigated as potentially discriminatory under the 2020 Rule and under this final rule as of its general 60-day effective date. However, if a Medicare Advantage plan contains a potentially discriminatory design feature related to integration, OCR would not investigate such an allegation under this final rule unless the alleged discrimination took place after the delayed applicability date of the first day of the first plan year beginning on or after January 1, 2025.

Further, OCR clarifies that any covered entity offering health insurance coverage or other health-related coverage subject to the delayed applicability date for benefit design is still required to comply with all other provisions of this final rule, as of the general effective dates and specific applicability dates set forth under § 92.1(b).

Summary of Regulatory Changes

For the reasons set forth in the Proposed Rule and considering the comments received, we are finalizing the provisions in § 92.1(a) as written and amending § 92.1(b), with modifications.

In § 92.1(b), we have included a table that clearly provides the applicability date for each provision. It appears below:

Section 1557 Requirement and provision	Date by which covered entities must comply
§ 92.7 Section 1557 Coordinator	Within 120 days of effective date.
§ 92.8 Policies and Procedures	Within one year of effective date.
§ 92.9 Training	Following a covered entity's implementation of the policies and procedures required by § 92.8, and no later than one year of effective date.
§ 92.10 Notice of nondiscrimination	Within 120 days of effective date.
§ 92.11 Notice of availability of language assistance services and auxiliary aids and services.	Within one year of effective date.
§ 92.207(b)(1) through (5) Nondiscrimination in health insurance coverage and other health-related coverage.	For health insurance coverage or other health-related coverage that was not subject to this part as of the date of publication of this rule, 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) Nondiscrimination in health insurance coverage and other health-related coverage.	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), (c) Use of patient care decision support tools.	Within 300 days of effective date.

Application (§ 92.2)

Proposed § 92.2 addressed the application of this regulation. OCR proposed in § 92.2(a) to apply the final rule, except as otherwise provided in the regulation, 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 program or activity administered by a title I entity. Title I entities include State Exchanges (including those on the Federal platform) and Federally-facilitated Exchanges, both of which were created under title I of the ACA.[10]

In § 92.2(b), we proposed that this regulation would not apply to an employer with regard to its employment practices, including the provision of employee health benefits. We noted that, although the 2016 and 2020 Rules applied to employment in very limited circumstances, OCR determined that the proposed approach would minimize confusion among individuals seeking relief under Federal Equal Employment Opportunity laws and would promote clarity regarding the filing and processing of employment discrimination complaints. We stated our belief that, as is the case with employment discrimination complaints generally, concerns regarding the provision of employee health benefits are best resolved by our Federal partners.

In § 92.2(c), we proposed that if any provision of this regulation is held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, it shall be severable from this part and not affect the remainder thereof or the application of the provision to other persons not similarly situated or to other, dissimilar circumstances.

We invited comment on the effects of the proposed scope of application of the regulation, including the application of this part to recipients of Federal financial assistance from executive agencies other than the Department; the application to programs and activities of the Department and other executive agencies; and the application to employment.

The comments and our responses regarding § 92.2 are set forth below.

Comment: Many commenters supported § 92.2(a), which commenters said would reinstate the scope of the section 1557 implementing regulation to that of the 2016 Rule and recognizes that section 1557 applies to Federal programs like Medicaid and Medicare, the State and Federal Marketplaces (referred to as ''Exchanges'' in this final rule) and the plans sold through them, as well as other commercial health plans if the issuer receives any form of Federal financial assistance. Commenters noted that ensuring section 1557 protections apply broadly to an array of entities and programs will ensure the greatest level of protection for individuals against discriminatory actions that may interfere with access to health care and health care coverage.

Many commenters noted that the Proposed Rule was consistent with congressional intent. These commenters noted that Congress was clear in extending nondiscrimination protections to a broad array of health programs and activities, and that section 1557 was intended to build and expand upon existing civil rights laws, while

[10] Section 1311 of the ACA (codified at 42 U.S.C. 18031) (establishing grants and requiring those grants to be used by States to create ''American Health Benefit Exchanges'') and section 1321(c) of the ACA (codified at 42 U.S.C. 18041(c)) (providing for the Secretary to establish an Exchange if a State elects not to establish an Exchange or fails to establish an Exchange under section 1311 of the ACA).

providing broad protection against discrimination in health care. These commenters further noted that Congress has repeatedly expressed that it intends civil rights laws to be broadly interpreted in order to effectuate their remedial purposes. Commenters also noted that the purpose of the ACA itself is to ensure broad access to and coverage of health care.

Response: We agree that section 1557 protections apply broadly and that this final rule is the best reading of the statute regarding the scope of applicability; as such, the 2022 NPRM properly identified those entities that are covered under section 1557.

Regarding plans sold through State and Federally-facilitated Exchanges, as discussed under the definition of ''Federal financial assistance'' at § 92.4, such plans are covered under this rule as a health program or activity when in receipt of Federal financial assistance, such as advance payments of the premium tax credit. This is consistent with the 2016 Rule. Further, as discussed under the definition of ''health program or activity'' at § 92.4, a health insurance issuer's other commercial health plans are covered under this final rule as part of the issuer's operations where the issuer is principally engaged in the provision or administration of any health projects, enterprises, ventures, or undertakings. For more information on the final rule's application to all operations of a health insurance issuer that is so principally engaged, please see the discussion below under the definition of ''health program or activity'' at § 92.4.

Comment: Some commenters requested that OCR clarify the extent to which a covered entity is required to oversee the section 1557 compliance of its vendors and subcontractors. For example, a health insurance issuer commented that an issuer should not be responsible for the discriminatory actions of a provider or facility with which the issuer has contracted for the provision of medical services. Another commenter requested clarification on when health insurance agents and brokers are subject to the rule, particularly when they are working under the auspices of a covered entity, such as an Exchange or a health insurance issuer. Other commenters suggested that subcontractors should be considered recipients by virtue of contracting with a recipient of Federal financial assistance.

Response: Health programs or activities may comprise more than one recipient of Federal financial assistance. For example, a primary recipient (or ''direct'' recipient) is an entity that accepts Federal financial assistance from a Federal agency. The direct recipient may then distribute the Federal financial assistance to a subrecipient (or ''indirect'' recipient) to carry out all or part of the health program or activity. Primary recipients and all subrecipients are covered and must comply with section 1557.[11] Under general civil rights principles, both the primary recipient and subrecipient are responsible for complying with applicable civil rights laws.[12] Therefore, if an entity receives Federal financial assistance—directly as a primary recipient or indirectly as a subrecipient—it would be a covered entity and responsible for complying with section 1557 and the part.

While both direct and indirect recipients must comply with section 1557 independently, a direct recipient may not absolve itself of its obligations by contracting with another entity to provide services or assistance for which it received Federal financial assistance or using an agent to do so.[13] Covered entities are responsible for the conduct of their subcontractors and cannot contract away their civil rights obligations through contractual arrangements with subcontractors. For example, section 1557 and the statutes referenced therein may cover a contractor that performs an essential function for the recipient, making the contractor itself a recipient. In *Frazier* v. *Board of Trustees,* 765 F.2d 1278, amended, 777 F.2d 329 (5th Cir. 1985), a case involving section 504, the court noted that the defendant hospital contracted out core medical functions, for which it received Federal financial assistance. The court ruled that this financial assistance to the hospital ''would not have been [provided] at all were it not for [the contractor's] performance as a de facto subdivision of [the hospital],'' and thus the contractor qualified as a recipient for purposes of section 504, *id.* at 1289–90.[14]

The obligation of health insurance agents and brokers as subcontractors is a fact-specific analysis depending on the contractual arrangement with a covered entity. If an Exchange or recipient, such as a health insurance issuer, contracts with an agent or broker to carry out responsibilities of the covered entity's health program or activity and uses Federal financial assistance to pay the agent or broker, then the agent or broker is a subrecipient and thus independently subject to all the provisions of section 1557. If a contractor does not receive Federal financial assistance—either as a primary recipient or subrecipient—it is not a recipient of Federal financial assistance and not subject to section 1557. We note that agents and brokers under contract with an Exchange could also be covered by the final rule as a health program or activity administered by a title I entity under § 92.2(a)(3). Conversely, if the agent or broker is assisting the public with purchasing health insurance coverage without any contractual arrangement on behalf of an Exchange or recipient and is not otherwise receiving Federal financial assistance, then they would not be considered subrecipients or subcontractors subject to the rule.

Comment: Some commenters stated that because the Federal Government now extensively subsidizes both medical care and health insurance coverage and other health-related coverage, the final rule will apply to practically all health care entities. They argued that because of this, it would be nearly impossible for medical professionals to work free of these regulations and, as a result, physicians and faith-based health care entities would effectively be barred from refusing to participate in pregnancy termination procedures.

Response: It has long been established that when an entity receives Federal funds, conditions may be placed on the receipt of those funds.[15] Not all providers receive Federal financial assistance; however, when they do, they must comply with applicable law. The

[11] For further discussion of this issue, *see* U.S. Dep't of Justice, Title VI Legal Manual, sec. V.D.4.

[12] Often, a recipient receives funds with the purpose and expectation that it will distribute the funds to one or more sub-grantees or indirect recipients. For example, in *Moreno* v. *Consol. Rail Corp.,* 99 F.3d 782 (6th Cir. 1996) (en banc), the U.S. Department of Transportation provided funds to the State of Michigan for use in upgrading railroad crossings. The state, in turn, provided these funds to Conrail. The Sixth Circuit found that Conrail was a recipient of Federal financial assistance, noting ''[i]t makes no difference, in our view, that the Federal funds of which Conrail is the recipient come to it through the State of Michigan rather than being paid to it by the United States directly.'' *Id.* at 787.

[13] U.S. Dep't of Justice Title VI Legal Manual, Sec. V.D.5.

[14] *But see Rose* v. *Cahee,* 727 F. Supp. 2d 728, 739 (E.D. Wis. 2010) (court declined to follow *Frazier,* limiting coverage of the funding assistance nondiscrimination cover the contractor of a recipient requirement to those entities receiving the funds directly and that ''are in a position to choose whether to do so'').

[15] The Supreme Court has generally treated these civil rights statutes as enacted based on Congress's Spending Clause Power, which generally permits Congress to attach conditions to the receipt of Federal financial assistance. *See Barnes* v. *Gorman,* 536 U.S. 181, 189 n.3 (2002) (referring to the Rehabilitation Act as ''Spending Clause legislation''); *id.* at 185–86 (''Title VI invokes Congress's power under the Spending Clause, U.S. Const., Art. 1. § 8, cl. 1, to place conditions on the grant of federal funds.'').

rule, however, does not ban physicians and faith-based or other health care entities from refusing to participate in pregnancy termination procedures. On the contrary, 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).[16] In addition, the rule has been revised at § 92.3(c) to recognize 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.'' Further, in this final rule, the process regarding exemptions related to religious freedom and conscience protections has been clarified. *See* § 92.302.

Comment: Some commenters supported the restoration of section 1557's application to all health programs or activities administered by the Department under § 92.2(a)(2). These commenters noted that the 2020 Rule exempts from section 1557 most of the Department's programs and activities by limiting the application to only those programs and activities established under title I of the ACA. These commenters opined that such an interpretation is contrary to the statutory text, design, and intent of section 1557 and the ACA generally. Other commenters noted that consistently applying section 1557 requirements throughout various programs, including the Department's programs, creates continuity in the interpretation and implementation of nondiscrimination standards. However, some commenters stated that OCR did not provide adequate explanation as to why this change in application is necessary or appropriate.

Response: For the reasons discussed in the 2022 NPRM, 87 FR 47838, applying this rule to all health programs and activities administered by the Department, not just those programs and activities established under title I of the Act, is the best reading of the statutory text of section 1557. The statutory language provides that section 1557's discrimination prohibitions apply to ''any program and activity that is administered by an executive agency or any entity established under this title.'' 42 U.S.C. 18116(a). As discussed in the 2022 NPRM, the operative word, ''or,'' distinguishes programs and activities operated by an executive agency from those operated by a title I entity. 87 FR 47829. To the extent there is ambiguity in the interpretation, finalizing the rule as proposed better reflects the statutory language as well as Congress's intent.[17] The application of section 1557 to every health program or activity administered by the Department ensures that nondiscrimination standards are interpreted and applied as consistently and as broadly as possible and provides for application of nondiscrimination standards to the Department consistent with the entities to which it provides Federal financial assistance.

Comment: Some commenters noted that under the most straightforward reading of section 1557, the regulatory framework should encompass all of the Department's programs and activities, not just ''health'' programs and activities, and they suggested that the Department extend the regulation's protections accordingly.

Response: We appreciate commenters' views on this issue. As we noted in the 2022 NPRM, OCR considered applying the rule to all programs and activities of the Department and sought comment on this issue. 87 FR 47838. Based on comments received and additional consideration, we are applying the final rule to the Department's health programs and activities, rather than all the Department's programs and activities, at this time. The Department may consider future rulemaking at a later date. For this final rule, however, OCR has determined that it is appropriate to apply the rule to the Department's ''health'' programs and activities given that the ACA itself is principally related to health care and the entirety of this section 1557 rulemaking seeks to regulate ''health'' programs and activities.

Comment: Commenters supported the rule's application to programs and activities administered by title I entities under § 92.2(a)(3), stating it was consistent with statutory text, Congressional intent, and the nondiscrimination purpose of section 1557 and the ACA.

Response: Proposed § 92.2(a)(3) applied section 1557 to ''every program or activity administered by a title I entity.'' In the 2022 NPRM, 87 FR 47838, OCR explained that it was unnecessary to include the modifier ''health'' to programs or activities of a title I entity because title I entities already meet the definition of ''health program or activity'' as set forth under § 92.4. While this remains true, we have reevaluated the regulatory text of § 92.2(b)(3) and determined that it should be revised to add the modifier ''health'' to a title I entity's ''program or activity'' for consistency with our interpretation that section 1557 applies to the Department's ''health'' programs or activities, as discussed in the previous comment. This technical revision does not limit or alter the scope of § 92.2(b)(3)'s application to the programs or activities of a title I entity, as we articulated in the 2022 NPRM. 87 FR 47838.

Comment: A few commenters opined that the rule should apply broadly to recipients of Federal financial assistance from any executive agency, not just the Department. These commenters noted that nothing in the statute suggests that Congress intended to limit the scope of section 1557's application in such a way.

Response: It is OCR's longstanding position that section 1557's discrimination prohibition is not limited to recipients of Federal financial assistance from the Department, but rather covers recipients' health programs or activities regardless of the executive agency providing the funding.[18] However, the final rule only applies to recipients of HHS funding, which is consistent with OCR's delegation of authority to ''develop and direct implementation of the requirements of Section 1557 . . . *as applied to* the Department and recipients of the Department's funds.'' 85 FR 37242 (emphasis added). Other Federal agencies possess section 1557 enforcement responsibility for the health programs and activities they fund and administer.

Comment: Some commenters recommended that the Department provide a model for other agencies to craft their own, more inclusive, and

[16] The application of this final rule to covered entities with conscience or religious freedom objections are discussed more fully below in §§ 92.3 (Relationship to other laws) and 92.302 (Notification of views regarding application of Federal religious freedom and conscience laws).

[17] *See, e.g., Griffin* v. *Breckenridge,* 403 U.S. 88, 97 (1971) (civil rights statutes should be construed broadly); *U.S.* v. *Price,* 383 U.S. 787, 801 (1966) (same); *see also N. Haven Bd. of Educ.* v. *Bell,* 456 U.S. 512, 521 (1982) (''[I]f we are to give Title IX the scope that its origins dictate, we must accord it a sweep as broad as its language.''); S. Rep. No. 64, 100th Cong., 2d Sess. 5–7 (1988), reprinted in 1988 U.S.C.C.A.N. 3, 7–9 (statement of Sen. Humphrey stating that title VI should be interpreted as broadly as necessary to eradicate discriminatory practices in programs that Federal funds supported).

[18] *See* U.S. Health & Hum. Servs., Off. for Civil Rts., Memo. from Jocelyn Samuels, Director, to Directors of Federal Offices for Civil Rights (Nov. 5, 2015), *https://www.hhs.gov/sites/default/files/2015_11_04_fed_civil_rights_section_1557_memo_508.pdf.*

more protective rules for non-health-related programs in line with other applicable non-discrimination statutes.

Response: OCR appreciates this recommendation and reiterates its desire to work with other agencies as necessary and appropriate. OCR only has authority to apply section 1557 to HHS and recipients of Departmental Federal financial assistance. This rule does not apply to programs and activities of other agencies and OCR is unable to regulate other agencies.

Comment: A number of commenters disagreed with the non-application of the rule to employment practices under § 92.2(b). Commenters opined that the categorical exclusion of employers is inconsistent with section 1557's statutory text and creates confusion. Some commenters noted that an agency to whom a complaint is referred may not adequately address claims of discrimination, including those of dependents. Commenters further noted that other employment discrimination laws, such as title VII of the Civil Rights Act of 1964 (title VII), 42 U.S.C. 2000e *et seq.,* and the Age Discrimination in Employment Act of 1967 (ADEA), 29 U.S.C. 621–634, require a claimant to file a complaint with a Federal agency before privately enforcing their rights. Some commenters requested that OCR clarify that this provision concerns only the processing of administrative complaints by OCR and that OCR's decision not to apply this rule to employment practices does not preclude employees from vindicating their section 1557 rights in court.

Other commenters supported proposed § 92.2(b) and noted it will help prevent wasteful duplication with other Federal laws and agencies that already cover unlawful employment discrimination.

Response: The Supreme Court has recognized that section 1557 authorizes a private right of action.[19] This final rule applies only to OCR's administrative enforcement of section 1557. As discussed in the 2022 NPRM, 87 FR 47838, we believe that other Federal agencies are better equipped to review and adjudicate employee health benefits and allegations of employment discrimination given their expertise under the existing employment nondiscrimination statutes they enforce.

Comment: Some commenters noted that employers are usually the sponsors of group health plans and raised concerns that OCR could therefor find an employer liable under section 1557 for the employee benefits it provides.

Response: This rule does not apply to employers or other plan sponsors with regard to their employment practices, including the provision of employee health benefits. As stated in the preamble to the Proposed Rule, 87 FR 47838, previous rules had limited application to employment. The 2016 Rule provided that employment practices included hiring, firing, promotions, or terms and conditions of employment, and therefore the 2016 Rule did not apply to those practices. However, the 2016 Rule applied to an employer with regard to its employee health benefit programs under certain circumstances as set forth under former § 92.208. The 2020 Rule, which repealed the 2016 Rule's reference to employment practices and employee health benefit programs, reverted to enforcing the statutorily referenced nondiscrimination statutes through their existing regulations. As discussed above, the Proposed Rule proposed to exclude employment practices, which included the provision of employee health benefit programs. OCR also recognizes that other sponsors of group health plans undertake similar employment practices, such as the provision of employee health benefits. For example, a joint board of trustees for a multi-employer group health plan (also known as a Taft-Hartley plan) consists of representatives from employers and unions to sponsor a group health plan, and similarly engages in the provision of an employee health benefit like employers that sponsor a single-employer plan. To ensure consistent application of the rule to entities engaging in similar employment functions, the final rule revises § 92.2(b) to provide that the rule does 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 employment practices, including the provision of employee health benefits.

Group health plans, employers, and sponsors of group health plans are generally separate entities from one another that require a separate, fact-specific analysis to determine whether each entity is subject to this rule. We discuss the relationship between plan sponsors, such as employers, joint boards of trustees or similar bodies, associations, and other groups that are plan sponsors of multi-employer Taft-Hartley plans or multiple-employer welfare arrangements (MEWAs), and group health plans in more detail in the discussion of group health plans in the ''health program or activity'' definition discussion under § 92.4.

Comment: Some commenters stated that ongoing litigation surrounding section 1557 and previous iterations of OCR's section 1557 regulations, as well as agency course reversal on multiple occasions, has created confusion and compliance burden on covered entities. They urged the Department to reinforce the importance of severability under § 92.2(c) amongst the various regulatory provisions of the rule.

Response: We appreciate concerns around ongoing litigation and agency reversal, and the resulting inconsistency in requirements. OCR has attempted to answer questions and reduce confusion raised by the previous versions of the rule. While this final rule is similar to the 2016 Rule, it provides greater clarity regarding section 1557's statutory protections from discrimination along with various provisions to help alleviate burdens while providing certainty about covered entities' obligations when compared to the 2016 and 2020 Rules. We believe the final rule enhances the benefits to individuals and minimizes the burdens on covered entities.

OCR notes that § 92.2(c) provides that if any provision of this part is held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, it shall be severable from this part and not affect the remainder thereof or the application of the provision to other persons not similarly situated or to other, dissimilar circumstances. For example, if a court were to invalidate the final rule's Notice of availability of language assistance services provision (Notice of Availability) at § 92.11, all other provisions of the rule would remain in effect, as those provisions ''could function sensibly without the stricken provision.'' [20] Thus, if the rule's Notice of Availability provision were invalidated, OCR would not enforce that provision. Or, for example, if a court were to invalidate the final rule's Section 1557 Coordinator requirement at § 92.7, OCR would not require covered entities to fill this position as part of their compliance with this final rule, while otherwise enforcing other administrative requirements such as the Policies and procedures requirement at § 92.8 and the Notice of nondiscrimination requirement at § 92.10.

Comment: Some commenters requested that the final rule restore the 2016 Rule clarification that any age

[19] *Cummings* v. *Premier Rehab Keller, P.L.L.C.,* 596 U.S. 212 (2022) (section 1557 provides a private right of action because the incorporated statutes do so).

[20] *MD/DC/DE Broadcasters Ass'n* v. *F.C.C.,* 253 F.3d 732, 734 (D.C. Cir. 2001) (internal quotations omitted).

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).

it is appropriate to adopt language suggested by the commenters.

Summary of Regulatory Changes

For the reasons set forth in the Proposed Rule and considering the comments received, we are finalizing the definition of ''auxiliary aids and services'' as proposed in § 92.4, with one technical correction in paragraph (1) to provide the correct cite for the title II definition of ''qualified interpreter'' by striking ''36.303(b)'' and replacing it with ''36.104.''

Companion. We proposed to define the ''companion'' to mean ''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.'' This term appeared in the 2016 Rule and has not been changed substantively.

Comment: Many commenters support the inclusion of the term ''companion'' in the definitions section of the regulation, and some highlighted that companions for persons with certain disabilities, such as brain injuries and other conditions with cognitive effects, as well as individuals with sensory disabilities, are critical to effective communication of very sensitive and important medical information. Some commenters suggested that OCR clarify that such companions should be selected by the patient and not the provider.

Response: OCR appreciates the commenters' support for inclusion of this definition. OCR declines to add additional language, as the definition of ''companion'' in this rule is consistent with the definition from 28 CFR 35.160(a)(2) under title II of the ADA, and with the proposed definition in OCR's notice of proposed rulemaking for section 504 at proposed 45 CFR 84.10.[35] We agree that the individual with a disability should be the one to determine who shall serve as their companion absent any concerns of conflict of interest or suspected abuse.

Summary of Regulatory Changes

For the reasons set forth in the Proposed Rule and considering the comments received, we are finalizing the definition of ''companion'' as proposed in § 92.4, without modification.

Federal financial assistance. We proposed to define the term ''Federal financial assistance'' to include grants, loans, and other types of assistance from the Federal Government, consistent with the definition of the term in the section 504 and the Age Act implementing regulations at 45 CFR 84.3(h) and 91.4, respectively. We also proposed to specifically include credits, subsidies, and contracts of insurance, in accordance with the statutory language of section 1557. 42 U.S.C. 18116(a). Consistent with the 2016 Rule, we proposed including a clause to clarify that Federal financial assistance includes Federal financial assistance that the Department plays a role in providing or administering.

Comment: Many commenters supported the inclusion of credits, subsidies, contracts of insurance, and grants and loans in this definition. Some commenters recommended expanding the definition of ''Federal financial assistance'' to include Federal disaster relief loans and pandemic relief grants and loans.

Response: The definition of ''Federal financial assistance'' includes funds provided by the Federal Government, including grants and loans, along with Federal financial assistance that the Department plays a role in providing or administering. Because the types of funds raised by the commenters already fall under the longstanding definition of ''Federal financial assistance,'' and the inclusion of specific types of Federal financial assistance would cause unnecessary confusion and may be read as unintentionally limiting the scope of what constitutes Federal financial assistance, we decline to revise the definition.

Comment: Some commenters requested that OCR clarify whether tax-exempt status is considered Federal financial assistance.

Response: OCR appreciates commenters' request for clarity. Generally, tax benefits, tax exemptions, tax deductions, and most tax credits are not included in the statutory or regulatory definitions of Federal financial assistance. *See, e.g.,* 42 U.S.C. 2000d–1 (title VI); 28 CFR. 42.102(c) (Department of Justice Title VI Regulation). Most courts that have considered the issue have concluded that typical tax benefits are not Federal financial assistance because they are not contractual in nature.[36]

Comment: Many commenters supported the definition's inclusion of 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.'' [37] A commenter expressed support for this definition's application to funds extended via programs operated by States under section 1332 State Innovation Waivers, 42 U.S.C. 18052, which could include funds extended to issuers receiving reimbursement through reinsurance programs and entities participating in programs intended to modify or replace Exchanges that would otherwise be within the scope of section 1557.

Response: OCR appreciates these comments and believes it is important to explicitly state in regulatory text that funds that the Department plays a role in providing or administering constitute Federal financial assistance. As explained in the Proposed Rule, 87 FR 47843, this includes funds the Department administers with the Department of the Treasury under the ACA, including advance payments of the premium tax credit, cost-sharing reductions,[38] and pass-through funding available to States with approved section 1332 waivers. Thus, an issuer participating in any Exchange that receives advance payments of the premium tax credit or cost-sharing reductions on behalf of any of its enrollees is receiving Federal financial assistance from the Department.

Section 1332 of the ACA permits a State to apply for a section 1332 waiver to pursue innovative strategies for providing residents with access to high quality, affordable health insurance while retaining the basic protections of the ACA. Section 1332 waiver funds constitute Federal financial assistance and States receiving such funds are recipients. As discussed in the 2022 NPRM, section 1332 allows States to apply to HHS and the Department of the Treasury to waive certain ACA requirements in the individual and small group markets if the waiver satisfies certain statutory

[35] *See* 88 FR 63392, 63465 (Sept. 14, 2023) (proposing to define ''companion'' consistent with ADA title II regulations).

[36] *See, e.g., Paralyzed Veterans of Am.* v. *Civil Aeronautics Bd.,* 752 F.2d 694, 708–09 (D.C. Cir. 1985); *Johnny's Icehouse, Inca* v. *Amateur Hockey Ass'n of Ill., Inc.,* 134 F. Supp. 2d 965, 971–7297172 (N.D. Ill. 2001); *Chaplin* v. *Consol. Edison Co.,* 628 F. Supp. 143, 145–46 (S.D.N.Y. 1986).

[37] *See* section 1412 of the ACA, codified at 42 U.S.C. 18082 (Advance determination and payment of premium tax credits and cost-sharing reductions).

[38] The Department is not currently making cost-sharing reduction payments to issuers. *See* Memo. from Eric Hargan, Acting Sec'y, U.S. Dep't of Health & Hum. Servs., to Seema Verma, Admin'r, Ctrs. for Medicare & Medicaid Servs. (enclosing Attorney General Jeff Sessions' legal opinion, dated October 11, 2017, regarding cost-sharing reduction payments) (Oct. 12, 2017), *https://www.hhs.gov/sites/default/files/csr-payment-memo.pdf.* If the Department begins making cost-sharing reduction payments in the future, such payments would be considered Federal financial assistance.

requirements.[39] 87 FR 47843. For example, under this provision, several States have utilized section 1332 waivers to introduce new or expanded plan options to consumers that lower premiums and/or expand access to coverage, or implemented reinsurance programs to lower premiums and stabilize the individual or small group market by compensating issuers for eligible high-cost claims for enrollees with significant medical costs. These State reinsurance programs use section 1332 pass-through funding to reimburse eligible issuers for high-cost enrollees. These States establish reimbursement eligibility criteria for issuers under the State's reinsurance program, which may include payments to issuers offering coverage both on and off the Exchange. Health insurance issuers receiving payments through a State's section 1332 waiver reinsurance program are subrecipients and therefore subject to section 1557. To the extent a State's waiver utilizes pass-through funding for provider reimbursement those providers would also be subrecipients and subject to section 1557; however pass-through funding received by individual consumers would not be subject to section 1557.

Summary of Regulatory Changes

For the reasons set forth in the Proposed Rule and considering the comments received, we are finalizing the definition of ''Federal financial assistance'' as proposed in § 92.4, without modification.

Health program or activity. OCR proposed to adopt a definition of ''health program or activity.'' In paragraph (1), we proposed defining health program or activity to mean any project, enterprise, venture, or undertaking to provide or administer health-related services, health insurance coverage, or other health-related coverage; provide assistance to persons in obtaining health-related services, health insurance coverage, or other health-related coverage; provide clinical, pharmaceutical, or medical care; engage in health research; or provide health education for health care professionals or others.

In paragraph (2), we proposed further defining ''health program or activity'' to include all of the operations of any entity principally engaged in the provision or administration of health projects, enterprises, ventures, or undertakings described in paragraph (1) (''principally engaged''). We proposed that whether such entities are administered by a government or a private entity, all of their operations would be covered under this part.[40] We also invited comment on the circumstances under which a group health plan might receive funds that could be considered Federal financial assistance from the Department, including the type and prevalence of funds received that could be considered Federal financial assistance under this part.

Comment: Commenters expressed a variety of views regarding the application of the rule to health insurance issuers as health programs or activities and the rule's application to all their operations when principally engaged in any project, enterprise, venture, or undertaking to provide or administer health-related services, health insurance coverage, or other health-related coverage, as set forth under paragraph (2) of the definition of ''health program or activity.''

Many commenters supported the inclusion of health insurance issuers and coverage of all their operations when so principally engaged. These commenters argued the 2020 Rule's approach, which applies to health insurance issuers only to the extent a specific plan receives Federal financial assistance, is contrary to the text of section 1557, the CRRA, and the broad remedial intent of Congress in enacting the ACA to ensure access to health insurance. Specifically, commenters argued the 2020 Rule is arbitrary and contrary to the plain language of section 1557, which applies to ''any health program or activity, *any part of which is receiving Federal financial assistance*'' (emphasis added) and specifically includes three examples of Federal financial assistance that refer to health insurance (''credits, subsidies, or contracts of insurance''). 42 U.S.C. 18116(a). This statutory language, commenters argued, affirms that Congress intended section 1557 to apply to the entire health program or activity, not just the parts that directly receive Federal financial assistance. Commenters noted that the statutory text should be construed broadly and stated that the Proposed Rule's application to health insurance will align with the application to all operations of other covered entities.

Many commenters raised objections to the 2020 Rule's provision at § 92.3(b) that covers all operations of an entity only when principally engaged ''in the business of providing *healthcare*'' (emphasis added), in combination with § 92.3(c) that specified a health insurance issuer was not considered to be principally engaged in the business of providing health care merely by virtue of providing health insurance, which resulted in the 2020 Rule not covering all operations of a recipient health insurance issuer. Commenters stated this approach was inconsistent with Congress's approach in the CRRA, which supports an expansive interpretation of section 1557's application to cover all operations of a recipient if any part of it receives Federal financial assistance. Specifically, one commenter asserted that the section 1557 statute's use of the CRRA language ''program or activity'' and ''any part of which,'' coupled with the statute's reference to title VI, title IX, section 504, and the Age Act, demonstrate Congress's intent to adopt the same broad application for section 1557. Commenters also argued the 2020 Rule's approach is inconsistent with the text of section 1557, which broadly applies to health programs or activities and is not limited to the delivery of health care. Commenters challenged the 2020 Rule's contention that health insurance is not health care, arguing that health insurance issuers are in fact engaged in the business of health care and that other parts of the ACA support this position. For example, ''health care entity'' is defined to include ''a health insurance plan'' under 42 U.S.C. 18113(b) and 42 U.S.C. 300gg–91(b)(1) defines ''health insurance coverage'' to mean benefits consisting of medical care.'' Among other things, commenters cited to section 1551 of the ACA, 42 U.S.C. 18111, which specifies that, unless otherwise indicated, the definitions in 42 U.S.C. 300gg–91 apply to title I of the ACA.

Conversely, other commenters urged the Department to retain the 2020 Rule's approach, asserting that the CRRA limits the scope of section 1557 with regard to all operations of a program or activity to only those that are ''principally engaged in the business of providing . . . *healthcare*'' (emphasis added).

Others argued that the Proposed Rule's application to health insurance is

[39] Sections 1332(a)–(b) of the ACA, codified at 42 U.S.C. 18052(a)–(b). States with approved waivers have specific terms and conditions (STCs) pursuant to which the state must also comply with all applicable Federal statutes relating to nondiscrimination, including section 1557. *See, e.g.,* Ctrs. for Medicare & Medicaid Servs., approval of New Jersey's extension application for a section 1332 State Innovation Waiver, STC 4 (Aug. 15, 2023), *https://www.cms.gov/files/document/1332-nj-extension-approval-letter-stcs-final.pdf.*

[40] *See, e.g., Fain* v. *Crouch,* 545 F. Supp. 3d 338, 343 (S.D.W. Va. 2021), *rehearing en banc granted,* No. 22–1927 (4th Cir. Apr. 12, 2023) (oral argument held Sept. 21, 2023) (argued with *Kadel* v. *Folwell,* No. 22–1721) (holding that defendant health plan was, ''by virtue of its acceptance of Federal assistance under its Medicare Advantage program,'' required to comply with section 1557 ''under its entire portfolio'').

too broad and should not apply to all operations of a health insurance issuer, particularly its lines of business that do not receive Federal financial assistance. Specifically, commenters noted that because health insurance issuers participate in some types of health insurance that receive Federal financial assistance and other types that do not, the Proposed Rule would require compliance even in activities that do not benefit from Federal financial assistance. Commenters opined that this interpretation goes beyond the scope of Congressional intent, where Congress did not apply the protections to *any* entity engaging in health programs and activities, but only to those health programs and activities that specifically receive Federal financial assistance. One organization asserted that the Proposed Rule could result in health insurance issuers incurring substantial costs and declining to participate in or withdrawing from the Exchanges, the Medicaid managed care market, or the Medicare Advantage market, resulting in reduced coverage options in those markets.

Response: In re-evaluating the 2020 Rule's interpretation of ''health program or activity'' as it relates to health insurance and in deciding to add a definition of ''health program or activity,'' OCR considered a number of factors, including the plain language of section 1557, the context of its placement within the ACA, long-standing civil rights principles, and relevant case law.

The 2020 Rule does not include a definition of ''health program or activity,'' but rather addresses the term under § 92.3, the scope of application section. The 2020 Rule provides that ''health program or activity'' encompasses ''all of the operations of entities principally engaged in the business of providing *healthcare*'' (emphasis added) and specifies that a health insurance issuer is not considered to be principally engaged in the business of providing health care merely by virtue of providing health insurance. 45 CFR 92.3. The 2020 Rule further provides that for entities not principally engaged in the business of providing health care, their operations are only covered under the rule to the extent such operation is a health program or activity that receives Federal financial assistance. 45 CFR 92.3(b). Thus, the 2020 Rule limits OCR's jurisdiction over health insurance issuers to only their plans that directly receive Federal financial assistance. This is in contrast to the 2016 Rule, which defined ''health program or activity'' to include all the operations of entities principally engaged in health services, health insurance coverage, or other health-related coverage, including health insurance issuers, at former 45 CFR 92.4.

OCR agrees with commenters' assessment that the Proposed Rule's approach to the inclusion of health insurance coverage and other health-related coverage in the definition of ''health program or activity'' is most consistent with section 1557's statutory text and Congressional intent. The statutory text demonstrates Congress's clear intent to apply section 1557 to health insurance coverage and other health-related coverage. This statutory text does not support the 2020 Rule's limiting ''health program or activity'' to encompass all of the operations of only those entities principally engaged in the business of providing ''healthcare.'' Under the plain language of the statute, section 1557 applies to any ''health'' program or activity not ''healthcare'' program or activity. And the provision of health insurance coverage and other health-related coverage is plainly classified under the term ''health.'' Private health insurance issuers exercise significant control over enrollees' access to health care and play a critical role in the business of health care, as insurance is an essential component of ensuring that people receive care in the current health care system. For example, a district court opinion on this issue held that a health insurance issuer, by virtue of being the ''gatekeeper'' to the plaintiff's health services, qualified as a '' 'health program' that Congress intended to rid of discrimination.'' [41]

Further, as we discussed in the Proposed Rule, 87 FR 47845, the fact that Congress placed section 1557 in title I of the ACA, a title that predominantly regulates health insurance coverage and other health-related coverage with the purpose of increasing access to care and reducing discriminatory insurance practices, demonstrates Congress's intent for section 1557 to protect individuals from discrimination in health insurance coverage and other health-related coverage.

While not dispositive, we do appreciate commenters' thoughts on whether health insurance issuers are in fact engaged in the business of providing health care. Commenters among other things, cited to section 1551 of the ACA, which specifies that, unless otherwise indicated, the definitions in 42 U.S.C. 300gg–91 shall apply with respect to title I of the ACA. Section 300gg–91(b)(1) defines the term ''health insurance coverage'' as ''benefits consisting of *medical care (provided directly, through insurance or reimbursement,* or otherwise and including items and services paid for as medical care) . . . .'' (Emphasis added.) The 2020 Rule specifies that ''medical care'' as used in that provision is limited to the ''amounts paid for'' certain medical services and that a health insurance issuer is not considered to be principally engaged in the business of providing health care merely by virtue of providing health insurance. However, the text of section 1557 does not support the 2020 Rule's position that the rule applies only to the business of providing ''healthcare.''

OCR found commenters' concerns regarding the negative consequences that could result from the Proposed Rule's scope of application to insurance issuers unpersuasive given the lack of information provided to substantiate their concerns. For example, one commenter cited to Exchange participation statistics that indicated certain issuers have limited or no Exchange participation.[42] However, the statistics do not demonstrate the reason for such issuers' lack of participation or provide evidence that an issuer's decision not to participate in an Exchange was due to apprehension that section 1557 would apply to its activities that did not receive Federal financial assistance.

The application of civil rights laws to all operations of an entity receiving Federal financial assistance is not new and did not originate with section 1557. For more than 35 years, under the CRRA, a recipient of Federal financial assistance that accepts Federal funds in any part of its program has been required to comply with title VI, section 504, and the Age Act in ''all of the[ir] operations.'' [43] The CRRA specifies that the entire program or activity, as defined in that statute, is required to comply with title VI, section 504, and the Age Act if any part of the program or activity receives Federal financial

[41] *Fain* v. *Crouch,* 545 F. Supp. 3d 338, 342–43 (S.D.W. Va. 2021) (finding '' 'health program or activity' under Section 1557 necessarily includes health insurance issuers'' and holding that defendant health plan was, ''by virtue of its acceptance of federal assistance under its Medicare Advantage program,'' required to comply with section 1557 ''under its entire portfolio''), *rehearing en banc granted,* No. 22–1927 (4th Cir. Apr. 12, 2023) (oral argument held Sept. 21, 2023) (argued with *Kadel* v. *Folwell,* No. 22–1721).

[42] Mark Farrah Assocs., *http://www.markfarrah.com* (statistics compiled using data from the National Association of Insurance Commissioners, the California Department of Managed Health Care, and CMS).

[43] Public Law 100–259, 102 Stat. 29 (Mar. 1988), codified at 20 U.S.C. 1687; 29 U.S.C. 794(b); 42 U.S.C. 2000d–4(a); 6107(4).

assistance. We note that the terms ''program'' and ''program or activity'' predate the CRRA in the underlying civil rights statutes, and the legislative history of the CRRA indicates that Congress did not believe it was enacting a new definition, but rather overturning an overly narrow construction of the term by the Supreme Court and thereby restoring what Congress and the executive branch had previously understood to be a broad, institution-wide application of the term ''program.'' *See* S. Rep. No. 100–64 (1987). OCR maintains that Congress adopted a similar approach in section 1557 by specifying in the statute that section 1557 applies when ''any part of'' the health program or activity receives Federal financial assistance.[44] Entities must comply with civil rights laws just as they must comply with any other State or Federal law that is applicable to their operations.

The 2020 Rule states it was applying the CRRA's definition of ''program or activity'' to cover all operations of entities under section 1557 only when they are ''principally engaged in the business of providing healthcare.'' We received some comments in support of the approach in that rulemaking, and while we appreciate the importance of the CRRA in shaping the interpretation of the scope of Federal civil rights protections under title VI, section 504, title IX, and the Age Act, it is not applicable here. Section 1557 employs the term ''program or activity'' without adopting by reference the CRRA or any of the underlying civil rights statutes. The 2020 Rule erred in applying the CRRA to narrow the application of section 1557 by excluding a significant portion of the health insurance industry. If Congress had intended to limit section 1557 to entities principally engaged in the business of providing ''healthcare,'' it could have provided as such in the statute. Instead, the statute expressly modified ''program or activity'' with ''health,'' without requiring that that entity be ''principally engaged in the business of providing healthcare.''

While Congress did not incorporate the CRRA into section 1557 wholesale, it stated that section 1557 applies to ''any health program or activity, *any part of which* is receiving Federal financial assistance.'' 42 U.S.C. 18116(a) (emphasis added). By modifying ''program or activity'' with ''health,'' and noting a health programs or activity is covered if ''any part'' of it receives Federal financial assistance, it is reasonable to infer that Congress intended the term ''health program or activity'' to be interpreted broadly and to include all of that entity's operations, if the entity that receives Federal funding is principally engaged in the provision or administration of health insurance coverage or other health-related coverage. And because ''health program and activity'' is undefined in the section 1557 statute, it is also reasonable to infer that those health programs or activities include health-related services, health insurance coverage, or other health-related coverage.

Comment: One commenter argued that, because the CRRA delineates the scope of coverage of section 1557's underlying civil rights statutes, failing to include this limitation in the final rule would expand the notion of Federal financial assistance to ultimate beneficiaries of the funding and would have significant effect on other civil rights laws dealing with funding, including title VI, title IX, and others.

Response: The commenter's concerns regarding interference with the longstanding principle that Federal civil rights laws do not apply to direct, unconditional assistance to ultimate beneficiaries are unsupported. Ultimate beneficiaries are the intended class of private individuals receiving Federal aid,[45] a concept that is not impacted or modified under this rulemaking. In fact, the definition of ''recipient'' in the final rule at § 92.4 adopts standard language that explicitly states that the term ''does not include any ultimate beneficiary.''

Comment: OCR received comments specifically related to the rule's application to health insurance issuers' other products and lines of business that do not receive Federal financial assistance, such as health insurance coverage sold off the Exchange, excepted benefits, short-term, limited-duration insurance, and third party administrator activities.

Response: These comments are addressed in the *Scope of Application* discussion under § 92.207 (Nondiscrimination in health insurance coverage and other health-related coverage).

Comment: Some commenters, including an association representing State insurance regulators, critiqued OCR's ''fungibility of funds'' rationale for including all operations of recipients that are principally engaged in the provision or administration of health insurance coverage. These commenters argued it is inappropriate to consider funding to be fully fungible in the context of health insurance, where issuers justify their premiums based on expected costs in a particular market, not across all operations, and thus Federal financial assistance for one type of coverage does not actuarially support or subsidize an issuer's operations in other markets. Commenters noted that entities have a myriad of corporate structures, and that Federal funds received by one legal entity might not be shared with sibling entities in unrelated business ventures. Commenters pointed to the 2016 Rule's analysis regarding liability of third party administrators, where OCR discussed that a third party administrator that is legally separate from an issuer is unlikely to be covered under the rule. 81 FR 31433.

Conversely, other commenters agreed with OCR's fungibility of funds rationale, and argued that Federal financial assistance going to any part of a health program or activity necessarily benefits the entity receiving such funds as a whole. These commenters noted that a narrower construction, in which nondiscrimination rules apply only to part of a recipient, makes it easier for discriminatory actors to structure their operations to evade responsibility and frustrates the purpose of the statute.

Response: As commenters noted, OCR discussed the fungibility of funds rationale as one means of support for the interpretation that all of a health insurance issuer's operations will be covered by the final rule when the health insurance issuer receives Federal financial assistance. *See* 87 FR 47844. However, we note that reliance on this rationale is not necessary to support OCR's interpretation that this final rule applies to all of the operations of a recipient that is ''principally engaged,'' as discussed above. Under the best reading of the statutory text, where an entity receives Federal financial assistance and that entity is ''principally engaged in the provision or administration of any health projects, enterprises, ventures, or undertakings described in paragraph (1)'' of the definition of ''health program or activity,'' the whole entity is defined as a health program or activity covered under section 1557 and must comply with the final rule.

We acknowledge that covered entities may structure their businesses in a variety of ways. Unless an entity that is principally engaged can demonstrate that part of their operations is truly a separate legal entity, as discussed below, a recipient that is principally engaged is liable for all its operations under the final rule.

[44] *Compare* CRRA, 20 U.S.C. 1687(4) (''any part of which is extended Federal financial assistance'') *with* section 1557, 42 U.S.C. 18116 (''any part of which is receiving Federal financial assistance'').

[45] U.S. Dep't of Justice, Title VI Legal Manual, section V.C.2.F.

Comment: One organization recommended that OCR explicitly identify patient billing and collections activities as ''health programs or activities'' by amending the definition to add a new paragraph (1)(vi) as follows: ''provide or administer billing and collections services for health-related services, including providing assistance to persons to obtain financial help or counseling.''

Response: This final rule, consistent with OCR's other civil rights implementing regulations, prohibits covered entities—directly or through contractual or other arrangements—from discriminating in patient billing and collection activities related to health programs and activities. For example, a hospital's in-house administration of billing would be covered and any contractual arrangement for collections of debt would also be covered. We decline to add the recommended language because it is unnecessary.

Comment: Many commenters strongly supported the Proposed Rule's explicit inclusion of health research in the definition of ''health program or activity.'' Some commenters recommended updating paragraph (1)(iv) to include ''clinical'' research for clarity and to update paragraph (2) to include: ''clinical trial sites including wherever potential clinical trial participants are screened or recruited'' in the list of entities considered ''principally engaged.'' In addition, other commenters recommended that OCR provide technical guidance in what ''inclusion'' in clinical research looks like and how it can be achieved through nondiscriminatory research protocols.

Response: OCR supports the request to include clinical research in the definition of ''health program and activity,'' and have revised paragraph (1)(iv) accordingly. Clinical research is the comprehensive study of the safety and effectiveness of the most promising advances in patient care, and is different from laboratory research as it involves people who volunteer to help the field better understand medicine and health.[46] However, we decline to add reference to physical sites, as the jurisdiction applies to the health program or activity regardless of where it takes place and whether it can be said to take place at a site at all. For example, if a hospital receives a grant from the National Institutes of Health to conduct a clinical study on the effects of Tuberous Sclerosis Complex, the hospital is prohibited from discriminating in its screening and recruitment activities wherever they take place, such as at the hospital itself, at community health fairs, online, or at the home of a hospital researcher who is working out of their own home.

Comment: One organizational commenter requested that OCR clarify section 1557's application to health research projects and activities to explicitly recognize that health research is conducted to answer specific questions, and that research protocols may target or exclude certain populations where nondiscriminatory justifications show that such criteria are appropriate, consistent with the 2016 Rule preamble.

Response: Consistent with the 2016 Rule, OCR does not intend the inclusion of health or clinical research within the definition of ''health program or activity'' to alter the fundamental nature in which research projects are designed, conducted, or funded. 81 FR 31385. As in the 2016 Rule, we note that criteria in research protocols that target or exclude certain populations are warranted where nondiscriminatory justifications establish that such criteria are appropriate with respect to the health or safety of the subjects, the scientific study design, or the purpose of the research. *See* 81 FR 31385.

Comment: Some commenters recommended that OCR narrow the definition of ''health program or activity'' to exclude programs and activities unrelated to health. These commenters also requested that OCR clarify what ''any project, enterprise, venture or undertaking to provide or administer health-related services'' means. For example, these commenters were unclear whether a health-related venture may include such things as vitamin manufacturing.

Response: The final rule applies to health programs and activities that receive Federal financial assistance from the Department (or that are administered by the Department or a title I entity) and does not apply generally to programs and activities that are unrelated to health. However, where an entity is principally engaged as set forth in paragraph (2) of the definition of ''health program or activity,'' all operations of the covered entity must comply with the final rule. This applies even where the covered entities' other operations are not necessarily health-related.

Though not an exhaustive list, ''health-related service'' would include the provision of medical, dental, and pharmaceutical care; preventive health services; physical, occupational, or speech therapy; behavioral health care; clinical trials; and transportation to and from such services when necessary to facilitate access to other health-related services.[47] Should an entity engaged in commercial vitamin manufacturing receive Federal financial assistance from the Department, OCR would conduct an analysis as to whether the program or activity in question meets the definition of ''health program or activity.''

Comment: A few commenters urged the Department to expressly list Medicaid programs, Children's Health Insurance Program (CHIP), or the Basic Health Program in its definition for ''health program or activity.''

Response: The 2016 Rule included Medicaid programs, CHIP and the Basic Health Program in its definition of ''health program or activity'' at former 45 CFR 92.4. As stated in the preamble to the 2022 NPRM, these entities would be covered in their entirety as operations of State or local health agencies and we sought comment on whether such programs should be explicitly referenced in the regulatory language. 87 FR 47844. For clarity and to reduce confusion, OCR accepts the recommendation to include State Medicaid programs, CHIP, and the Basic Health Program in paragraph (2) of the definition of ''health program or activity.''

Comment: Numerous commenters objected to the 2022 NPRM's proposal to not explicitly include group health plans[48] in the list of entities considered to be principally engaged in paragraph (2) of the ''health program or activity''

[46] John Hopkins Medicine, Research, *Understanding Clinical Trials, Clinical Research: What Is It?, https://www.hopkinsmedicine.org/research/understanding-clinical-trials/clinical-research-what-is-it.html.*

[47] *See, e.g.,* 42 CFR 431.53 (requiring a state Medicaid plan to specify that the Medicaid agency will ensure ''necessary transportation for beneficiaries to and from providers'').

[48] ''Group health plan'' is defined in the Employee Retirement Income Security Act (ERISA) as an employee welfare benefit plan to the extent that the plan provides medical care (as defined in paragraph (2) and including items and services paid for as medical care) to employees or their dependents (as defined under the terms of the plan) directly or through insurance, reimbursement, or otherwise. Such term shall not include any qualified small employer health reimbursement arrangement (as defined in 26 U.S.C. 9831(d)(2)). 29 U.S.C. 1191b(a)(1); *see also* 42 U.S.C. 300gg–91(a)(1). ''Employee welfare benefit plan'' is defined in ERISA as any plan, fund, or program which was heretofore or is hereafter established or maintained by an employer or by an employee organization, or by both, to the extent that such plan, fund, or program was established or is maintained for the purpose of providing for its participants or their beneficiaries, through the purchase of insurance or otherwise, (A) medical, surgical, or hospital care or benefits, or benefits in the event of sickness, accident, disability, death or unemployment, or vacation benefits, apprenticeship or other training programs, or day care centers, scholarship funds, or prepaid legal services, or (B) any benefit described in 29 U.S.C. 186(c) (other than pensions on retirement or death, and insurance to provide such pensions). 29 U.S.C. 1002(1).

definition. Expressing concerns that this would result in confusion that the rule excludes group health plans, commenters urged OCR to reinstate the 2016 Rule's approach by expressly including group health plans in the definition of ''health program or activity.'' Former 45 CFR 92.4.

Commenters further suggested that the rule clarify that group health plans are covered entities when the group health plan itself receives Federal financial assistance or when the employer sponsoring the group health plan receives Federal financial assistance, such as through an Employer Group Waiver Plan (EGWP) or Retiree Drug Subsidy (RDS) plan. Some commenters argued that an employer and a group health plan should not be treated as distinct entities for purposes of section 1557 jurisdiction, and that group health plans should be considered indirect recipients of Federal financial assistance when the employer receives Federal funds.

Other commenters stated that employers are usually the sponsors of group health plans and were concerned that OCR's case-by-case analysis may find an employer liable under section 1557 based on the employee benefits it provides. Several commenters expressed concerns with OCR's proposed approach to conduct a case-by-case review to determine whether a group health plan is a covered entity and requested that OCR provide additional clarity on when employers and group health plans are liable under the rule.

Response: Commenters' concerns that group health plans would never be subject to the rule if they are not expressly included in the definition of ''health program or activity'' are unwarranted. The list of entities included as principally engaged, at paragraph (2), is not exhaustive. The fact that a group health plan is not expressly included in paragraph (2) does not affect the determination of whether a group health plan is principally engaged under this definition. As group health plans provide or administer group health coverage, they would be operating a health program or activity under the rule and would be subject to this rule if in receipt of Federal financial assistance. Further, recipient group health plans, like health insurance issuers, would be considered to be principally engaged in the provision or administration of health insurance coverage or other health-related coverage, meaning all their operations would be covered.

In the 2022 NPRM, we declined to expressly include group health plans in the definition of ''health program or activity'' in an attempt to reduce confusion because many group health plans do not receive Federal financial assistance. 87 FR 47845. It remains OCR's understanding that many group health plans do not receive Federal financial assistance, and thus we decline commenters' request to add group health plans to the non-exhaustive list of entities that are considered principally engaged that is provided in paragraph (2) of the definition of ''health program or activity.''

A group health plan that receives Federal financial assistance itself is distinct from other entities that might separately receive Federal financial assistance, such as the plan sponsor of the group health plan or the third party administrator administering the plan. As such, a group health plan does not necessarily become a covered entity under this rule by virtue of the plan sponsor or third party administrator's receipt of Federal financial assistance. Single employers that are plan sponsors of single-employer group health plans and joint boards of trustees or similar bodies, associations, and other groups that are plan sponsors of multiemployer Taft-Hartley plans or multiple employer welfare arrangements (MEWAs) do not become covered entities under the rule due to their employment practices, including the provision of employee health benefits. Later in this section, we address how OCR will determine whether related business entities are considered separate legal entities under section 1557.

When OCR receives a complaint alleging discrimination related to a group health plan, we will conduct a fact-specific analysis to determine if the group health plan is a recipient or subrecipient of Federal financial assistance. We decline to take the position that a group health plan is an indirect recipient of Federal financial assistance whenever the plan sponsor receives Federal financial assistance. Determining whether an entity is an indirect recipient requires a fact-specific inquiry.[49]

Entities that receive Federal financial assistance from the Department for an EGWP or RDS plan would be subject to this rule, though we note that employers and other plan sponsors are not subject to this rule with regard to their employment practices, pursuant to § 92.2(b). This includes when the Federal financial assistance received is for their employee health benefits. For more information about employer and plan sponsor liability, see the previous discussion under § 92.2(b).

In addition, as noted in the Proposed Rule, covered entities that contract with a group health plan could be subject to this rule themselves, regardless of the group health plan's liability. For instance, recipient health insurance issuers may be covered under this rule when offering health insurance coverage to a fully-insured group health plan or when providing third party administrator services for a self-funded group health plan.[50] We also noted in the Proposed Rule at 87 FR 47845 that even if a group health plan is not subject to section 1557, group health plans may be subject to other Federal nondiscrimination requirements.[51]

Comment: Some commenters urged OCR to expressly include pharmacy benefit managers in the definition of ''health program or activity.'' Commenters argued it was important to do so because pharmacy benefit managers play a significant role in developing and administering prescription drug benefits, and section 1557 can serve to prevent certain practices that may result in discriminatory access to medications, such as coverage criteria, utilization management practices, limitations on

[49] *See, e.g., Doe One* v. *CVS Pharmacy, Inc.,* No. 18–CV–01031–EMC, 2022 WL 3139516, slip op. at 7, 9 (N.D. Cal. Aug. 5, 2022) (analyzing whether defendant pharmacy benefit manager is an indirect recipient of Federal financial assistance from defendant pharmacy chain and, relying on the section 1557 statute and 2020 Rule, holding that CVS Pharmacy, Inc. is principally engaged in the business of health care and all of its operations are covered by section 1557, including its pharmacy benefit managers Caremark, L.L.C. and Caremark PCS Health, L.L.C.).

[50] *See, e.g., Tovar* v. *Essentia Health,* 857 F.3d 771, 778 (8th Cir. 2017) (holding that a third party administrator could be liable under section 1557 for damages arising from discriminatory terms in a self-funded employer-provided health plan if the third party administrator provided the employer with a discriminatory plan document, notwithstanding the fact that the employer subsequently adopted the plan and maintained control over its terms); *C.P.* v. *Blue Cross Blue Shield of Ill.,* No. 20–cv–6145, 2022 WL 17788148, *7–9 (W.D. Wash. Dec. 19, 2022) (relying on the section 1557 statute because the ''2020 Rule is contrary to the statutory law, and the rule appears to be arbitrary, capricious and contrary to law,'' and holding that a health insurance issuer acting as a third party administrator for a self-funded employer-provided plan is a covered entity under section 1557, regardless of whether the discriminatory exclusion originated with the third party administrator, and ERISA's requirement that decisions be made in accordance with the plan documents is no defense as ERISA expressly provides that it is not to be construed to invalidate or impair Federal laws like section 1557).

[51] For example, group health plans and health insurance issuers offering group or individual health insurance coverage are generally prohibited from establishing any rule for eligibility, benefits, or premiums or contributions that discriminates based on any health factor. 26 U.S.C. 9802; 29 U.S.C. 1182; 42 U.S.C. 300gg–4; 26 CFR 54.9802–1; 29 CFR 2590.702; 45 CFR 146.121, 147.110.

where medicines can be dispensed, and high out of pocket costs.

Response: We decline to list pharmacy benefit managers expressly in paragraph (2) of the definition of ''health program or activity.'' Pharmacy benefit managers are entities that manage prescription drug benefits for issuers, group health plans, Medicare Part D drug plans, and other payers, such as State Medicaid programs (collectively known as ''payers'').[52] In their role of administering prescription drug benefits on behalf of payers, pharmacy benefit managers develop drug formularies and related policies, create pharmacy networks, reimburse pharmacies for patients' prescriptions, negotiate rebates and fees with drug manufacturers, process enrollees' claims and appeals, and review drug utilization, among other things.[53] These activities constitute the operation of health programs and activities under section 1557.

If pharmacy benefit managers receive Federal financial assistance from the Department, either directly or indirectly, they are subject to this rule. Further, if they are principally engaged under paragraph (2), all their operations are covered by the rule.

As discussed previously, the fact that a type of entity—such as a pharmacy benefit manager—is not expressly included in the definition of ''health program or activity'' does not mean that those entities are excluded from the rule or could never be subject to section 1557 jurisdiction. Even if a pharmacy benefit manager does not receive direct Federal financial assistance, we note that the three largest pharmacy benefit managers are integrated with large health insurance or pharmacy companies, and thus could be covered under the rule as part of the operations of a health program or activity receiving Federal financial assistance.[54]

Determining whether a pharmacy benefit manager is subject to the rule as part of the operations of a recipient health program or activity is a fact-specific analysis based on the corporate structure of the entity.

Comment: Commenters requested that OCR provide more clarity on how it will analyze whether corporate subsidiaries and related business entities are subject to section 1557 as part of a covered entity's operations. Specifically, some commenters were concerned about health insurance issuers that receive Federal financial assistance avoiding responsibility through use of subsidiaries in their other activities, such as third party administrators or pharmacy benefit managers. Conversely, other commenters expressed concerns that the rule would apply too broadly to an issuer's business ventures that are unrelated to their federally funded activities.

Response: As stated throughout this section, if any part of a health program or activity receives Federal financial assistance and the entity administering said health program or activity is principally engaged as provided in paragraph (2), then all the operations of the recipient are subject to the rule. If a part of a recipient's operations is determined to be a separate legal entity independent from its federally funded activities, that part would not be subject to the rule. When determining whether an entity's subsidiaries or other entities are legally separate from the federally funded activities, OCR may consider—among other things—the organizational structure and the interrelatedness between the entities, such as the degree of common ownership, management, and control between the entities, and whether the entities share centralized control of labor relations; whether the entity has some ability to accept or reject the Federal funding or exercise controlling authority over a federally funded program;[55] and whether the purpose of the legal separation was to avoid liability or avoid the application of civil rights law requirements, meaning it is intended to allow the entity to continue to discriminate.[56]

Summary of Regulatory Changes

For the reasons set forth in the Proposed Rule and considering the comments received, we are finalizing the definition of ''health program or activity'' as proposed in § 92.4, with modifications. We have revised paragraph (1)(iv) to include clinical research, such that it will now read: ''Engage in health or clinical research.'' We have also revised paragraph (2) to include ''a State Medicaid program, Children's Health Insurance Program, and Basic Health Program'' as examples of entities principally engaged under this definition.

Information and communication technology (ICT). We proposed to define the term ''ICT'' to mean ''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.'' We also provided examples of ICT in our proposed definition.

Comment: Some commenters urged OCR to include ''electronic health records (EHRs)'' as an example within the definition of ''information and communication technology''.

Response: We appreciate that there are many different examples that can fit within the definition of ''information and communication technology''. We agree that EHRs meet the definition of ''information and communication technology''; however, we believe that it is unnecessary to specify this in the final rule.

Summary of Regulatory Changes

For the reasons set forth in the Proposed Rule and considering the comments received, we are finalizing the definition of ''information and communication technology'' as proposed in § 92.4, without modification.

Language assistance services. OCR proposed to define the term ''language assistance services'' to include, but not be limited to: (1) oral language assistance, including interpretation in non-English languages provided in-person or remotely by a qualified interpreter for a limited English proficient individual, and the use of services of qualified bilingual or multilingual staff to communicate directly with limited English proficient

[52] Staff of H. Comm. on Oversight & Reform, 117th Cong., *A View from Congress: Role of Pharmacy Benefit Managers in Pharmaceutical Markets,* 6 (Dec. 10, 2021), *https://oversight.house.gov/wp-content/uploads/2021/12/PBM-Report-12102021.pdf*.

[53] *See, e.g.,* U.S. Gov't Accountability Off., GAO 19–19–498, *Medicare Part D: Use of Pharmacy Benefit Managers and Efforts to Manage Drug Expenditures and Utilization,* 14–15, 39–42 (2019), *https://www.gao.gov/assets/gao-19-498.pdf*; Visante, *Pharmacy Benefit Managers (PBMs): Generating Savings for Plan Sponsors and Consumers,* pp. 3–4 (2023), *https://www.pcmanet.org/wp-content/uploads/2023/01/Pharmacy-Benefit-Managers-PBMs-Generating-Savings-for-Plan-Sponsors-and-Consumers-January-2023.pdf*.

[54] *See Doe One* v. *CVS Pharmacy, Inc.,* No. 18–cv–01031–EMC, 2022 WL 3139516, slip op. at 7, 9 (N.D. Cal., Aug. 5, 2022) (relying on the section 1557 statute and 2020 Rule when finding that CVS Pharmacy, Inc. is principally engaged in the business of health care and all of its operations are covered by section 1557, including its pharmacy benefit managers Caremark, L.L.C. and Caremark PCS Health, L.L.C.).

[55] *See id. Cf. Papa* v. *Katy Indus., Inc.,* 166 F.3d 937, 939 (7th Cir. 1999), *cert. denied,* 528 U.S. 1019 (1999) (ADA, ADEA); *Arrowsmith* v. *Shelbourne, Inc.,* 69 F.3d 1235, 1240–42 (2d Cir. 1995) (title VII); *Valesky* v. *Aquinas Acad.,* 2011 U.S. Dist. LEXIS 103791, No. 09–800 (W.D. Pa. Sept. 14, 2011) (title IX); *Russo* v *Diocese of Greenberg,* 2010 U.S. Dist. LEXIS 96338, No. 09–1169 (W.D. Pa. Sept. 15, 2010) (title IX, section 504); *Margeson* v. *Springfield Terminal Railway Co.,* 1993 U.S. Dist. LEXIS 12243, No. CIV.A. 91–11475–Z (D. Mass. Aug. 24, 1993) (section 504).

[56] *Papa* v. *Katy Indus., Inc.,* 166 F.3d 937, 941 (7th Cir. 1999), *cert. denied,* 528 U.S. 1019 (1999).

individuals; (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. The definitions of oral language assistance and written translation appeared in both the 2016 Rule at former § 92.4 and the 2020 Rule at § 92.101 in paragraphs (2)(i) and (iii) and have not been changed. The 2016 Rule did not explicitly include a written notice of availability of language assistance services in the definition of ''language assistance services,'' but rather included the term ''taglines,'' which was defined to mean ''short statements written in non-English languages that indicate the availability of language assistance services free of charge.''

Comment: One commenter recommended that the definition of ''language assistance services'' include assistance with form completion in another language. The commenter noted that many individuals with limited English proficiency (LEP) as well as many others (including older individuals and those with limited access to technology) have difficulty completing online forms to apply for health benefits or report life changes.

Response: OCR appreciates the suggestion and agrees it is critical for individuals with LEP to receive language assistance in completing forms. The definition of ''language assistance services'' is intended to provide a non-exhaustive list of some of the means by which a covered entity may facilitate such access—namely, oral interpretation and written translation as provided by qualified interpreters and translators, respectively. This definition works together with the requirements at § 92.201, which provide that covered entities must take reasonable steps to provide meaningful access to individuals with LEP. If an individual with LEP needs assistance with form completion in a covered health program or activity, a covered entity must provide language assistance services consistent with the requirements at § 92.201. OCR declines to modify the definition of ''language assistance services'' as suggested because the context in which services are provided is not germane to the definition.

Summary of Regulatory Changes

For the reasons set forth in the Proposed Rule and considering the comments received, we are finalizing the definition of ''language assistance services'' as proposed in § 92.4, with modification. As discussed in the following summary of regulatory changes to the proposed term ''limited English proficient individual,'' we are revising the term to ''individual with limited English proficiency'' in § 92.4.

Limited English proficient individual. OCR proposed to define the term ''limited English proficient individual'' to mean ''an individual whose primary language for communication is not English and who has a limited ability to read, write, speak, or understand English.'' Further, OCR proposed that a ''limited English proficient individual'' ''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).'' These definitions appeared in the 2016 Rule and have not changed substantively. Former 45 CFR 92.4 (2016 Rule). OCR sought comment on whether to use the term ''limited English proficient individual'' or ''individual with limited English proficiency'' throughout the rule.

Comment: Some commenters recommended the final rule adopt the language either ''people with limited English proficiency'' or ''individual with limited English proficiency'' instead of ''limited English proficient individual.''

Response: OCR agrees with this recommendation and OCR is finalizing the rule with the term ''individual with limited English proficiency'' throughout.

Comment: Several commenters supported the proposed definition's emphasis that an individual with LEP includes those who may be competent in English for certain types of communication but still have limited English proficiency for other purposes. Commenters explained that this will ensure providers and other covered entities understand that people who have some English competency may still need translated written materials. Commenters noted this will improve language access and have far-reaching consequences for patients who both seek and receive care, which will also reduce barriers to quality health care for individuals with LEP.

Response: We appreciate the support of inclusion of additional details around what it means to be ''limited English proficient'' and are finalizing the definition as proposed.

Comment: A few commenters that agreed with the proposed definition urged that the word ''and'' be replaced with ''or'' to read ''an individual whose primary language for communication is not English *or* who has a limited ability to read, write, speak, or understand English . . .'' These commenters explained that there are many people in the United States whose primary language is English but who have a limited ability to read, write, speak, or understand English, for reasons that may or may not be related to disability, who deserve protection from discrimination.

Response: OCR appreciates the commenters' recommendation and recognizes that there are many individuals whose primary language is English but who have a limited ability to read, write, speak, or understand English. However, section 1557's language access provisions rely on the statute's prohibition on national origin discrimination.[57] For individuals with LEP, the lack of proficiency in English and the use of non-English languages is often tied to their national origin. Changing the definition to include an individual who has a limited ability to read, write, speak, or understand English, but whose primary language is English, would go beyond national origin discrimination. With respect to individuals who have a limited ability to read, write, speak, or understand English related to disability, § 92.202 addresses requirements for effective communication for individuals with disabilities, which is a long-standing requirement.

Summary of Regulatory Changes

For the reasons set forth in the Proposed Rule and considering the comments received, we are finalizing the definition of ''limited English proficient individual'' as proposed in § 92.4, with modification. We are changing ''limited English proficient individual'' to ''individual with limited English proficiency'' in § 92.4 and throughout the final rule.

Machine translation. OCR proposed to define the term ''machine translation'' to mean ''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.'' Neither the 2016 Rule nor the 2020 Rule addressed machine translation. We invited comment on the adequacy of this new definition.

Comment: We received many comments in support of the inclusion of a definition of ''machine translation''. One commenter supported the language as proposed but noted the importance of adaptability and potential for future regulation or guidance over time as

[57] *See Lau* v. *Nichols,* 414 U.S. 563, 568–69 (1974).

technology changes. For example, machine translation companies may develop technology that includes some level of human review but remains insufficient for the purposes of conforming with the intent of this rule.

Response: We appreciate commenters' support for the inclusion of this definition. The requirement to provide written translations via a qualified translator included at § 92.201(c)(2) continues to apply, regardless of whether human or machine translation is provided. Section 92.201(c)(3) requires a human translator to review machine translation under certain circumstances. The circumstances outlined in § 92.201(c)(3) set a minimum requirement for when machine translations must be reviewed by a qualified human translator—including circumstances that are critical to one's rights or benefits. Thus, any machine translation technologies that are developed must include such review if they are to meet the requirements of this rule. OCR will continue to monitor the progression of this technology and will revisit regulatory updates as well as consider issuance of future guidance as needed.

Comment: One commenter stated that the definition of ''machine translation'' should include reference to the use of software or automated tools. Specifically, the commenter recommended modifying the language to read ''machine translation is the use of automated translation software or tools, without the assistance of . . .''

Response: OCR appreciates the commenter's suggestion to explicitly refer to software or automated tools; however, the definition as proposed sufficiently accounts for translations that would be generated by software or automated tools as it refers to ''automated translation.''

Summary of Regulatory Changes

For the reasons set forth in the Proposed Rule and considering the comments received, we are finalizing the definition of ''machine translation'' as proposed in § 92.4, with modification. We are making a technical correction to change ''automated translations'' to ''automated translation.''

National Origin. We proposed to define the term ''national origin'' to mean ''a person's, or their ancestor's, place of origin or a person's manifestation of the physical, cultural, or linguistic characteristics of a national origin group.'' This is consistent with the 2016 Rule's definition of ''national origin,'' and with the well-established definition of the term that the Equal Employment Opportunity Commission (EEOC) uses in its interpretation of title VII.[58]

Comment: Various commenters discussed the need to include this definition to address entrenched inequities and practices that can constitute national origin discrimination but are not always recognized. This includes the failure to take reasonable steps to provide meaningful access for individuals with LEP, even though such a failure has been long recognized as a form of national origin discrimination. Commenters added that there are also clear intersections between LEP status and race and ethnicity because the great majority of individuals with LEP are people of color; however, they noted that when individuals seek to vindicate their civil rights, they often must choose between pursuing a claim based on either their LEP status or race. Commenters also provided examples of how some people have been denied benefits they are entitled to due to national original discrimination. Several national organizations and local service providers commented that refugees, migrant workers, and other immigrants experience barriers to federally funded or provided health care due to fears related to their immigration status.

Response: OCR appreciates commenters' support for inclusion of this definition. We recognize that individuals can experience both national origin and race discrimination (or national origin discrimination and discrimination on another protected basis) and are finalizing new regulatory language that provides additional clarity and addresses such instances in which individuals may experience discrimination under multiple bases. *See* discussion regarding § 92.101.

OCR appreciates comments related to immigration status. While section 1557 does not prohibit discrimination on the basis of immigration status, we note that differential treatment such as requiring additional verification or documentation from individuals based on their appearance, name, accent, LEP, or suspected immigration status may violate section 1557 and other civil rights laws.[59]

Summary of Regulatory Changes

For the reasons set forth in the Proposed Rule and considering the comments received, we are finalizing the definition of ''national origin'' as proposed in § 92.4, with modification. We are making a technical correction to change ''ancestor's'' to ''ancestors'.''

Patient care decision support tool. The Proposed Rule described but did not include a definition in § 92.4 for, the term ''clinical algorithms.'' *See* 87 FR 47880. Many commenters supported the inclusion of a provision such as proposed § 92.210, addressing nondiscrimination in the use of clinical algorithms in decision-making, but recommended OCR clarify that the provision applies to tools used to assess health status, recommend care, determine eligibility, allocate resources, conduct utilization review, and provide disease management guidance. Further, commenters requested that OCR define what tools are covered under § 92.210.

Based on comments received, we are replacing the term ''clinical algorithm'' with the more precise term ''patient care decision support tool,'' and we are adding a definition for ''patient care decision support tool'' to mean ''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.'' The definition of ''patient care decision support tool'' reaffirms that § 92.210 applies to tools used in clinical decision-making that affect the care that patients receive. This includes tools, described in the Proposed Rule, used by covered entities such as hospitals, providers, and payers (health insurance issuers) in their health programs and activities for ''screening, risk prediction, diagnosis, prognosis, clinical decision-making, treatment planning, health care operations, and allocation of resources'' as applied to the patient. 87 FR 47880. We clarify that tools used for these activities include tools used in covered entities' health programs and activities to assess health status, recommend care, provide disease management guidance, determine eligibility and conduct utilization review[60] related to patient care that is

[58] 29 CFR 1606.1; *see, also,* U.S. Equal Emp. Opportunity Comm'n, *EEOC Enforcement Guidance on National Origin Discrimination, https://www.eeoc.gov/laws/guidance/eeoc-enforcement-guidance-national-origin-discrimination#_Toc451518799.*

[59] *See, e.g.,* U.S. Dep't of Justice, *Guidance to State and Local Governments and Other Federally Assisted Recipients Engaged in Emergency Preparedness, Response, Mitigation, and Recovery Activities on Compliance with Title VI of the Civil Rights Act of 1964, Section D, https://www.justice.gov/crt/fcs/EmergenciesGuidance.*

[60] *See, e.g.,* Patrick Rucker et al., *How Cigna Saves Millions by Having Its Doctors Reject Claims Without Reading Them,* ProPublica (March 25, 2023), *https://www.propublica.org/article/cigna-pxdx-medical-health-insurance-rejection-claims*; Casey Ross & Bob Herman, *Denied by AI: How Medicare Advantage Plans Use Algorithms to Cut Off Care for Seniors in Need,* STAT News (March 13, 2023), *https://www.statnews.com/2023/03/13/medicare-advantage-plans-denial-artificial-intelligence/.*

directed by a provider, among other things, all of which impact clinical decision-making. Please see our discussion regarding § 92.210, where we discuss ''patient care decision support tool'' in more detail, including examples of tools to which § 92.210 does not apply.

Summary of Regulatory Changes

Considering the comments received, we are finalizing the definition of ''patient care decision support tool'' in § 92.4 to mean ''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. OCR proposed to define the term ''qualified bilingual/multilingual staff'' to mean a member of a covered entity's workforce who is designated by the covered entity to provide oral language assistance directly to an individual in their primary language 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 LEP in their primary language.

Comment: Some commenters urged that additional attention should be given to assessing qualifications for self-identified bilingual/multilingual staff abilities to provide services in languages other than English, and that policies and procedures should be developed to assess and retain their competency. Additionally, some commenters recommended establishing qualifications for bilingual/multilingual staff who may also be expected to serve as interpreters, and added that they should be compensated appropriately. Commenters stated that research has shown that bilingual staff who are not qualified interpreters often do not feel comfortable serving as interpreters. A commenter posited that bilingual/multilingual staff must be provided training and compensation opportunities to support professional development and prevent staff turnover and burnout.

Response: OCR appreciates the commenters' suggestions to establish assessment requirements for qualified bilingual/multilingual staff; however, we believe the current definition establishes sufficient requirements and guidelines regarding the necessary skills a qualified bilingual/multilingual staff member must have. The definition sets forth a two-prong definition to ensure proficiency, effectiveness, and impartiality in direct communications with individuals with LEP in their primary languages, including any necessary specialized vocabulary, terminology, and phraseology. Similar to the rule's definitions for qualified interpreters and qualified translators, OCR has established the necessary skills that must be held to meet the definition, while providing covered entities the flexibility by which to have these skills assessed. We note that an individual's self-identification as bilingual or multilingual alone is insufficient to determine whether they meet this definition, and covered entities should determine processes by which they will independently determine and periodically assess an individual's qualifications.

While qualified bilingual/multilingual employees may also be qualified interpreters, the ability to interpret is a separate skill. Anyone whom a covered entity allows to serve as an interpreter must be qualified to do so, consistent with the definition of ''qualified interpreter for an individual with limited English proficiency'' in this section, independent of whether they have been identified as a qualified bilingual/multilingual staff member. OCR will consider developing guidance and providing technical assistance for covered entities on mechanisms for covered entities to assess if staff members meet the requirements.

Consistent with the Department's approach on language access, OCR encourages covered entities to provide training and compensation opportunities to support professional development for bilingual/multilingual staff.

Summary of Regulatory Changes

For the reasons set forth in the Proposed Rule and considering the comments received, we are finalizing the definition of ''qualified bilingual/multilingual staff'' as proposed in § 92.4, with modification. As discussed in the summary of regulatory changes to the proposed term ''limited English proficient individual,'' we are revising the term to ''individual with limited English proficiency'' in § 92.4.

Qualified interpreter for an individual with a disability. We proposed to define the term ''qualified interpreter for an individual with a disability'' to mean ''an interpreter who . . . is able to interpret effectively, accurately, and impartially, both receptively and expressively, using any necessary specialized vocabulary.'' Such an interpreter may interpret via a video remote interpreting service (VRI) or in person. We also provided a non-exhaustive list of examples of qualified interpreters, to include sign language interpreters, oral transliterators, and cued-language transliterators.

Comment: Most of the commenters recommended that OCR amend this definition to include the three (3) parts of the definition of ''qualified interpreter for an individual with limited English proficiency'', which requires that the qualified interpreter: (1) has demonstrated proficiency, (2) is able to interpret effectively, accurately, and impartially, (3) and adheres to generally accepted interpreter ethics principles. Commenters noted that these revisions would provide alignment between the different types of interpreters and recognize that similar standards should apply regardless of whether an interpreter is interpreting for an individual with LEP or a person with a disability.

Commenters recommended that the definition include that a qualified interpreter for a person with a disability demonstrate proficiency. For sign language interpreters, this should include proficiency in speaking or communicating in and understanding both English and a relevant sign language, noting that not all individuals who are deaf or hard of hearing are signers of American Sign Language (ASL). Some commenters also recommended that in order to be proficient, Certified Deaf Interpreters (CDI) must have specialized training in Deaf interpreting in addition to the basic CDI training. For transliterators, these commenters recommended that the rule require proficiency in the relevant alternative communication modality, such as cued speech or oral transliteration.

Commenters further stated that an interpreter for an individual with a disability should communicate ''without changes, omissions, or additions while preserving the tone, sentiment, and emotional level of the original statement.''

Finally, commenters stated that an interpreter for an individual with a disability must also adhere to the principles contained in recognized standards of practice and professional codes of ethics for health care interpreters, such as those of the National Council on Interpreting in Health Care and the Registry of Interpreters for the Deaf.

Response: We appreciate commenters' recommendation to revise the definition

of ''qualified interpreter for an individual with a disability'' to align more closely with the definition of ''qualified interpreter for an individual with limited English proficiency''. While the proposed definition is consistent with the ADA, we agree that the standards for a qualified interpreter should be equivalent regardless of whether an individual has LEP or has a disability. We have revised the definition for consistency among the standards, which is also consistent with the 2016 Rule's definition at former 45 CFR 92.4.

Comment: Some commenters recommended aligning the two qualified interpreter definitions but recommended that a revised definition be expanded to recognize qualified interpreters who have demonstrated proficiency in speaking and understanding two non-English languages. These commenters noted that not all interpreters for people with disabilities are interpreting between English and another language. For example, these commenters noted that a CDI may be interpreting between an individual who is deaf and uses a unique version of ASL and a non-American sign language, or home signs unfamiliar to the medical interpreter. Commenters were concerned that a definition that specified interpretation ''between English and non-English language'' would exclude CDIs and cued-language transliterators. These commenters recommended a multi-pronged definition where several contexts are taken into consideration and is inclusive of ASL-to-English interpretation, ASL-to-ASL CDI interpretation, and cued-language transliteration.

Response: As proposed, the definition of ''qualified interpreter for an individual with a disability'' does not reference ''English'' or a ''non-English language,'' but rather included a non-exhaustive list of examples of qualified interpreters inclusive of sign language interpreters, oral transliterators, and cued-language transliterators. However, as previously discussed, we have revised the definition of ''qualified interpreter for an individual with a disability'' to be more aligned with the definition of ''qualified interpreter for an individual with limited English proficiency.'' The revised definition includes language that is inclusive of different types of interpretation and also includes the non-exhaustive list of examples from the proposed definition.

Comment: Some commenters noted that a covered entity must not use the services of staff who use sign language or another communication modality to act as interpreters and relay information to individuals with disabilities unless they meet the definition of a ''qualified interpreter for an individual with a disability'' found within this section, and they meet the unique needs of the individual for whom the services of an interpreter is being provided.

Response: The definition of a ''qualified interpreter for an individual with a disability'' addresses these concerns; and anyone designated by a covered entity to serve as an interpreter for an individual with a disability must be qualified to do so.

Comment: Some commenters recommended that the definition of ''qualified interpreter for a person with a disability'' take into consideration applicable State law governing licensure of interpreters if any are available in the State where the covered entity provides services. These commenters noted that the process of who can serve as a qualified interpreter differs from State to State, and OCR should adopt language that reflects the minimum standards of State laws governing qualifications of sign language interpreters, if any.

Response: OCR understands and appreciates commenters raised concerns. Covered entities may use adherence to State law governing licensure as a means by which to demonstrate compliance with this definition, provided licensure demonstrates the individual possesses the requirements provided in the definition. OCR declines to adopt language that incorporates any State law licensure requirements as a minimum standard of compliance with this rule.

Comment: Some commenters raised concerns over the qualifications of interpreters. Commenters recommended that the definition include the requirement that an interpreter be certified or assessed by a formal process that objectively measures the competency of the individual. Other commenters recommended that health care entities include a screening system to ensure quality assurance of the abilities of the sign language interpreters to meet the needs of the patients.

Response: OCR appreciates the commenters' recommendations to require certification for qualified interpreters and agrees that covered entities should ensure that the use of interpreter services provides for effective communication. OCR will take into account certification in assessing compliance with this regulation; however, as we will discuss below in the response for certification of qualified interpreter for an individual with LEP in § 92.201, we decline to require certification in the definition of ''qualified interpreter for an individual with a disability.''

Summary of Regulatory Changes

For the reasons set forth in the Proposed Rule and considering the comments received, we are finalizing the definition of ''qualified interpreter for an individual with a disability'' in § 92.4, to more closely align with the definition of ''qualified interpreter for an individual with limited English proficiency,'' such that it now 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. Qualified interpreters include, for example, sign language interpreters, oral transliterators, and cued-language transliterators.

Qualified interpreter for a limited English proficient individual. OCR proposed to define the term ''qualified interpreter for a limited English proficient individual'' to mean 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; (2) is able to interpret 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 oral statement; and (3) adheres to generally accepted interpreter ethics principles, including client confidentiality. This definition is consistent with both the 2016 Rule at former § 92.4 and the 2020 Rule at § 92.101(b)(3)(i).

Comment: Some commenters who otherwise supported this definition expressed concern that, as written, it may inadvertently create difficulties for interpreting in certain languages, especially indigenous languages of Central and South America. These

commenters recommended that the definition be amended to allow for the use of services of relay interpreters, such as those who are proficient in an indigenous language and another language such as Spanish. Commenters explained that these interpreters may not be fluent in spoken English or trained to interpret to and from spoken English, and that those who are qualified to interpret between two non-English languages are critical in providing meaningful access for many isolated and marginalized communities. Furthermore, a few of these commenters recommended the inclusion of the following definition for relay interpreting: ''relay interpreting means a form of simultaneous interpreting when the speech is rendered from an intermediate language rather than directly from the source language.''

One commenter recommended adding ''and dialect'' after ''spoken language'' under paragraph (1) to acknowledge that speakers of a language may not always be qualified to interpret for a person who speaks a variation in that language and adding ''understanding and'' before ''using necessary specialized vocabulary or terms'' under paragraph (2) to indicate that providing effective interpretation for complex situations, such as communicating a treatment regimen, requires understanding of the terminology being used, particularly given the consequences of a miscommunication.

Response: OCR appreciates and understands concerns that the proposed definition may inadvertently create obstacles for meaningful access in certain languages. For example, if a Zapotec-speaking patient with LEP attended a medical appointment and the hospital could not find an individual qualified to interpret between Zapotec and English after reasonable efforts, the hospital could utilize the services of two qualified interpreters that could perform relay interpretation between Zapotec and Spanish and Spanish and English. While relay interpretation may introduce challenges related to accuracy, it may be necessary to afford meaningful access for individuals who speak languages, dialects, or variants not common to the area where they are receiving services.

For this reason, we are revising the definition of a ''qualified interpreter for an individual with limited English proficiency'' to provide that the qualified interpreter (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); and (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. This provision makes clear that specialized skills and vocabulary may be needed for less commonly spoken languages as well as dialects.

In light of these modifications to the definition of ''qualified interpreter for an individual with limited English proficiency'', we are also adding and finalizing a definition of ''relay interpretation'' to mean 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.

Lastly, OCR appreciates the commenter's suggestion to add ''understanding and'' before ''using necessary specialized vocabulary or terms'' under paragraph (2). However, the interpreter themself does not need to *understand* complex medical concepts behind medical terms but rather must be able to interpret said terms effectively and accurately. OCR is of the view that the interpretation should directly convey the provider and patient's words and phrases in order to avoid the risk that the individual's message was not accurately communicated. Further, paragraph (1) already requires that the interpreter have ''proficiency in speaking *and understanding*'' the languages at issue (emphasis added).

Comment: A few commenters recommended the definition address how an individual would demonstrate proficiency in English and another language (*i.e.,* through use of an established standard for describing language ability, such as the Common European Framework of Reference of Languages [61]). Some commenters recommended implementing a certification requirement and suggested implementing a national credential requirement that establishes interpretation proficiency for enforcement purposes. Some commenters requested that OCR lay out examples of when it would be appropriate to require qualified interpreters to obtain certification in order to comply with section 1557. Commenters expressed their belief that the proposed definition could be easily misinterpreted and result in assigning the least skilled interpreter for a medical encounter.

Response: OCR appreciates the commenters' suggestions to establish certification requirements for qualified interpreters; however, there are currently no consistent certification standards and there is also a lack of certification available for a significant number of languages. The requirements in this definition provide sufficient standards for determining interpreter qualifications. Individuals that hold a certification will still need to meet the standards provided in this definition. For covered entities seeking information on certification, we encourage covered entities to review the Department of Justice's (DOJ) resource regarding what it means to be a certified linguist.[62]

Comment: One commenter encouraged OCR to include ''via a video remote interpreting service'' to the definition because telehealth can be an important tool for expanding access to interpretation for individuals with LEP.

Response: The definition as proposed and finalized includes interpreter services provided via remote interpreting services and is therefore inclusive of video remote interpreting as drafted.

Comment: One commenter noted that we use the phrase ''use an interpreter'' in our text. They recommended we use the wording ''utilize the services of an interpreter'' instead.

Response: OCR agrees that we are referring to the utilization of interpreter services and have adjusted the use of this phrase accordingly.

Summary of Regulatory Changes

For the reasons set forth in the Proposed Rule and considering the comments we received, we are revising the definition for a ''qualified interpreter for an individual with limited English proficiency'' as proposed in § 92.4, with modifications. To account for concerns related to relay

[61] Council of Europe, *Common European Framework of Reference for Languages (CEFR), https://www.coe.int/en/web/common-european-framework-reference-languages/introduction-and-context.*

[62] U.S. Dep't of Justice, Fed. Coordination & Compliance Section, *What Does It Mean to Be a Certified Linguist* (2014), *https://www.justice.gov/crt/page/file/1255916/download.*

interpreting, we are revising paragraph (1) to add ''(qualified interpreters for relay interpretation must demonstrate proficiency in two non-English spoken languages).'' As discussed in the summary of regulatory changes to the proposed term ''limited English proficient individual'' we are revising the term to ''individual with limited English proficiency'' in § 92.4. We are also adding a definition of ''relay interpretation'' to § 92.4 to mean 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.

Qualified Reader. We proposed to define the term ''qualified reader'' to mean ''a person who is able to read effectively, accurately, and impartially using any necessary specialized vocabulary,'' which comes from the ADA title II regulation at 28 CFR 35.160 through 35.164. This definition, which did not appear in the 2016 or 2020 Rules, was included to provide clarity to both covered entities and protected individuals about the necessary qualifications of a reader when required under this regulation.

Comment: Commenters supported the addition of ''qualified reader'' to the proposed list of definitions.

Response: OCR appreciates the commenters support for adding the definition of ''qualified reader'' to the proposed list of definitions.

Summary of Regulatory Changes

For the reasons set forth in the Proposed Rule and considering the comments we received, we are finalizing the definition of ''qualified reader'' as proposed in § 92.4, without modification.

Qualified Translator. OCR proposed to define the term ''qualified translator'' to mean 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. This definition of ''qualified translator'' appeared in the 2016 Rule at § 92.4 and appears in the 2020 Rule at § 92.102(b)(2)(ii) and has not been changed.

Comment: One commenter recommended that the definition of a ''qualified translator'' include the requirement that such individuals, for purposes of providing translation services, be certified or assessed by a formal process that objectively measures the competency of the individual. A number of commenters stated that high quality translation is essential to providing equal access to health care and health services. Some added that oral interpretation is critical to ensuring understanding of written translations, some of which have been inaccurate or insufficient to convey the complicated medical and technical terms translated in the communications.

Response: OCR appreciates the commenter's suggestion to require that a qualified translator be certified or objectively assessed to verify competency in translating. For the reasons we provided when declining to require certification of qualified interpreters for individuals with LEP, we decline to specify the means by which a covered entity may determine that an individual meets the definition of ''qualified translator''. In order to be qualified, translators must meet the definition provided in the rule. OCR also notes that reasonable steps to provide meaningful access may require the provision of both written translation and oral interpreting, and thus utilizing the services of both a qualified translator and a qualified interpreter may be necessary under certain circumstances.

Summary of Regulatory Changes

For the reasons set forth in the Proposed Rule and considering the comments received, we are finalizing the definition of ''qualified translator'' as proposed in § 92.4, without modification.

State. The 2022 NPRM did not propose a definition of the term ''State.'' However, based on comments received, we became aware that there may be some confusion as to what encompasses ''State'' for purposes of this final rule. We therefore have decided to include a definition of ''State.''

Summary of Regulatory Changes

Considering the comments received, we are finalizing a definition of ''State'' in § 92.4 to mean ''each of the several States, the District of Columbia, the Commonwealth of Puerto Rico, Guam, American Samoa, the Virgin Islands, the Trust Territory of the Pacific Islands, and the Commonwealth of the Northern Mariana Islands.'' This definition is consistent with the ADA regulations at 28 CFR 35.104.

Telehealth. The 2022 NPRM did not propose a definition of the term ''telehealth.'' However, based on comments received, we became aware that there may be some confusion as to what encompasses ''telehealth'' for purposes of this final rule. We therefore have decided to include a definition of ''telehealth.''

Summary of Regulatory Changes

Considering the comments received, we are finalizing a definition of ''telehealth'' in § 92.4 to mean 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. This definition is consistent with the Health Resources and Services Administration and the Office of the National Coordinator for Health Information Technology definitions referenced in the 2022 NPRM, 87 FR 47884.

Assurances Required (§ 92.5)

In § 92.5 of the 2022 NPRM, we proposed retaining the requirement of the 2016 and 2020 Rules, at former § 92.5 and current § 92.4 respectively, for recipients to submit assurances of compliance to OCR. In paragraph (a), we proposed that each entity applying for Federal financial assistance, each issuer seeking certification to participate in an Exchange, and each State seeking approval to operate a State Exchange is required to submit an assurance that its health programs and activities will be operated in compliance with section 1557 and this part, consistent with similar requirements found in the implementing regulations for title VI, title IX, section 504, and the Age Act. The duration of obligation (proposed paragraph (b)), and covenants language (proposed paragraph (c)) adopt the corresponding requirements found in the section 504 regulation at 45 CFR 84.5.

The comments and our responses regarding § 92.5 are set forth below.

Comment: Commenters expressed support for the assurances provision included in the 2022 NPRM because it

is consistent with other Federal civil rights regulations and the 2016 and 2020 Rules, and it is reasonable for OCR to require recipients of Federal financial assistance to comply with section 1557 as a condition of receiving that funding. One organizational commenter recommended revising this requirement to conditioning prospective recipients' receipt of Department Federal financial assistance on recipients': (1) collection of demographic data such as race, ethnicity, spoken and written language, disability status, age, sex, gender identity, sex characteristics, and sexual orientation; and (2) submission of a written proposal (including through written policies and procedures) about how they intend to provide language assistance services, auxiliary aids and services, and whether an entity's proposed budget includes funding to meet these identified needs.

Response: We appreciate the suggestion to include a data collection requirement in this provision, but do not believe such a requirement is appropriate, as this language is longstanding and consistent across civil rights regulations. We address data collection in further detail later in this preamble, when discussing responses to our request for comment on the issue.

We also decline to revise § 92.5 to require Federal financial assistance applicants to provide OCR with budget information and a written proposal about how they intend to provide language assistance services and auxiliary aids and services as a condition of receiving Federal financial assistance. The combined requirements at §§ 92.8 (Policies and procedures), 92.201 (Meaningful access for individuals with LEP), 92.202 (Effective communication for individuals with disabilities), and 92.205 (Requirement to make reasonable modifications) address the commenter's concerns regarding a recipient's obligation and ability to provide language assistance services and auxiliary aids and services.

Comment: One commenter raised concerns that proposed § 92.5's requirement that recipients make assurances to comply with all provisions of the rule does not take into account situations where a third party administrator could otherwise lawfully administer a plan sponsored by a religious employer that does not conform to OCR's current interpretation of section 1557 with regard to the prohibition on sex discrimination. Specifically, the commenter suggested that a third party administrator may be inhibited from submitting an assurance required by § 92.5 because (1) of the Employee Retirement Security Act of 1974 (ERISA), 29 U.S.C. 1104(a)(1)(D), which for example, obligates such a third party administrator to administer the religious employer's self-insured health plan in accordance with terms that may conflict with section 1557's prohibition of sex discrimination; and (2) there are injunctions that currently prohibit OCR from enforcing prohibitions on sex discrimination against religious employers and those acting in concert with them.[63]

Response: OCR complies with court orders, including court-ordered injunctions. If a recipient third party administrator is covered by any current court order or court-ordered injunction, OCR would not find the third party administrator to be in violation of section 1557 or this rule for its activities that are covered by the injunction, and such an entity would not need to provide an assurance under § 92.5 to the extent it conflicts with a current court order or court-ordered injunction by which they are covered.

Regarding the commenter's point that third party administrators are required under ERISA to administer plans consistent with the plan's terms, OCR addresses this issue in detail under the *third party administrator* section of § 92.207. In short, while we acknowledge that ERISA requires plans to be administered consistent with the documents and instruments governing the plan,[64] ERISA further provides that it is not to be construed to impair or supersede other Federal laws, including regulations issued under such laws.[65] Courts have held that ERISA's requirement to comply with the terms of the plan must not be construed to invalidate or impair section 1557.[66]

[63] *Franciscan All.,* 553 F. Supp. 3d at 378.

[64] 29 U.S.C. 1104(a)(1)(D) (''[A] fiduciary shall discharge his duties with respect to a plan solely in the interest of the participants and beneficiaries and . . . in accordance with the documents and instruments governing the plan insofar as such documents and instruments are consistent with the provisions of this subchapter and subchapter III.'').

[65] 29 U.S.C. 1144(d) (''Nothing in this subchapter shall be construed to alter, amend, modify, invalidate, impair, or supersede any law of the United States (except as provided in sections 1031 and 1137(b) of this title) or any rule or regulation issued under any such law.'').

[66] *See, e.g., C. P. by & through Pritchard* v. *Blue Cross Blue Shield of Ill.,* No. 3:20–CV–06145–RJB, 2022 WL 17788148, at *8, 10 (W.D. Wash. Dec. 19, 2022) (holding that ERISA's requirement at 29 U.S.C. 1104(a)(1)(D) to administer a plan's terms as written ''is subservient to Section 1557, outlawing discrimination, which is dominant''); *Tovar* v. *Essentia Health,* 342 F. Supp. 3d 947, 954 (D. Minn. 2018) (''The Court will not construe ERISA to impair Section 1557. Nothing in Section 1557, explicitly or implicitly, suggests that TPAs are exempt from the statute's nondiscrimination requirements.'').

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 § 92.5, without modification.

Remedial Action and Voluntary Action (§ 92.6)

In § 92.6, OCR proposed to include requirements regarding remedial and voluntary action, which would reinstate former § 92.6 in the 2016 Rule and is consistent with parallel requirements in the implementing regulations for section 504, title IX, and the Age Act. The 2020 Rule does not include a similar provision. In § 92.6(a)(1) of the 2022 NPRM, we proposed requiring recipients or State Exchanges that have been found by the Director to have engaged in discriminatory conduct in their health programs and activities in violation of this part to take voluntary actions to remediate the effects of such discriminatory conduct. Similarly, we proposed that under § 92.6(a)(2), where a recipient exercises control over another recipient that has discriminated, the Director may require either or both entities to take remedial action. Under proposed § 92.6(a)(3), a recipient or State Exchange must take remedial action if OCR requires such action to redress the harm experienced by an individual who was subjected to prohibited discrimination. Under proposed § 92.6(b), a covered entity may voluntarily take nondiscriminatory steps to overcome the effects of the conditions that limited an individual's ability to participate in a health program or activity based on their race, color, national origin, sex, age, or disability.

The comments and our responses regarding § 92.6 are set forth below.

Comment: Commenters generally supported the requirement that a recipient remedy instances of confirmed discrimination and the voluntary action provision that allows for covered entities to address effects of past discrimination.

One commenter recommended that we limit the application of this provision to avoid exposing recipients to unfair and specious claims of discrimination. Specifically, the commenter suggested that the remedial action be limited to: (1) individuals who applied to participate in a health program or activity but were unable to participate due to alleged discrimination; or (2) individuals who had been participants in a health program or activity but are no longer participants due to alleged discrimination.

Response: This provision is an essential tool in remediating findings of discrimination and encouraging recipients to take voluntary actions to overcome potential discrimination. The suggested revisions to § 92.6 are unnecessary, as they generally request implementing conditions that are already present. For example, § 92.6(a)(1) requires remedial action by a recipient or State Exchange only *after* a finding of discrimination. Section 92.6(a)(3) limits any required remedial action in the spirit of the commenter's recommendation, namely providing that recipients and State Exchanges take remedial action with respect to individuals who were or would have been participants in the health program or activity had the discrimination not occurred.

Covered entities are prohibited from discriminating and as such should take steps to ensure nondiscrimination, even in the absence of a finding of discrimination by OCR. Where a covered entity has identified conditions that currently or in the past had resulted in limited participation in their health programs and activities by individuals protected by this rule, they are encouraged to take the voluntary action contemplated in § 92.6(b).

We also note that regulations for section 504, title IX, and the Age Act require recipients to take remedial action, and recipients have complied with the remedial action provisions in those civil rights statutes for more than 40 years.[67] For example, where there is a finding that a recipient engaged in disability discrimination, the recipient's remedial action to overcome the effects of the disability discrimination would likely satisfy this provision's remedial action requirement as well as section 504's remedial action requirement at 45 CFR 84.6(a).

Comment: Another commenter expressed concern about the obligation this provision places on a recipient that exercises control over another recipient that is found to have engaged in discrimination prohibited by section 1557. The commenter recommended that OCR revise the provision so that only the recipient that OCR found to have engaged in unlawful discrimination (and not the controlling entity) take remedial action and that OCR enumerate specific remedial actions OCR may require and the circumstances under which OCR may require them.

Response: The word ''control'' has appeared in civil rights regulations enforced by OCR for many years, and its meaning has been established over time. As we explained in the preamble for the 2016 Rule, OCR's experience and the longstanding approach for controlling entities to secure appropriate action from discriminating entities over which they have control has played an important role in remedying discrimination. 81 FR 31393. Given that nothing has changed in OCR's experience in the intervening years regarding the principles of ''control'' as applied here, we decline to define the term ''control.''

While we appreciate the commenter's request to list the remedial actions OCR may require of a recipient or State Exchange found in violation of this part, the remedial actions that a recipient or State Exchange must take to address confirmed discrimination will be subject to the facts involved in a particular case. A review of past resolution agreements provides useful, though not exhaustive, examples of the variety of means by which OCR achieves corrective action.[68]

Comment: One commenter recommended that OCR revise § 92.6 to require a recipient or State Exchange to notify participants, enrollees, and beneficiaries of any finding of discrimination by the Director and the remedial action the recipient has taken or will take to address the confirmed discrimination.

Response: We recognize the benefit that notice of confirmed discrimination and the steps a recipient or State Exchange will take to remedy the discrimination can provide to participants, enrollees, and beneficiaries. While we encourage recipients and State Exchanges to provide notice to participants, we decline to require they do so. Current Federal civil rights regulations with similar remedial and voluntary action provisions do not include a notice requirement, and we do not believe imposing such a requirement on recipients and State Exchanges is warranted at this time. We note, however, it is OCR's practice to notify the public via a press release or posting on our website when a violation has been found or a resolution has been reached.[69] Additionally, OCR has established a Civil Rights listserv to inform the public about civil rights settlement and enforcement activities, press releases, FAQs, guidance, and technical assistance materials. To subscribe to OCR's Civil Rights listserv, please visit *https://list.nih.gov/cgi-bin/wa.exe?SUBED1=OCR-CIVILRIGHTS-LIST&A=1.*

Comment: One commenter recommended that, for § 92.6(b) (voluntary action), we replace ''may'' with ''must'' to require covered entities to take nondiscriminatory steps to overcome effects that result or resulted in limiting participants ability to participate in the covered entity's health program or activities based on the participants' race, color, national origin, sex, age, or disability.

Response: Such a revision would alter the voluntary nature of the provision, which encourages covered entities to take nondiscriminatory steps on their own accord to make their programs more inclusive absent a finding of discrimination. We note that, when there is a finding that prohibited discrimination occurred, § 92.6(a) mandates the offending recipient or State Exchange to take action to remedy such discrimination.

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 § 92.6, without modification.

Designation and Responsibilities of a Section 1557 Coordinator (§ 92.7)

In proposed § 92.7(a), OCR proposed requiring covered entities with 15 or more employees to designate at least one employee to serve as a Section 1557 Coordinator (''Coordinator'') to coordinate their efforts to comply with and carry out the covered entity's responsibilities under section 1557 and the part. OCR also proposed to permit covered entities to, as appropriate, assign one or more designees to carry out some of the responsibilities of the Coordinator.

In § 92.7(b), we proposed a list of responsibilities of the Coordinator. We invited comment on this requirement, including whether OCR should require covered entities with fewer than 15 employees to designate a Coordinator and, if so, whether there should be a requisite number of employees or whether all covered entities should be required to designate a Coordinator. We further sought comment on whether the enumeration of responsibilities of the Coordinator is beneficial and sufficiently comprehensive. We also requested comment on how the

[67] *See* 45 CFR 84.6(a) and (b) (section 504); 86.3(a) and (b) (title IX); and 91.48 (Age Act).

[68] U.S. Dep't of Health & Hum. Servs., Off. for Civil Rts., *Recent Civil Rights Resolution Agreements & Compliance Reviews, https://www.hhs.gov/civil-rights/for-providers/compliance-enforcement/agreements/index.html.*

[69] U.S. Dep't of Health & Hum. Servs., Off. for Civil Rts., *Civil Rights News Releases & Bulletins, https://www.hhs.gov/civil-rights/newsroom/index.html.*

Department can support Coordinators, including through the provision of training, so that they understand their duties, the protections afforded by section 1557, and the rationales for both.

The comments and our responses regarding § 92.7 are set forth below.

Comment: Commenters on this provision overwhelmingly supported the Coordinator requirement at § 92.7. A number of supportive commenters indicated that civil rights violations often occur due to ignorance, neglect, and administrative indifference, and Coordinators will equip providers with critical civil rights knowledge and the ability to recognize and adequately care for patients at risk for poor health outcomes. Other commenters similarly emphasized that the Coordinator requirement will equip covered entities with an internal resource dedicated to section 1557 implementation and compliance, and that this is especially critical for small covered entities and covered entities in rural communities. Commenters cited a number of other reasons for their support of the Coordinator requirement, including that having a Coordinator will help covered entities proactively protect civil rights; will provide central points of contact for language access; and will allow covered entities and OCR to better identify patterns or practices of discrimination, which will aid covered entities in delivering effective and efficient care.

One commenter expressed concern about the possibility that Coordinators evolve and become ineffective by privileging the institutions they serve rather than appropriately conducting thorough investigations of grievances. Relatedly, another commenter recommended that OCR revise § 92.7 to require covered entities' Coordinators to be independently minded or independent from the covered entity to ensure impartiality and transparency and to require that Coordinators be able to work independently.

Many of these commenters cited the COVID–19 Public Health Emergency as a reason for their support of the Coordinator requirement. Specifically, they stated that the health outcomes resulting from the COVID–19 pandemic highlighted covered entities' ignorance of civil rights regulations with respect to individuals from marginalized communities.

Response: We agree with commenters regarding the myriad benefits of the Coordinator requirement, particularly with regard to increasing covered entities' ability to proactively prevent discrimination before it happens and hopefully more thoroughly address it when it does. Coordinators are expected to perform their impartially, which will also benefit covered entities through ensuring compliance with section 1557.

OCR appreciates commenters' concerns that Coordinators be sufficiently independent from a covered entity to ensure impartiality and transparency. We note that a covered entity may run the risk of noncompliance with section 1557 if an investigation reveals that its Coordinator did not carry out their obligations under section 1557 in an impartial manner. By having a Coordinator, with specific compliance responsibilities, OCR expects that covered entities will be cognizant of the importance of compliance with civil rights requirements, including in times of public health emergencies or other crises.

Comment: Other commenters opposed the Coordinator requirement, contending that it will increase the burdens covered entities will face.

One commenter reiterated the 2020 Rule's reasoning for eliminating the Coordinator requirement by stating that regulations for underlying civil rights statutes requiring coordinators is sufficient for section 1557 enforcement. Another commenter stated covered entities can meet section 1557 compliance obligations without a Coordinator. Yet another commenter recommended that OCR instead encourage practices to adopt a collaborative approach where all staff take an active role in ensuring nondiscrimination.

Response: The role of the Coordinator is to promote effective and efficient implementation of section 1557 and the part, and in so doing decrease compliance inefficiencies and promote meaningful investigations of allegations of potential civil rights violations.

OCR remains confident that the benefits to a covered entity and the public of the Coordinator requirement outweigh any potential burdens. Time spent coordinating a covered entity's section 1557 compliance program is an investment that will likely result in improved, nondiscriminatory health care delivery and saving resources otherwise spent responding to potential OCR investigations and private litigation. Even if a covered entity is subject to a civil rights complaint or litigation, its Coordinator's presence and active coordination efforts may enable the covered entity to more quickly resolve a complaint or litigation.

This rule addresses the confusion that the 2020 Rule creates surrounding the extent to which covered entities were required to maintain a Coordinator for purposes of section 1557 compliance. The 2020 Rule does not clarify, for example, whether a covered entity's existing section 504 coordinator—whose role relates to ensuring a recipient's efforts to comply section 504 alone, per 45 CFR 84.7—must also ensure the covered entity's compliance with section 1557's prohibition of discrimination based on race, color, national origin, age, or sex. OCR is providing for a specific Section 1557 Coordinator, rather than relying on the requirements found in the implementing regulations for the referenced statutes, to resolve any confusion as to covered entities' responsibilities.

Comment: Some commenters requested that OCR clarify that Coordinators are responsible for covered entities' internal section 1557 oversight and that covered entities may have other staff members implement various Coordinator activities. These commenters recommended that OCR revise § 92.7(b) to add ''or designee'' after ''Section 1557 Coordinator'' to confirm that one or more staff can assist the Coordinator with the enumerated Coordinator responsibilities. Some commenters requested clarity about whether a covered entity's Coordinator can also serve in other capacities within the covered entity's organization, and whether the Coordinator requirement obligates covered entities to hire a new employee to serve as a Coordinator, and if so, whether the job description must list all of the Coordinator responsibilities enumerated at § 92.7(b).

Response: Section 92.7(a) expressly states that a covered entity may assign one or more designees to assist the Coordinator in carrying out their responsibilities. However, the Coordinator must retain ultimate oversight for ensuring the covered entity's compliance with this part. In general, it is the covered entity's prerogative to designate any qualified individual to serve as its Coordinator. A covered entity does not need to hire a new employee for the role, and the Coordinator may serve in other capacities and have responsibilities in addition to their Coordinator responsibilities at § 92.7(b); so long as those responsibilities do not create a conflict of interest or otherwise prevent the Coordinator from effectively carrying out their responsibilities.

Comment: Some commenters recommended that OCR not require covered entities to list a Coordinator's name and contact information in their publicly available Notice of Nondiscrimination because of the constant need to update Coordinators'

names and contact information due to turnover and to avoid potential harassment from section 1557 opponents. Instead, these commenters requested that OCR allow covered entities to list the Section 1557 Coordinator job title instead of an individual's name.

Response: OCR appreciates the challenges associated with updating specific contact information; for this reason, nothing in § 92.8 (Policies and procedures) or § 92.10 (Notice of nondiscrimination) require covered entities to include a Coordinator's name. As proposed, and finalized, §§ 92.8(b) and 92.10(a)(1)(v) both require ''contact information'' for the Coordinator; providing the job title rather than an individual's name is sufficient to meet this requirement. However, contact information in the form of a phone number, email address, and mailing address must also be provided. A covered entity may establish a general phone number, email address, and/or mailing address to meet this requirement. Absent this information, individuals who need to reach the Coordinator will have no knowledge of how to do so.

While this rule does not apply to employment practices, as discussed in § 92.2(b), employees of covered entities remain protected against retaliation as provided in §§ 92.303 and 92.304. If a covered entity's staff is harassing the Coordinator because of the Coordinator's job responsibilities, the covered entity should take appropriate measures to address the harassment, and, if the harassment is based on one or more characteristics protected by the Federal laws enforced by the EEOC, the Coordinator may file a charge of discrimination with the EEOC at *https://www.eeoc.gov/filing-charge-discrimination.*[70] If staff, including a covered entity's Coordinator, are being threatened by other covered entity staff or by individuals external to the covered entity, we strongly encourage reporting these threats to the FBI at 1–800–225–5324 or via *www.fbi.gov/tips.*

Comment: One commenter requested that OCR clarify whether a large health system made up of several covered entities can have a single Coordinator for the entire health system or whether each covered entity needs to have its own Coordinator. Another commenter stated that it is impossible for one Coordinator to oversee section 1557 compliance for an entire large health care system, with another suggesting that there should be at least one Coordinator for every 250 employees for covered entities with 500 or more employees.

Response: In order to provide covered entities with flexibility, OCR clarifies that large health systems may customize their Coordinator and designee configurations as long as each individual covered entity has either a Coordinator or designee responsible for section 1557 compliance. Because a covered entity is better positioned to determine how to ensure that the coordinator(s) can effectively perform all of their duties, we decline to revise the Coordinator requirement so that a covered entity is required to designate one Coordinator for every 250 employees.

Comment: A significant number of commenters recommended that all covered entities, regardless of size, have a Coordinator because ensuring section 1557 compliance is integral to providing nondiscriminatory health care services. Another commenter noted that the requirement aligns with the Joint Commission's recent standards requiring accredited hospitals and similar facilities to designate an individual to lead activities to reduce health disparities.

Several commenters stated that the 15-employee threshold is arbitrary, arcane, and inconsistent with protecting civil rights to the maximum extent possible. Others stated the position is critical for smaller covered entities that provide services to individuals with disabilities, particularly in rural and low-income communities, and for covered entities that provide long-term services and supports to older adults and people with disabilities who use home and community-based services. Others referenced that smaller covered entities include mental health providers, social workers, psychologists, counselors, and family and marriage therapists.

One commenter suggested that covered entities with fewer than 15 employees could still voluntarily designate a Coordinator.

Response: OCR appreciates comments received regarding the application of the Coordinator provision. While all covered entities, regardless of size, would benefit from having a dedicated Coordinator on staff, we decline to extend the requirement to all covered entities beyond those with 15 or more employees, in an effort to reduce unnecessary or counterproductive administrative obligations on small providers. OCR does not find this limitation to be arbitrary, as it is consistent with section 504's coordinator requirement, 45 CFR 84.7(a), and was also included in the 2016 Rule at former § 92.7. We note that covered entities with fewer than 15 employees retain the option of designating a Coordinator.

Comment: Other commenters thought the 15-employee threshold was appropriate, and that applying the requirement to smaller entities would result in burdens and costs for small and solo practices. Another commenter recommended increasing the employee threshold so that only covered entities with 50 or more employees be required to designate a Coordinator. Another commenter recommended that covered entities that fall within the Small Business Association's (SBA) classification[71] of a small business not be required to designate a Coordinator. Another commenter recommended that the Coordinator requirement be removed altogether.

Response: The Coordinator requirement is a vital step in encouraging proactive civil rights compliance; therefore, OCR declines to remove this provision. We also decline to increase the employee threshold for the Coordinator requirement to 50 or more employees. Though the coordinator requirement in title II of the ADA is limited to public entities with 50 or more employees, 28 CFR 35.107, the 15-employee threshold in section 504 is more appropriate for section 1557. Section 504 covered entities are more analogous to section 1557 covered entities given that they are recipients of Federal financial assistance of all sizes; ADA title II covered entities, however, are all State or local governments. For similar reasons, we believe that that the SBA classification of a small business—which was set in a very different context serving very different purposes—is inappropriate for this rule.

Comment: Some commenters requested additional clarity about the 15-employee threshold. For example, commenters asked whether part-time, contractor, and sub-contractor employees would count toward a covered entity's employee total or if

[70] The EEOC is responsible for enforcing Federal laws that make it illegal to discriminate against an employee because of the person's race, color, religion, sex (including pregnancy, childbirth or related medical conditions, gender identity, and sexual orientation), national origin, age (40 or older), disability or genetic information. *See* U.S. Equal Emp. Opportunity Comm'n, *Overview, https://www.eeoc.gov/overview.*

[71] U.S. Small Business Ass'n, *Basic Requirements: Meet Size Standards, https://www.sba.gov/federal-contracting/contracting-guide/basic-requirements#section-header-6* (The SBA assigns a size standard to each NAICS code. Most manufacturing companies with 500 employees or fewer, and most non-manufacturing businesses with average annual receipts under $7.5 million, will qualify as a small business.).

only full-time employees would count. One commenter suggested that, without this clarification, some covered entities will engage in hiring and human resources practices that undermine and abuse the 15-employee threshold. Another commenter also sought to clarify whether only clinical staff should count toward the 15-employee threshold and whether administrative staff should count as well.

Response: With respect to the employees who will count towards the 15 or more-employee threshold, OCR will consider the total number of individuals employed by a covered entity. This includes full-time and part-time employees and independent contractors. All employees, regardless of job classification (*e.g.,* clinical versus clerical), will count toward the threshold. We intend for this clarification to reduce concerns that the 15-employee threshold may lead to questionable employment practices.

Comment: One commenter indicated that the Coordinator requirement implicates religiously affiliated covered entities' authority to hire people who share their religious beliefs because requiring religiously affiliated covered entities to have a Coordinator may compromise the religiously affiliated covered entity's religious beliefs if its Coordinator has fundamentally different beliefs or viewpoints.

Response: Nothing in the regulatory text requires a covered entity to designate a Coordinator with a particular viewpoint or particular beliefs. No part of this final rule prevents a religiously affiliated recipient from designating or hiring an employee who shares the entity's religious beliefs as its Coordinator, provided that the individual is qualified to effectively and impartially perform the role required by the regulation. In addition, where title VII applies to a recipient's employment and hiring decisions, section 1557 does not interfere or otherwise conflict with requirements or protections afforded under title VII.

Comment: Several commenters supported the 2022 NPRM's inclusion of an enumerated list of Coordinator responsibilities at § 92.7(b). Many of these commenters appreciate the flexibility for covered entities to spread or delegate responsibilities to one or more designees within a covered entity's organization. Some commenters requested that OCR consider revising § 92.7(b) to add an additional responsibility that Coordinators coordinate with other covered entities, as necessary, to ensure that individuals who are interacting with multiple entities receive the required language assistance services and/or auxiliary aids and services. A different commenter felt that the enumerated list of Coordinator responsibilities at § 92.7(b) is too prescriptive and recommended that OCR allow each covered entity the opportunity to determine their Coordinator's responsibilities.

Response: The responsibilities enumerated at § 92.7(b) provide a baseline for expected duties while allowing covered entities the flexibility, discretion, and ability to structure responsibility for such duties to their Coordinator(s) or designee(s). A covered entity may assign duties beyond those enumerated at § 92.7(b), at its discretion.

With respect to situations where two covered entities are interacting with the same individual with LEP, individual with a disability, or individual with a disability with LEP, both covered entities are responsible for ensuring that individuals receive the appropriate language assistance services and/or auxiliary aids and services required by this rule under §§ 92.201 and 92.202. Some agencies may find that coordination between their Section 1557 Coordinators will help to more effectively meet the needs of these individuals, but OCR declines to implement a requirement to this effect as each covered entity has an obligation under this part regardless of what services they believe another covered entity may be providing.

Comment: Another commenter recommended that a covered entity's Coordinator not handle section 1557 grievances given that a covered entity may have an existing grievance collection point, which allows it to quickly address grievances through existing structures. A different commenter recommended that OCR clarify that a covered entity can assign Coordinator responsibilities to a group or division instead of one or more specific individuals because organizations may already have individuals specifically trained and responsible for ensuring nondiscrimination.

Response: These regulations do not prohibit a Coordinator from working within existing organizational structures that receive and investigate grievances or perform other Coordinator responsibilities identified in § 92.7(b). As discussed above, this provision provides a covered entity wide latitude to designate one or more Coordinator(s) and to assign one or more designee(s) to assist the Coordinator with their responsibilities, including collecting and addressing grievances. A covered entity may also assign Coordinator responsibilities to a group or division, provided that the covered entity identifies an individual Coordinator who retains ultimate oversight for coordinating section 1557 compliance.

Comment: One commenter recommended that OCR make clear that, when performing their grievance responsibilities, the Coordinator is required to collect specific data, including: alleged basis or bases of discrimination; the date the grievance was filed; the date of the alleged discriminatory action; and the grievance resolution. This commenter indicated that this data should not include individually identifying information and indicated that the covered entity, through the Coordinator, should be responsible for the privacy of the data that they collect while fulfilling their coordinator role. A different commenter recommended that OCR require Coordinators to review grievance data in order to identify potential and actual discriminatory trends.

Response: OCR appreciates the commenter's suggestion regarding the data that must be retained for each grievance. However, we decline to include these details here as the data points the commenter suggested are already in § 92.8(c)(2), which discusses the information that must be retained in grievance records. Although this final rule does not require covered entities to collect data on trends across the organization, we highly encourage all Coordinators to review grievance data to identify and address any potential and actual discriminatory trends revealed in such data. We discuss this in greater detail at § 92.8(c) (grievance procedure).

Comment: Multiple commenters requested that OCR provide training and other resources to help covered entities implement the Coordinator requirement. Some commenters requested that OCR provide (1) training for people who are new to the Coordinator role and for providers who are updating the role; (2) facts sheets to introduce section 1557 to the Coordinator and other staff throughout the organization; and (3) checklists that can be consulted and used to confirm the Coordinator's responsibilities. One commenter requested that OCR training for Coordinators include civil rights, cultural, and implicit bias training.

Response: OCR commits to serve as a resource and partner with covered entities that need help regarding their Coordinator obligations. As discussed in further detail at § 92.8 (Policies and procedures), we plan to make various resources available to assist Coordinators with their responsibilities.

Comment: One commenter asked how OCR will audit covered entities'

compliance with the Coordinator requirement and whether the Coordinator post will be eligible for the Federal matching rate as an administrative activity under section 1903(a)(7) of the Social Security Act.

Response: Consistent with current practice, OCR will determine a covered entity's compliance with the Coordinator requirement during complaint investigations and affirmative compliance reviews. With regard to the commenter's inquiry regarding the availability of Federal financial participation under section 1903(a)(7) of the Social Security Act, 42 U.S.C. 1396b(a)(7), OCR does not administer Medicaid and therefore this comment is outside of the scope of this rulemaking.

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 § 92.7, without modification.

Policies and Procedures (§ 92.8)

At § 92.8 of the 2022 NPRM, OCR proposed requiring covered entities to develop and implement written policies and procedures that are designed to facilitate compliance with the requirements of the part. We proposed requiring each covered entity, in its health programs and activities, to adopt and implement a nondiscrimination policy, grievance procedures (for covered entities employing 15 or more persons), language access procedures, auxiliary aids and services procedures, and procedures for reasonable modifications for individuals with disabilities (collectively, ''Section 1557 Policies and Procedures'').

In § 92.8(a), we proposed a general requirement for covered entities to implement written Section 1557 Policies and Procedures. 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 the part.

In § 92.8(b), we proposed requiring each covered entity to implement a written nondiscrimination policy that, at minimum, provides the contact information for the Section 1557 Coordinator (if applicable) and states that the covered entity in its health programs and activities: is prohibited from unlawfully discriminating on the basis of race, color, national origin (including limited English proficiency and primary language), sex (including pregnancy, sexual orientation, gender identity, and sex characteristics), age, or disability; and provides language assistance services and appropriate auxiliary aids and services free of charge, when necessary for compliance with section 1557 or the part.

In § 92.8(c), we proposed addressing the requirements for covered entities with 15 or more employees with regard to grievance procedures and recordkeeping in their health programs and activities, including ensuring that the grievance procedure is accessible to individuals with LEP and individuals with disabilities.

In § 92.8(c)(1), we proposed requiring that covered entities with 15 or more employees establish written civil rights grievance procedures.

In § 92.8(c)(2), we proposed that a covered entity must retain records related to grievances filed with it that allege discrimination on the basis of race, color, national origin, sex, age, or disability in its health programs and activities for no less than three (3) years from the date of the filing of the grievance.

In § 92.8(c)(3), we proposed that a covered entity keep confidential the identity of an individual who has filed a grievance, except as required by law or to the extent necessary to carry out the purposes of this proposed regulation, including the conduct of any investigation.

We invited comment on the record retention requirement, particularly with regard to patient privacy concerns or concerns regarding potentially unauthorized use of information included in such records. We also sought comment on best practices for record retention of grievance procedures, including strategies for ensuring patient privacy.

In § 92.8(d), we proposed requiring covered entities to develop and implement written language access procedures to support compliance with requirements to take reasonable steps to provide meaningful access to individuals with LEP in their health programs and activities under proposed § 92.201.

In § 92.8(e), we proposed requiring covered entities to develop and implement written effective communication procedures to support compliance with requirements to take appropriate steps to ensure that communications in their health programs and activities with individuals with disabilities are as effective as communications with individuals without disabilities under proposed § 92.202.

In § 92.8(f), we proposed requiring covered entities to develop and implement written procedures for making reasonable modifications to their policies, practices, or procedures that allow individuals with disabilities equal opportunity to participate in their health programs and activities as required under proposed § 92.205.

In § 92.8(g), we proposed that a covered entity may combine the content of the policies and procedures required by this provision with any policies and procedures pursuant to other civil rights statutory protections if they clearly comply with section 1557 and the provisions in the part.

We sought comment on this proposed provision and whether there may be alternative measures that OCR should consider to proactively prevent discrimination, and whether they would be more or less burdensome than what was proposed. We also invited comment from all covered entities that had previously implemented or were currently implementing any of the proposed procedures; consumers who interact with covered health programs and activities; and community-based organizations that work with individuals with LEP and individuals with disabilities. We also requested comment on whether covered entities employing fewer than 15 people should be required to have a grievance procedure, including the benefits of a less formal resolution process.

The comments and our responses regarding § 92.8 are set forth below.

General Comments

Comment: Many commenters expressed support for the Section 1557 Policies and Procedures requirement at § 92.8, noting that, in their view, it will help prevent discrimination and health disparities; requires providers to proactively engage in the process of avoiding discrimination; elevates covered entities and their employees' knowledge about their section 1557 obligations; and alleviates the burden on patients to file complaints in order to trigger section 1557 compliance and enforcement. Some commenters supported the requirement because the 2020 Rule leaves requirements for policies and procedures disjointed, confusing, and ineffective.

Some commenters recommended that OCR strengthen this requirement by requiring covered entities to evaluate the effectiveness of their Section 1557 Policies and Procedures and update them when necessary to ensure consistency.

Response: Covered entities' Section 1557 Policies and Procedures should be dynamic and updated to ensure covered entities comply with changes in the law

and meet their section 1557 obligations. In addition, when covered entities' operations change, this may necessitate revising Section 1557 Policies and Procedures to maintain section 1557 compliance.

Accordingly, we have added § 92.8(h) to address when it is required and permissible for a covered entity to revise their Section 1557 Policies and Procedures. Section 92.8(h)(1) explains that a covered entity must review and revise its policies and procedures, as necessary, to ensure they are current and in compliance with section 1557 and this rule. Section 92.8(h)(2) states that a covered entity may change its policies and procedures at any time, provided that the changed policies comply with section 1557 and the part.

Comment: Some commenters who opposed this requirement cited covered entities' existing compliance burdens and the resources needed to draft Section 1557 Policies and Procedures. Some commenters requested that, if OCR maintains the requirement in the final rule, OCR make template Section 1557 Policies and Procedures available for covered entities to use and tailor to their organizations as far in advance of the final rule's effective date as possible.

One commenter stated that existing Federal and State regulations prevent covered entities from focusing on high-quality care, and that this requirement is an unfunded mandate. One commenter recommended that OCR should continue previously permitted flexibility and allow covered entities to develop Section 1557 Policies and Procedures voluntarily.

Response: To assist covered entities' compliance with this requirement, OCR has developed Section 1557 Policies and Procedures templates that are available on OCR's website at *www.hhs.gov/1557*, which are designed to assist covered entities in tailoring their own Section 1557 Policies and Procedures. We reiterate the requirement that a covered entity's Section 1557 Policies and Procedures must be reasonably designed, take into account a covered entity's size, complexity, and the type of health programs or activities provided. A covered entity should view these templates as a starting point for adopting and implementing Section 1557 Policies and Procedures that are specific to their health programs and activities. The templates provided may be insufficient for large covered entities given the range in complexity and structure of those entities, and entities must ensure that their Section 1557 Policies and Procedures reflect the appropriate scope.

Comment: Some commenters recommended that OCR not require covered entities to identify the names of their respective Coordinators in their Section 1557 Policies and Procedures required by § 92.8(b), (d), (e), and (f) because high employee turnover may make coordinators' names obsolete and require constant changes.

Response: OCR notes that nothing in § 92.8 requires a covered entity to identify the Coordinator by name; rather, § 92.8(b), (d), (e), and (f) require the Coordinator's current contact information. The referenced provisions require sufficient information for an individual who needs assistance in implementing the procedures to reach the Coordinator. Thus, a covered entity could choose to list the position title with a phone number, email address, and mailing address.

Comment: One commenter requested that OCR clarify, especially with respect to large health systems (such as hospitals, clinics, home care entities, and home medical equipment retail settings), the regulatory language related to scalability.

Response: OCR recognizes that covered entities—including not only recipients, but also the Department and title I entities—need flexibility when developing and implementing their Section 1557 Policies and Procedures. A covered entity should consider its size, capabilities, the costs of specific measures, the operational impact, and the composition of the patient populations they serve in deciding the appropriate scale of their Section 1557 Policies and Procedures. Thus, OCR expects the scope and detail of a covered entity's Section 1557 Policies and Procedures to vary accordingly.

Comment: Some commenters requested that OCR include additional required policies and procedures, such as policies and procedures regarding service animals, protecting civil rights in public health emergencies, assessing the competency of bilingual/multilingual staff, and telehealth. Specifically, one commenter recommended requiring a telehealth procedure designed to assist covered entity employees communicate with patients before, during, and after telehealth visits, and that this telehealth procedure could address pre-appointment telehealth screenings to ensure that patients have the necessary equipment or technology for their appointments and to determine whether the patient has the requisite technological skills to participate in a telehealth session. The proposed telehealth procedure would require covered entities to provide telehealth training resources for patients who lack skills or familiarity with telehealth prior to their appointments. Other commenters recommended that covered entities' procedures ensure accessibility for individuals with physical and/or behavioral health disabilities and specifically comply with the U.S. Access Board's Standards for Accessible Medical Diagnostic Equipment. 82 FR 2810 (Jan. 9, 2017).

Response: OCR recognizes the benefit of policies and procedures to support civil rights compliance. However, we recognize that developing and implementing such policies and procedures is not without an initial burden on the covered entities, and the continued—though much diminished—effort of maintaining the procedures and employee familiarity with such procedures. For that reason, we decline to require additional policies and procedures at this time. However, covered entities are encouraged to develop and implement policies and procedures related to service animals, protecting civil rights during public health emergencies, assessing bilingual and multilingual staff members' competency, nondiscriminatory provision of telehealth,[72] accessible medical equipment, or any other situation they choose in order to ensure compliance with section 1557. For more about section 1557's accessibility requirements, please refer to our discussion for § 92.204, which requires covered entities to make their buildings and facilities accessible to individuals with disabilities. In addition, please see the discussion of medical diagnostic equipment under § 92.207. Please also see the discussion of § 92.211 related to nondiscrimination in the delivery of health programs and activities through telehealth services.

Summary of UUegulatory changes

For the reasons set forth in the Proposed Rule and considering the comments received, we are finalizing the policies and procedures requirement provision at § 92.8 as proposed, with modifications. We have added a paragraph (h) that explains that a covered entity must review and revise its policies and procedures, as necessary, to ensure they are current and in compliance with section 1557 and this rule and that a covered entity

[72] *See, e.g.,* U.S. Dep't of Health & Hum. Servs., Off. for Civil Rts.; U.S. Dep't of Justice, Civil Rts. Div., *Guidance on Nondiscrimination in Telehealth: Federal Protections to Ensure Accessibility to People with Disabilities and Limited English Proficient Persons, https://www.hhs.gov/sites/default/files/guidance-on-nondiscrimination-in-telehealth.pdf.*

may change its policies and procedures at any time, provided that the changed policies comply with section 1557 and this rule.

Nondiscrimination Policy

Comment: Many commenters supported the Nondiscrimination Policy at proposed § 92.8(b). Some commenters recommended that OCR revise the language in this Policy so that the description of prohibited sex discrimination is consistent with the description of sex discrimination included in § 92.101 (*i.e.,* revise to include sex stereotypes and pregnancy or related conditions). Some of these commenters further recommended that OCR also specify that ''pregnancy or related conditions'' includes termination of pregnancy. Other commenters requested that OCR further revise § 92.8(b)'s reference to sex discrimination and make a corresponding revision to § 92.101(a)(2) by adding ''transgender status'' to the description of sex discrimination for both provisions.

Response: OCR appreciates the need for consistency across the regulation, and to ensure that the public is aware of the various types of discrimination included under the umbrella of sex discrimination. We clarify that a Nondiscrimination Policy's prohibition of sex discrimination encompasses protections afforded for various types of sex discrimination such as pregnancy, including termination of pregnancy or related conditions, and we have revised the parenthetical in § 92.8(b) to explain that this provision's reference to sex discrimination is consistent with the various types of sex discrimination described at § 92.101(a)(2), which includes ''gender identity.'' We decline to add ''transgender status'' to the regulatory text, as the term ''gender identity'' necessarily encompasses ''transgender status'' and these terms are often used interchangeably.[73]

At the same time, we want to emphasize that 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). HHS will comply with this provision.[74] For further discussion regarding what constitutes sex discrimination, including the application of religious freedom and conscience protections in this context, please see the discussion at § 92.101(a)(2).

Comment: One commenter expressed opposition to § 92.8(b) because it would increase paperwork without benefiting or improving the quality of care.

Response: As we noted above, many commenters, some of which are providers and professional medical associations, support the requirement to have a Nondiscrimination Policy. Peer-reviewed medical publications acknowledge that a health care organization's written policies and procedures can improve quality of care and mitigate the legal risk of causing patient harm.[75] Indeed, research suggests that the mere existence of policies that prohibit discrimination helps reduce health and other inequities.[76] Thus, we disagree with the commenter's contention that § 92.8(b) increases paperwork without benefitting or improving quality of care particularly for individuals who belong to communities with a history of experiencing discrimination in health care settings.

Comment: A few commenters expressed First Amendment concerns related to the overarching Section 1557 Policies and Procedures requirement, particularly the Nondiscrimination Policy requirement. One of these commenters recommended that, with respect to the Section 1557 Policy and Procedures requirement, OCR should clarify that covered entities retain free speech protections to the extent that sex discrimination does not result if a covered entity acknowledges a patient's sex assigned at birth. An organizational commenter stated that the Nondiscrimination Policy is problematic under the First Amendment because requiring a covered entity to state that it does not discriminate on the bases of pregnancy, sexual orientation, gender identity, and sex characteristics constrains freedom of speech and freedom of association.

Response: OCR acknowledges the comments regarding protections on the basis of sex, particularly as they relate to nondiscrimination on the basis of pregnancy or related conditions, sexual orientation, and gender identity. As noted above, we have revised § 92.8(b) by removing descriptions of sex discrimination and by cross-referencing § 92.101(a)(2) and that provision's description of sex discrimination. Thus, a covered entity's Nondiscrimination Policy need not explicitly include the various forms of prohibited sex discrimination to address any potential First Amendment concern. However, we emphasize that these concerns do not negate a covered entity's obligation to implement Section 1557 Policies and Procedures.

We also note here that we have amended the regulatory text to add, as a best practice towards compliance, that a recipient's Nondiscrimination Policy reflect assurance of exemptions that have been triggered or that have been granted to that recipient under § 92.302.

Summary of Regulatory Changes

For the reasons set forth in the Proposed Rule and considering the comments received, we are finalizing the Nondiscrimination Policy requirement at § 92.8(b) as proposed, with modifications. We are revising § 92.8(b)(1) to adjust the explanatory parenthetical for sex in the Nondiscrimination Policy to state ''consistent with the scope of sex discrimination described at § 92.101(a)(2).'' We are revising § 92.8(b) to add paragraph (b)(2) that states, ''OCR considers it a best practice toward achieving compliance for a covered

[73] *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).

[74] The application of this final rule to covered entities with religious freedom or conscience objections is discussed more fully below in §§ 92.3 (Relationship to other laws) and 92.302 (Notification of views regarding application of Federal religious freedom and conscience laws).

[75] *See* James O'Donnell et al., *Policies and Procedures: Enhancing Pharmacy Practice and Limiting Risk,* 37 Health Care & L. 341 (2012), *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3411206/*; Savithiri Ratnapalan et al., *Organizational Learning in Health Care Organizations,* 2 Systems 24–33 (2014), *https://www.mdpi.com/2079-8954/2/1/24.*

[76] *See generally* Douglas Almond & Kenneth Chay, *Civil Rights, The War on Poverty, and Black-White Convergence in Infant Mortality in the Rural South and Mississippi,* Mass. Inst. of Tech., Dep't of Economics, Working Paper Series, SSRN, (2007), *https://papers.ssrn.com/sol3/papers.cfm?abstract_id=961021*; Doughlas Almond & Kenneth Chay, *The Long-Run and Intergenerational Impact of Poor Infant Health: Evidence from Cohorts Born During the Civil Rights Era,* Nat'l Bureau of Econ. Rsch (2006), *https://users.nber.org/~almond/chay_npc_paper.pdf*; Nancy Krieger et al., *The Unique Impact of Abolition of Jim Crow Laws on Reducing Inequities in Infant Death Rates and Implications for Choice of Comparison Groups in Analyzing Societal Determinants of Health,* 103 a.m. J. of Pub. Health, 2234 (2013), *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3828968/*; John J. Donahue III & James Heckman, *Continuous Versus Episodic Change: The Impact of Civil Rights Policy on the Economic Status of Blacks,* NBER Working Papers Series, SSRN, (2007), *https://papers.ssrn.com/sol3/papers.cfm?abstract_id=474003*; David Card & Alan Krueger, *Trends in Relative Black-White Earnings Revisited,* 83 The Am. Econ. Rev. 85–91 (1993), *https://www.jstor.org/stable/2117645#:~:text=For%20both%20of%20these%20cohorts,1939%20cohort%20is%20especially%20noteworthy.*

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.''

Grievance Procedures

Comment: In general, commenters supported the grievance procedures requirement at § 92.8(c), including because allowing patients to voice concerns to providers builds trust between patients and providers.

Response: OCR's enforcement experience reveals that grievance procedures help covered entities lower compliance costs and provide covered entities the opportunity to resolve grievances—through direct communication with the individual raising the grievance—in the quickest possible manner without OCR's involvement.

Comment: Some commenters recommended that OCR require covered entities to adjudicate grievances quickly, and some of these commenters specifically requested that OCR add timeframes by which section 1557 grievances must be both acknowledged and resolved because covered entities may either belatedly or never acknowledge a complaint or take longer than perceived as necessary to resolve grievances. Others requested that OCR define ''prompt and equitable'' resolution, with one stating that ''equitable'' is a subjective construct and suggested that OCR consider requiring covered entities to resolve grievances by affording the aggrieved individual appropriate access to the health program or activity at issue. Relatedly, another commenter asked that OCR consider differentiating between pretreatment grievances and other grievances, because denials of care and coverage can result in the postponement or foregoing of care altogether and can require patients to wait for the resolution of a grievance before seeking care from an alternate provider.

Response: We appreciate these commenters' desire for additional specificity regarding what is meant by ''prompt and equitable'' resolution of a grievance. This terminology is consistent with grievance procedures requirements found in the Department's section 504 and title IX regulations at 45 CFR 84.7(b) and 86.8(b), respectively.

Imposing a single timeframe by which a covered entity must resolve a grievance does not account for the fact that covered entities vary in size, resources, and capabilities, and so one timeframe may not be appropriate for all entities. Multiple factors may impact the length of time required to evaluate and resolve a particular grievance and to ensure a fair process and reliable outcome, including the nature of the grievance. This is balanced by the fact that prompt resolution of complaints is necessary to further section 1557's nondiscrimination objective. We encourage individuals to file complaints with OCR if they have filed a grievance that they do not believe has been resolved in a prompt and equitable manner. OCR's investigation of such a complaint may determine whether a covered entity's grievances procedures truly provide for prompt and equitable resolutions, and if they do not, OCR may seek corrective actions from the covered entity. For these reasons, we decline to add timeframes within which covered entities are required to address grievances, and we decline to define the term ''prompt and equitable.''

Comment: Some commenters recommended that OCR require covered entities to notify individuals of the ability to file a grievance. Other commenters requested that OCR revise § 92.8(c) to require a covered entity's process for filing grievances be simple, not burdensome, and accessible to individuals with LEP and individuals with disabilities.

Response: To the extent covered entities are required to have grievance procedures, covered entities are also required to include information about the availability of their grievance procedures and how to file a grievance in their Notice of Nondiscrimination, per § 92.10(a)(1)(vi). All covered entities, regardless of size, must also include information in the Notice of Nondiscrimination on how to file a discrimination complaint with OCR, per § 92.10(a)(1)(vii).

In addition, the grievance process must be accessible to individuals with LEP and individuals with disabilities, consistent with section 1557 and this regulation. If an individual finds that a covered entity's grievance process is generally overly burdensome to the point it is ineffective or nonexistent and thus hindering the prompt and equitable resolution of grievances, we recommend the individual file a complaint with OCR.

Comment: Many commenters on this provision recommended that OCR require all covered entities (not just those with 15 or more employees) to have grievance procedures, while others either requested that OCR maintain the 15-employee threshold or eliminate the requirement altogether.

Commenters in support of eliminating the 15-employee threshold contended that a covered entity's size does not protect patients from discrimination and the threshold is inequitable because it deprives patients of smaller covered entities the opportunity to directly engage with the covered entity to address alleged discrimination. According to commenters, individuals with disabilities face significant barriers to care when seeking and receiving services from smaller covered entities, and the 15-employee threshold unjustly deprives individuals with disabilities of the opportunity to address these barriers through grievances.

Further, commenters remarked that regulatory carve outs and distinctions are confusing and difficult for both covered entities and patients when determining applicable requirements and protections. Commenters expressed concern that individuals from marginalized communities would be confused about why they could not submit a grievance with a covered entity with fewer than 15 employees simply due to the size of the covered entity, when other requirements in the rule apply regardless of covered entity size.

Commenters also raised the following issues countering inclusion of a 15-employee threshold: the statutory text of section 1557 is not so limited; the limitation is inconsistent with expanding section 1557's application; an individual should have the ability to address discrimination in the first instance directly to the covered entity; and a covered entity with fewer than 15 employees that has grievance procedures will be able to resolve discrimination complaints more promptly at an earlier stage without formal OCR investigation.

Citing the burden on smaller covered entities, some commenters requested that OCR maintain the grievance procedures requirement only for covered entities with at least 15 employees, eliminate the procedures altogether or utilize the SBA's definition of small business.

Response: We appreciate commenters' concerns about the 15-employee threshold and recognize that individuals are not immune from experiencing discrimination when interacting with smaller covered entities. However, OCR declines to apply this requirement to all covered entities and note that this approach is consistent with OCR's section 504 regulation, which similarly limits the grievance procedure requirement. *See* 45 CFR 84.7(a). Individuals remain able to file complaints with OCR when they experience discrimination in health programs and activities and may also raise concerns to smaller covered

entities outside of a formal grievance process.

Given the benefits of having grievance procedures, we encourage smaller covered entities to voluntarily implement such procedures, which may help them more meaningfully engage with all individuals, including members of underserved communities, and better identify potential barriers to accessing their health programs and activities.

Comment: Some commenters pointed to the Health Insurance Portability and Accountability Act of 1996 (HIPAA) as precedent and demonstrable evidence that the Department believes providers of all sizes have the ability to comply with a Federal requirement to implement a process for handling complaints. These commenters suggested that all HIPAA-covered entities, including those with fewer than 15 employees, have experience implementing a process for receiving, handling, and investigating privacy complaints, which these covered entities can modify or replicate, if necessary, to include section 1557 discrimination grievances.

Response: OCR appreciates commenters' observation that HIPAA-covered entities of all sizes have experience implementing a complaint process. However, we are unpersuaded that the potential burden to smaller covered entities with existing HIPAA complaint processes would be minimal because these entities would need to revise their existing policies, train relevant staff, and process civil rights-related grievances in addition to processing HIPAA-related complaints. This is similar to our position in response to comments received in response to the 2015 NPRM. 81 FR 31395. Nothing in this rule prohibits entities of fewer than 15 employees from voluntarily creating a grievance process.

Comment: In support of requiring all covered entities to have grievance procedures, commenters suggested that covered entities could have less extensive or detailed grievance procedures, and that such a procedure would not need to involve significant staff or resources. These commenters recommended that OCR develop model grievance procedures for smaller covered entities to help them comply with the grievance procedures requirement.

Response: To assist all covered entities—including those with fewer than 15 employees that may wish to voluntarily implement a grievance procedure—we have made available sample grievance procedures on OCR's website at *www.hhs.gov/1557*. We note that the sample grievance procedure available on OCR's website is more appropriate for smaller covered entities, and we remind covered entities that the rule's general Section 1557 Policies and Procedures requirement is founded on the principle of scalability. Accordingly, the sample grievance procedure on our website may not be adequate for a larger covered entity or health system made up of several covered entities.

Comment: Many commenters supported the record retention requirement at § 92.8(c)(2). Under this provision, we proposed that covered entities must retain records for a minimum of three (3) calendar years, and each record must include the name and contact information of the complainant, the alleged discriminatory action and alleged basis or bases of discrimination, the date the grievance was filed, the grievance resolution, and any pertinent information.

Some commenters expressed that this requirement will help covered entities identify potential patterns and practices of discrimination of which they may not have otherwise been aware. Other commenters who supported this requirement expressed concern about patient privacy and recommended that OCR require covered entities to deidentify information related to the grievance during the retention period.

Response: We appreciate commenters' support for this new provision and recognize the importance of ensuring patient privacy related to recordkeeping. Section 92.8(c)(3) requires covered entities to keep confidential the identity of the individual who submits a grievance, subject to limited exceptions. We decline to revise the records retention requirement to require covered entities to deidentify that information related to the grievance.

Many section 1557 covered entities must also comply with the HIPAA Privacy and Security Rules, which requires HIPAA covered entities to protect and secure all protected health information that a covered entity or business associate creates, receives, maintains, or transmits. If a covered entity discloses an individual's protected health information in violation of the HIPAA Rules, then the covered entity is subject to OCR's HIPAA enforcement measures.[77] If a section 1557 covered entity maintains grievance records beyond three (3) calendar years, the covered entity may deidentify the information after the records retention period has elapsed. Even where a section 1557 covered entity is not subject to HIPAA, that section 1557 entity must still comply with all applicable Federal and State privacy laws.

Comment: One commenter requested that OCR revise § 92.8(c)(2) so that a covered entity be required to retain only ''actionable'' grievances because large, covered entities may receive grievances that are not related to section 1557's protections. This commenter gave an example that a complaint may be employment-related, and therefore § 92.8(c)(2) should not require a covered entity to retain such a grievance.

Another commenter raised a similar concern and recommended that OCR completely eliminate any record retention requirement as they relate to grievances because it is difficult to know when a grievance triggers the retention requirement. This commenter requested that, if OCR retains the grievance records retention requirement, that it only apply to covered entities with 15 or more employees.

Response: Section 92.8(c)(2) applies only to covered entities that are required to have grievance procedures (*i.e.,* those with 15 or more employees), and this provision expressly specifies that covered entities retain grievances it receives pursuant to the grievance procedures requirement at § 92.8(c)(1) that allege discrimination on the basis of race, color, national origin, sex, age, or disability in the covered entity's health programs or activities. Thus, covered entities need not retain records pertaining to employment-related grievances or grievances that do not allege discrimination based on race, color, national origin, sex, age, or disability in the covered entity's health programs or activities. If a covered entity cannot determine whether a complaint relates to section 1557, the covered entity should contact the complainant to obtain sufficient information to either investigate the grievance or determine if the complaint should be handled under a different process. We note that a covered entity's dismissal of a grievance constitutes its resolution of the grievance.

Comment: One commenter who expressed support for the retention requirement opined that the proposed three-year retention period is less burdensome than the seven-year retention requirement applicable to most records for hospice and palliative care. Another commenter recommended that covered entities be required to retain grievance-related records permanently due to the low costs associated with maintaining these records electronically, and a covered entity could find older records useful in

[77] *See* 45 CFR 160.312 and 160.400 through 160.414.

litigation. Another commenter recommended that OCR adopt a four-year retention period to match section 1557's four-year statute of limitations [78] because a retention period shorter than section 1557's statute of limitations would prevent private litigants from obtaining grievance-related evidence relevant to a section 1557 claim. One commenter also recommended that OCR revise § 92.8(c)(2) so that the timeframe for covered entities to retain grievance records starts once the covered entity resolves the grievance rather than when the covered entity receives it.

Response: OCR has determined that the three-year record retention requirement strikes the appropriate balance between covered entities' burden concerns and the need for OCR to access this vital information in the course of a complaint investigation or compliance review. As stated in the 2022 NPRM, we understand that many covered entities already have a practice of retaining grievance records, and nothing in this rule prevents a covered entity from retaining records longer if they so choose. 87 FR 47849.

We appreciate commenters' recommendation that OCR specify that the retention obligation starts on the date that the covered entity resolves the grievance rather than on the date that the complainant filed the grievance, and we are revising § 92.8(c)(2) to reflect this change. Grievances take varying amounts of time to resolve, and starting the retention obligation on the date of receipt could potentially result in a covered entity disposing of records pertaining to a grievance prior to the resolution of the grievance. This change necessitates that we further revise § 92.8(c)(2) to require a covered entity's grievance records also include the date that the covered entity resolved a grievance.

Summary of Regulatory Changes

For the reasons set forth in the Proposed Rule and considering the comments received, we are finalizing the Grievance Procedure requirement provision at § 92.8(c) as proposed, with modifications. We are revising § 92.8(c)(2) to explain that the grievances that a covered entity must retain are those filed pursuant to its grievance procedures required by § 92.8(c)(1) that allege discrimination based on race, color, national origin, sex, age, and disability in a covered entity's health programs or activities, and that the records include the date the grievance was resolved. We are also clarifying at § 92.8(c)(2) that the retention period for grievance procedures starts on the date the covered entity resolves the grievance.

Language Access Procedures

Comment: Most commenters on this provision expressed support for the proposed language access procedures requirement at proposed § 92.8(d). Some commenters recommended that OCR revise § 92.8(d) to make clear that a covered entity's language access obligations extend to companions of patients, beneficiaries, enrollees, and applicants.

Response: It has been OCR's practice to require covered entities to provide language assistance services for LEP companions of patients, beneficiaries, enrollees, and applicants when necessary. Rather than revising § 92.8(d), we are revising § 92.201 (Meaningful access for individuals with LEP) to codify this requirement. We discuss this further when addressing comments related to § 92.201. Because the language access procedures are intended to assist covered entities in complying with their language access obligations under § 92.201, they should ensure that companions are included.

Comment: One commenter recommended that OCR allow covered entities the flexibility to identify the process and business rules that they currently use to identify individuals with LEP, how to provide language assistance services, and how to create and store translated materials and resources. This commenter suggested that § 92.8(d) reads as if it is intended for smaller covered entities that provide language assistance services in an ad hoc manner.

Response: Section 92.8(d) applies to covered entities of all sizes, allowing flexibility for covered entities to scale their language assistance services procedures as needed. Section 92.8(d) does not restrict the manner in which a covered entity implements its language access procedures, which may include the use of pre-existing business tools that meet the necessary requirements. For example, § 92.8(d) does not dictate how covered entities' employees identify individuals with LEP or how covered entities obtain language assistance services from qualified interpreters and translators (*i.e.,* through contract interpreters, in-house interpreters, etc.).

Comment: Some commenters indicated that often patients with LEP have to repeat a language access intake process with every visit to a covered entity, even when they have already gone through such a process and their language access needs have been previously identified by the covered entity. To avoid this situation, commenters recommended that OCR require covered entities to note in a patient's records whether the patient needs language assistance services, and if so, the specific language and services needed.

Response: OCR understands that repeatedly having to request necessary language assistance services from the same covered entity can be frustrating and may result in wasted time or the cancellation of an appointment if the needed services are unavailable. While the commenters' suggestion for covered entities to document the specific language assistance services needs in the patient with LEP's record is a best practice that we encourage for inclusion in a covered entities' language access procedures, OCR declines to revise § 92.8(d). As drafted, the provision allows covered entities the flexibility needed to comply.

Comment: Some commenters requested that OCR revise § 92.8(d) with text: (1) directly from § 92.201 related to covered entities' obligation to provide each individual with LEP with meaningful access; and (2) that aligns with Executive Order 13166 (''Improving Access to Services for Persons with Limited English Proficiency''); [79] title VI; Medicaid's commitment to enhancing access through culturally competent care as defined in 42 CFR 440.262; and the Agency for Healthcare Research and Quality's ''Improving Patient Safety Systems for Patients with Limited English Proficiency'' guide.[80]

Response: Section 92.8(d) already references covered entities' obligations under § 92.201, so it is unnecessary to restate that language here. We decline to modify the provision to add language from the suggested requirements and resources, as this provision relates to covered entities' obligation under section 1557.

Comment: Many commenters sought clarity about whether the language

[78] *See, e.g., Tomei* v. *Parkwest Med. Ctr.,* 24 F.4th 508, 515 (6th Cir. 2022) (holding the catchall Federal statute of limitations at 28 U.S.C. 1658(a) applies to claims under section 1557 because section 1557 lacks an express statute of limitations); *but see Solis* v. *Our Lady of the Lake Ascension Cmty. Hosp., Inc.,* No. CV 18–56–SDD–RLB, 2020 WL 2754917, at *4 (M.D. La. May 27, 2020) (applying the Rehabilitation Act statute of limitations to a section 1557 claim of disability discrimination).

[79] E.O. 13166, 65 FR 50121 (Aug. 11, 2000).

[80] U.S. Dep't of Health & Hum. Servs., Agency for Healthcare Rsch. and Quality, *Improving Patient Safety Systems for Patients With Limited English Proficiency: A Guide for Hospitals* (2012), *https://www.ahrq.gov/sites/default/files/publications/files/lepguide.pdf.*

access ''procedures'' required by § 92.8(d) differ from documents commonly referred to as language access ''plans.'' Noting OCR's longstanding recognition of the benefits of having a language access plan, as expressed in the Department's ''2003 Guidance to Federal Financial Assistance Recipients Regarding Title VI Prohibition Against National Origin Discrimination Affecting Limited English Proficient Persons'' (HHS LEP Guidance), 68 FR 47311 (Aug. 8, 2003), many commenters recommended that OCR modify § 92.8(d) to clarify that covered entities must develop and implement a language access plan before developing language access procedures because developing effective policies and procedures require such advance planning and give covered entities clear policies to follow when seeing patients with LEP.

According to these commenters, formal language access plans require a covered entity to consider and evaluate the needs of a service area, providing a better understanding of populations, prevalence of specific language groups, language access needs, and scope of services needed to provide meaningful access. Commenters highlighted the rapid growth of pockets of individuals with LEP with distinct language and cultural conventions, including indigenous immigrant populations from Central and South America, and the changing language needs for recent arrival of refugees from Afghanistan, Ukraine, Russia, and other non-English speaking countries.

In contrast, one commenter appreciated that the Proposed Rule did not require covered entities to implement language access plans and noted that small, covered entities lack resources, including time, administrative effort, and financial resources to implement a language access plan. Citing the 2015 NPRM, the commenter stated the cost to develop a language access plan at $1,135 per small, covered entity,[81] and recommended that OCR finalize the rule without requiring covered entities to develop and implement a language access plan.

Response: OCR appreciates commenters' emphasis on the value of language access plans, which as commenters noted, are distinct from the language access procedures required under this section. Covered entities are not explicitly required to analyze the specific populations with LEP in their service areas. However, in order to develop effective language access procedures and ensure compliance with the obligations at § 92.201, a covered entity will need to engage in some form of analysis to identify the language access needs in their service area.

For example, when finalizing a list of preferred language assistance services providers, a covered entity will need to determine which providers are most capable of meeting the language needs of the individuals with LEP within the service area. To best inform its decision-making process, a covered entity may first attempt to identify the non-English languages most spoken in the relevant service area and confirm that interpreter and translation service providers can accommodate those languages. The HHS LEP Guidance, cited by commenters, is still instructive and relevant and provides helpful information in how to develop a strategy for delivery of language assistance services. *See* 68 FR 47313–22. Covered entities are also encouraged to use the language access planning resources provided at *https://www.lep.gov/language-access-planning* or reference HHS's 2023 Language Access Plan for guidance at *https://www.hhs.gov/sites/default/files/Language-Access-Plan-2023_0.pdf*.

Covered entities with language access plans are often better prepared to provide individuals with LEP with meaningful access to their health programs and activities. For covered entities that have developed, implemented, and maintained language access plans, we highly encourage those covered entities to sustain that practice and to consider modifying their plans to include the elements required by § 92.8(d), to the extent it is not already included. To the extent a covered entity's language access plan meets the requirements of § 92.8(d), a separate procedures document will not be required regardless of whether the document is referred to as a ''plan'' or ''procedures.''

Comment: Some commenters recommended that OCR delete the requirement in § 92.8(d) for covered entities to identify the names of qualified bilingual/multilingual staff members due to employee turnover, with one commenter also requesting that OCR eliminate the requirement to maintain a list and location of electronic and written translated materials because such a requirement would be an onerous, inefficient use of time due to frequent changes to translated materials. Another commenter indicated that these requirements are especially difficult for large, covered entities, and that health insurance issuers in particular should have the option to provide business rules and rationale with respect to how and where they store documents rather than create a duplicative process. This commenter also recommended that OCR allow covered entities to articulate the process for accessing language services and contact information for the covered entity's department or functional group responsible for translations.

Response: OCR acknowledges that covered entities may need to periodically revise their language access procedures to reflect changes to qualified bilingual/multilingual staff; however, these staff members play a critical role in the delivery of timely language assistance services and therefore it is imperative that employees be able to identify qualified bilingual/multilingual staff members as quickly as possible through the use of a current directory. We decline to remove the requirement that language access procedures include a current list of qualified bilingual/multilingual staff members.

Timely and effective language assistance services are also best served by maintaining a current list of translated materials. OCR notes commenters' concerns regarding the practicality and burden of maintaining a list of the physical location of all written translated materials. For this reason, we are revising the requirement to no longer require the location of written translated materials, but only how to access electronic translated materials (*i.e.,* their location on a covered entity's network, intranet, or external-facing website).

Section 92.8(d) requires covered entities to include contact information for their Coordinator and how employees obtain services of qualified interpreters, translators, and multilingual/bilingual staff. This allows for covered entities to articulate the process for accessing language services; if this function has been delegated to a department or functional group, contact information for that department or functional group should be included in the language access procedures.

Comment: Some commenters recommended that the Department secure resources for small, covered entities to support their provision of language assistance services. For example, one commenter recommended that OCR contract with a telephonic interpretation service and allow small, covered entities to opt-in to using that service. Another commenter suggested that OCR partner with the U.S. Department of Education to invest in medical interpreter training for smaller language communities because investing in these communities would

[81] The $1,135 figure is derived from the 2015 NPRM for section 1557 on ''training costs'' for small entities. *See* 80 FR 54213.

result in higher quality health care. Another commenter requested that OCR make available sample policies and procedures; best practices for working with language assistance companies, identifying qualified (and unqualified) interpreters, and producing accurate and quality translations; and training videos.

Response: OCR appreciates these commenters' suggestions for providing resources to assist small, covered entities and, we are committed to making sample language access procedures available on our website at *www.hhs.gov/1557*. However, it is not appropriate for OCR, as a Federal agency, to endorse private interpreter or translator service providers. We are also unable to provide a telephonic interpretation contract into which small, covered entities could voluntarily participate.

OCR also appreciates the importance of interpreter training for less frequently encountered languages and is committed to developing a robust health care work force. To illustrate this commitment, the Department announced a ''Promoting Equitable Access to Language Services in Health and Human Services'' initiative in Fall 2022, for which grants were awarded to 11 organizations to develop and test methods of informing individuals with LEP about the availability of language assistance services in health care settings.[82]

Summary of Regulatory Changes

For the reasons set forth in the Proposed Rule and considering the comments received, we are finalizing the Language Access procedures requirement provision at § 92.8(d) as proposed, with modifications. We are revising § 92.8(d) to require language access procedures to strike the requirement to include the location of any written or electronic materials and adding a requirement to include ''how to access electronic translations.'' We replaced ''publication date'' with ''date of issuance'' to better account for translated materials that may be in hard copy or electronic format. We are also making one technical revision. We are replacing ''limited English proficient individual'' with ''individual with limited English proficiency,'' consistent with modifications elsewhere.

[82] U.S. Dep't of Health & Hum. Servs., Off. of Minority Health, *FY 2022 Grants Awards: Promoting Equitable Access to Language Services in Health and Human Services* (October 11, 2022), *https://minorityhealth.hhs.gov/fy-2022-grant-awards#:~:text=Grant%20period%3A%20 2022%2D2025,in%20health%20care%2D related%20settings.*

Effective Communication Procedures

Comment: Comments related to proposed § 92.8(e), regarding effective communication procedures, were similar to the language access procedures comments. Many commenters requested that OCR require covered entities to develop and implement a broad ''communication access plan,'' which would address effective communication and accessibility for individuals with disabilities, including individuals with disabilities who also have LEP. Commenters recommended that covered entities be required to develop communication access plans prior to developing their effective communication procedures. Some commenters suggested that a covered entity's effective communication procedures should also include how to determine the sign language an individual with a communication disability uses and whether the individual needs the services of an interpreter team, such as a certified deaf interpreter and an American Sign Language interpreter. One commenter recommended that we add a requirement for covered entities to create section 1557, ADA, and section 504 communication access plans along with the effective communication procedures requirement.

Response: Advance planning is an essential component of developing and implementing effective procedures that will ensure compliance with the obligations at § 92.202, which necessitate consideration of the various aids and services that may be required to deliver effective communication. Thus, while covered entities are not explicitly required to engage in advance planning, their ability to comply with § 92.202 will be best supported though robust procedures that are developed though a thoughtful and thorough process.

Covered entities may include more information in their respective effective communication procedures than § 92.8(e) requires, and we encourage covered entities that are already implementing communication access plans to maintain that practice. Covered entities with active communication access plans are permitted to modify such plans to include the information required by § 92.8(e); to the extent a covered entity's communication access plan meets the requirements of § 92.8(e), a separate procedures document will not be required regardless of whether the document is referred to as a ''communication access plan'' or ''effective communication procedures.'' While OCR appreciates the similarities between section 1557, section 504, and ADA's effective communication requirement, section 1557 is a distinct statute and imposing requirements for a similar procedure under the ADA and section 504 is outside the authority of this rulemaking.

Comment: One commenter requested that OCR make clear in the final rule that covered entities must implement effective communication and language access requirements in a well-coordinated, comprehensive, seamless, and equally effective manner such as through a standard operating procedure. This commenter also recommended that we inform covered entities that effective communication and language access requirements are of equal, paramount importance and closely interdependent with each other, and the commenter suggested that we issue guidance recommending effective communication and language access coordination.

Response: We agree with the commenter that effective communication and language access requirements are equally important, and effective communication and language access requirements can be interdependent, particularly when communicating with individuals with disabilities who have LEP. Though covered entities would ideally implement their effective communication and language access requirements in a well-coordinated, comprehensive, seamless, and equally effective manner, we decline to revise either paragraph (d) or (e) of § 92.8 or include any additional regulatory provisions imposing such standards on covered entities, in part, because such standards would be difficult to objectively measure.

Comment: Another commenter recommended that we revise § 92.8(e) to require covered entities' effective communication procedures include information about how covered entities will assess staff members' competency as qualified interpreters or qualified readers.

Response: We discuss assessment of interpreters at § 92.4; because of the flexibility allowed by the definition regarding how a covered entity chooses to assess the qualifications of interpreters (and readers), we decline to require this information be included in the procedures.

Comment: Some commenters recommended that OCR clarify that a covered entity's effective communication procedures apply to individuals with any disability that affects an individual's ability to communicate. Further, these

commenters also requested that we clarify that a covered entity's auxiliary aids and services options are not limited to qualified interpreters. Another commenter recommended that we include examples of accommodations, assistance, and opportunities for individuals with speech-related disabilities in the preamble and accompanying guiding documents.

Response: Covered entities' effective communication responsibilities, further discussed at § 92.202, apply to communication with all people with disabilities and a covered entity's effective communication procedures must equip employees with the information and tools necessary to meet the needs of individuals with many different types of disabilities. These may include, but are not limited to, sensory, manual, or speaking disabilities. Covered entities' obligations to provide auxiliary aids and services extend beyond qualified interpreters. A non-exhaustive list of auxiliary aids and services can be found in the definition of ''auxiliary aids and services'' in § 92.4.

Summary of Regulatory Changes

For the reasons set forth in the Proposed Rule and considering the comments received, we are finalizing the Effective Communication Procedures requirement provision at § 92.8(e) as proposed, without modifications.

Reasonable Modification Procedures

Comment: Many commenters supported the reasonable modification procedures requirement under proposed § 92.8(f), with some noting that many covered entities, particularly smaller covered entities, are unaware of their obligation to reasonably modify their policies and procedures when necessary to avoid discrimination on the basis of disability. Some commenters recommended that OCR proactively provide examples of the types of reasonable modifications that covered entities should consider as a means of increasing the likelihood that a covered entity's reasonable modifications procedures are adequate. One commenter urged OCR to include a statement in the final rule's preamble or guidance that a reasonable modification can include communicating in a more accessible modality (*e.g.,* via email), if the patient requests it.

Response: It is OCR's intent that requiring a reasonable modification procedure will address the lack of knowledge on behalf of covered entities that commenters raised, and will increase covered entities' ability to respond appropriately to requests. OCR believes this will raise overall compliance with the requirement at § 92.205 to provide reasonable modifications, and will benefit both covered entities and individuals seeking access to health programs or activities.

The vast range of potential reasonable modifications available or necessary do not lend themselves to an exhaustive list and so we are not able to include such a list here. However, many reasonable modifications involve reasonable changes in the way that an entity does something or permits an individual to do something. For example, a covered entity that generally communicates with patients via phone but receives a request from an individual with a disability to receive communication via email as a modification should generally grant that request, unless the covered entity can demonstrate that doing so would fundamentally alter the nature of the health program or activity. Other examples include allowing an individual with a disability whose disability makes attending morning appointments difficult to schedule afternoon appointments when appointments may not generally be available at that time, or allowing an individual with a disability to attend appointments via telehealth instead of in person when such modification does not fundamentally alter the nature of the service being provided. To be clear, there is no exhaustive list of what constitutes a reasonable modification, nor must covered entities develop one. Rather, covered entities are required to implement written procedures describing their process by which an individual with a disability may request a reasonable modification and how a covered entity processes and responds to such requests.

Comment: One commenter stated that a covered entity must provide reasonable modifications to an individual with a disability in the absence of an affirmative request for the modification if the covered entity had knowledge of the individual's disability or when the individual's disability is obvious. Relatedly, another commenter requested that OCR revise § 92.8(f) to reflect that an individual's failure to request a reasonable modification does not always excuse the covered entity from providing a reasonable modification if the modification does not result in a fundamental alteration.

Response: Section 92.8(f) is an administrative requirement to implement a procedure by which a reasonable modification can be requested, evaluated, and granted. However, as noted in the 2022 NPRM, failure to request a reasonable modification does not always excuse the covered entity from providing a reasonable modification to avoid discrimination on the basis of disability, as long as the modification would not result in a fundamental alteration of the health program or activity. 87 FR 47850. For example, when a covered entity has knowledge of an individual's disability and needs, or when an individual's disability and needs are obvious, a covered entity must provide modifications in the absence of a request.[83]

Comment: Some commenters noted a common occurrence where patients with disabilities must repeatedly request the same reasonable modifications or auxiliary aids and services from the same covered entity for each visit. These commenters urged OCR to include additional language in the final rule preamble and guidance for covered entities to minimize patients' burdens of having to repeatedly notify, request, monitor, and enforce the covered entity's obligation to remove access barriers.

Response: These commenters' recommendations mirror similar comments related to experiences of patients with LEP who must repeatedly request the same language assistance services from the same covered entity. Such a practice may be inefficient and may violate the requirements of this part if they result in the delay or denial of access to a health program or activity. *See* discussion of § 92.201. While we strongly recommend that covered entities engage in the best practice of documenting in patients' medical records the specific reasonable modifications requested by patients with disabilities, in an effort to avoid overly prescriptive requirements we decline to revise § 92.8(f).

Comment: Commenters recommended that OCR require covered entities to appoint an individual to ensure compliance with the reasonable modification requirement. This person would: inquire whether patients need communications-related modifications; ensure such modifications are provided promptly; and monitor the patient's stay

[83] *See, e.g., Greer* v. *Richardson Indep. Sch. Dist.,* 472 F. App'x 287, 296 (5th Cir. 2012) (holding that a ''failure to expressly 'request' an accommodation is not fatal to an ADA claim where the defendant otherwise had knowledge of the individual's disability and needs but took no action''); *Duvall* v. *Cnty. of Kitsap,* 260 F.3d 1124, 1139 (9th Cir. 2001) (''When the plaintiff has alerted the public entity to his need for accommodation (or where the need for accommodation is obvious . . .), the public entity is on notice that an accommodation is required . . .'').

to ensure the modification is provided through the duration of the entire stay. This person would also be responsible for ensuring the covered entity is otherwise complying with the requirement to provide auxiliary aids and services.

Response: This rule, at § 92.7, requires designation of a Section 1557 Coordinator by covered entities that employ 15 or more persons. The Coordinator is responsible for ensuring compliance with section 1557's requirements, including the requirement to provide auxiliary aids and services at § 92.202 and to make reasonable modifications at § 92.205. A covered entity may delegate responsibility for the actual provision of auxiliary aids and reasonable modifications, and implementation of the corresponding procedures, to an individual other than the Coordinator, such as a designee; however, we decline to require the designation of an additional employee to implement these requirements.

Comment: One commenter recommended that OCR revise the regulatory text for § 92.8(f) to substitute the modifier ''reasonable'' with ''reasonable and appropriate.''

Response: We decline to adopt the commenter's suggested regulatory revision because ''reasonable modification'' is a term of art with a long history of enforcement in the disability context. We note that, consistent with similar longstanding disability rights law enforcement, we use ''appropriate'' in §§ 92.8(e) and 92.202(b) when describing the auxiliary aids and services that a covered entity must use to effectively communicate with individuals with disabilities.

Summary of Regulatory Changes

For the reasons set forth in the Proposed Rule and considering the comments received, we are finalizing the Reasonable Modification Procedures requirement provision at § 92.8(f) as proposed, without modifications.

Training (§ 92.9)

In § 92.9, we proposed requiring covered entities to train relevant employees in their health programs and activities on their Section 1557 Policies and Procedures.

In § 92.9(a), we proposed a general requirement that covered entities train relevant employees of their health programs and activities on the Section 1557 Policies and Procedures required by proposed § 92.8.

In § 92.9(b), we specified when covered entities must train relevant employees on their Section 1557 Policies and Procedures.

In § 92.9(b)(1), we proposed that covered entities would be required to train existing relevant employees on their Section 1557 Policies and Procedures as soon as practicable, but no later than one (1) year after the effective date of the final rule.

In § 92.9(b)(2), we proposed that covered entities train new relevant employees within a reasonable period of time after they join a covered entity's workforce.

In § 92.9(b)(3), we proposed requiring covered entities to train relevant employees whose roles are affected by material changes to the covered entity's Section 1557 Policies and Procedures and any other civil rights policies or procedures the covered entity has implemented.

In § 92.9(c), we proposed requiring covered entities to contemporaneously document their employees' completion of the training required by this section in written or electronic form and maintain said documentation for no less than three (3) calendar years.

We invited comment on the experiences of covered entities in implementing training such as that required by proposed § 92.9, examples of where training made a difference in compliance, the timing of required training, whether covered entities would like the flexibility to include this required training as part of their existing annual compliance training, what types of changes would constitute a material change such that a covered entity would need to retrain staff, and how long training records must be retained. We also sought general comment on this proposal, including the effectiveness of civil rights training programs, the benefits experienced by covered entity staff and the people they serve, as well as the costs associated with the proposed training requirements. We further requested comment on whether the Section 1557 Policies and Procedures requirements and training requirements may increase the likelihood of compliance with the substantive legal requirements of section 1557.

The comments and our responses regarding § 92.9 are set forth below.

Comment: Many commenters on this provision expressed support for the training requirement and provided a range of reasons, including because the training is intended to impart knowledge and awareness of civil rights requirements and responsibilities; it will serve as an additional safeguard against discrimination and help reduce health disparities; and it will help providers connect patients to the services they need.

Commenters believed that a covered entity's staff need to understand section 1557 requirements, especially considering increased instances of employee turnover. One commenter also encouraged OCR to repeat the language in the Proposed Rule and remind covered entities that ''the more thoroughly a covered entity trains its staff on its Section 1557 Policies and Procedures, the more likely it is that the covered entity will successfully provide services to individuals in a nondiscriminatory manner.'' 87 FR 47850.

Some commenters said that civil rights violations occur due to lack of awareness and that training on covered entities' Section 1557 Policies and Procedures will help eliminate discrimination in health care because it promotes knowledge about how to deliver and administer health programs and activities to all patients, including patients who are members of communities that have experienced discrimination in health care services.

Some commenters suggested that OCR provide additional detail regarding the contents and delivery of the training, including by being more explicit about the nature and standards for determining adequacy of training. Conversely, one commenter recommended that OCR not make the training requirement overly prescriptive, and another asked OCR to give covered entities the authority to determine the training elements that best fit covered entities' operations.

Some commenters opposed the training requirement, referencing existing compliance burdens for providers, particularly small providers. Some commenters requested that OCR abandon the training requirement in the final rule because the requirement lacks specificity, is weak, vague, difficult to enforce, ineffective, will require more paperwork, and will confuse specialty clinics like dental offices; one commenter requested that OCR specifically exempt dermatology practices from the training requirement.

Many of the commenters that opposed the training requirement added that, if the rule is finalized as proposed, OCR should develop and provide educational materials and training resources, including materials to test trained employees' understanding of the new requirements.

Response: Section 92.9 requires covered entities to train relevant employees on their tailored Section 1557 Policies and Procedures, which will serve as a proactive safeguard against discrimination. Given this benefit, we decline to remove this

provision or exempt specific fields of practice from compliance with this requirement.

Recognizing the resources needed to comply with the training requirement, § 92.9 allows covered entities flexibility in designing the training they provide. However, the efficacy of the training—and its civil rights compliance benefit—will depend on a covered entity's effort in developing and conducting the training. OCR's experience with enforcing HIPAA's training requirement, 45 CFR 164.530(b), has found that employee-related violations are more limited where the required HIPAA training is routinely provided compared to where it is not. We anticipate that the section 1557 training requirement will similarly result in covered entities' employees being more aware of section 1557's discrimination prohibitions and establish a foundation by which covered entities' employees more consistently comply with nondiscrimination requirements.

With respect to the commenters' view that the training requirement will be difficult to enforce, the document retention requirement in § 92.9(c) is designed to assist with this. Moreover, OCR has been successfully enforcing HIPAA covered entities' compliance with HIPAA training requirements for more than 20 years. Through investigations, OCR evaluates covered entities' compliance with training requirements, and, when necessary, OCR ensures that a covered entity takes corrective actions to comply with said requirement.

To support compliance with this rule, OCR has made materials available on our website at *www.hhs.gov/1557*; however, the training required under § 92.9 must be based on the covered entity's own policies and procedures. Thus, while OCR is providing general resources on section 1557 requirements, they must be supplemented by the covered entity to include information regarding their specific Section 1557 Policies and Procedures.

Comment: Several commenters asked OCR to clarify whether covered entities could incorporate training on their Section 1557 Policies and Procedures with existing employee and annual compliance training instead of mandating a stand-alone training. One commenter recommended that covered entities train their employees on their respective Section 1557 Policies and Procedures separately because combining this training can result in information overload if employees are trained on multiple issues at the same training.

Response: This rule does not require or prohibit covered entities from incorporating the training required under § 92.9 with pre-existing employee or annual compliance trainings. We encourage covered entities to regularly train employees on their Section 1557 Policies and Procedures, possibly alongside other annual compliance trainings, and we recommend that covered entities offer section 1557 trainings in a manner that will result in maximum knowledge retention. While the rule does not specify the frequency with which trainings must be provided, covered entities should keep in mind that they must train new employees within a reasonable period of time after the employee joins a covered entity's workforce.

Comment: We received several comments recommending that OCR clarify the term ''relevant employees'' who must be trained under § 92.9. Many commenters recommended that we define ''relevant employees'' in the final rule's definitions section at § 92.4 or within § 92.9 itself. Some commenters suggested that ''relevant employees'' should include: employees whose roles and responsibilities require interfacing with patients and the public; employees who make decisions about patient care and covered entity operations that impact patient care; employees in leadership and supervisory roles who make decisions that affect nondiscrimination; and employees, including C-suite leadership (*i.e.,* the chief executive officer, chief financial officer, chief operating officer, and chief information officer), who are responsible for executing and making decisions regarding financial assistance, patient billing, and collections. Citing the importance of interactions between covered entities and patients in the long-term services and supports context, one commenter recommended that ''relevant employees'' should include temporary staff who interact with the public or clients.

Response: We appreciate commenters' recommendations to define ''relevant employee.'' Though we described a covered entity's relevant staff who must receive the training required in the 2022 NPRM, 87 FR 47851, based on comments received, we agree that including more specificity in the final rule text will add additional clarity for covered entities. We have provided a description of ''relevant employee(s)'' in new § 92.9(b)(4), which that, for purposes of the section, ''relevant employees'' includes 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. Below, we specify that relevant employees may include temporary employees in addition to permanent employees and have revised the regulatory text accordingly.

Comment: Other commenters recommended that OCR require covered entities to train all of their employees on the covered entities' Section 1557 Policies and Procedures because all employees may encounter a patient at any time, and they should understand basic section 1557 concepts. One commenter suggested that if OCR does not require covered entities to train all of their employees, then we should broaden who we consider to be ''relevant employees'' because employees who do not have direct patient interaction or policy-making roles may still have section 1557 responsibilities, and many of these employees are likely to engage in incidental patient interaction during the course of their work.

Response: A covered entity has the discretion to train all of its employees to eliminate the burden of determining who the covered entity believes is and is not a relevant employee. OCR notes that an employee who makes decisions that indirectly affect patients' health care or financial obligations meets the definition for ''relevant employee'' at § 92.9(b)(4), and therefore a covered entity would need to train such an employee pursuant to this provision. However, given the diversity of covered entities under this rule, we decline to mandate training for all staff. For example, to do so may cause confusion for covered entities that operate a health program that is part of a larger operation (*e.g.,* a retail grocery store that also operates a covered pharmacy).

Comment: Some commenters recommended that, due to high staff turnover and the common practice of hiring temporary, contract, or travel staff, OCR should consider allowing temporary staff to transfer prior, completed training from one facility to another to limit burden and redundancy. These commenters also asked OCR to permit training completion documentation from one covered entity to meet the documentation requirement for another covered entity as a means to limit burden and redundancy.

Response: Section 92.9 requires a covered entity to train employees on its

specifically tailored Section 1557 Policies and Procedures. Thus, Covered Entity A's Section 1557 Policies and Procedures will be different from Covered Entity B's Section 1557 Policies and Procedures, and therefore a temporary employee's training on Covered Entity A's policies and procedures will not be transferable to Covered Entity B. Though temporary, contractor, and travel employees may be with an entity for a limited amount of time, that does not minimize the likelihood that these employees may still encounter an individual with LEP or an individual with a disability who may need language assistance services, effective communication, or a reasonable modification. Covered entities that hire temporary, contract, and travel employees will still need to train these employees, document such training, and maintain that documentation for the requisite amount of time. We note that this approach is consistent with OCR's enforcement of the HIPAA training requirement.

Comment: Several commenters requested that OCR require covered entities to train their employees beyond their respective Section 1557 Policies and Procedures. For example, commenters suggested that OCR require covered entities to train their employees on a variety of issues including: how to work with interpreters (in person, over the telephone, and via remote video); cultural competence, including how employees should address stigma experienced by individuals with LEP and individuals with disabilities; interacting with people with disabilities (including individuals who are deaf, hard of hearing, deafblind, and deaf-disabled); and how to competently address transgender and nonbinary patients.

Some commenters recommended that covered entities invite individuals with disabilities and other diverse backgrounds to help conduct required training because learning from people with lived experiences will help covered entities achieve effective communication and reduce biases. Another commenter recommended that OCR work with stakeholders to develop appropriate training materials.

Response: We encourage covered entities to consider investing in their workforces by providing employees additional civil rights and nondiscrimination training beyond what § 92.9 requires. For example, covered entities may deploy interactive civil rights trainings that involve questions and answers and that more actively engages participants rather than the use of training formats like pre-recorded sessions to maximize comprehension of complex civil rights concepts. OCR also acknowledges that hiring, collaborating with, or otherwise engaging individuals with disabilities and other individuals from underserved communities to provide input on training (and the underlying Section 1557 Policies and Procedures) is a best practice. Further, engaging with these same groups to provide training regarding best practices and other civil rights-related issues will give a covered entity's employees valuable perspective about the importance of delivering compassionate, inclusive, and responsive health care.

However, we decline to expand the scope of the training requirement at this time. It is our position that the training on the Section 1557 Policies and Procedures required in § 92.9 strikes the appropriate balance between covered entities' burden concerns and the need for awareness of this vital information. We note that OCR has provided a general resource on section 1557 requirements that can supplement covered entities' Section 1557 Policies and Procedures training, available at *www.hhs.gov/1557*.

Summary of Regulatory Changes

For the reasons set forth in the Proposed Rule and considering the comments received, we are finalizing § 92.9 as proposed, with modifications. We are revising § 92.9(b)(1) to specify that a covered entity must begin training its relevant employees no later than 30 days after a covered entity implements its policies and procedures required by § 92.8 and no later than 300 days after the effective date of the part. We are including a definition of ''relevant employee(s),'' for purposes of the section only, at § 92.9(b)(4) to provide: ''for the purposes of this section 'relevant employees' includes permanent and temporary employees . . . .'' Lastly, we are modifying § 92.9(c) to clarify that covered entities are required to retain (rather than ''maintain'') training documentation for the requisite time period.

Notice of Nondiscrimination (§ 92.10)

In § 92.10(a), we proposed requiring covered entities to provide a notice of nondiscrimination, relating to their health programs and activities, to participants, beneficiaries, enrollees, and applicants of their health programs and activities, and to members of the public (''Notice of Nondiscrimination''). Section 92.10(a)(1) proposed the required contents of the Notice of Nondiscrimination. Section 92.10(a)(2) proposed when and where covered entities must provide the Notice of Nondiscrimination.

In § 92.10(b), we proposed that a covered entity may combine the content of the notice required by § 92.10(a) of this section with the notices required by title VI, section 504, title IX, and the Age Act implementing regulations [84] if the combined notice clearly informs individuals of their civil rights under section 1557 and the part and meets the requirements outlined in proposed § 92.10(a)(1).

We invited comment on whether the Notice of Nondiscrimination requirement as proposed is practical, likely to be effective, and responsive to concerns raised regarding the 2016 and 2020 Rules, including the sufficiency of the contents of the notice and requirements regarding when and where covered entities must provide this notice. We sought comment on the best ways to provide an accessible notice to individuals with disabilities who may require auxiliary aids and services and the best way in which to provide the notice in a manner accessible to individuals with LEP.

The comments and our responses regarding § 92.10 are set forth below.

Comment: Many commenters strongly support the notice requirements set forth in §§ 92.10 and 92.11 (Notice of Availability), stating that such notices are needed to help people know their rights and will reduce health disparities, especially for persons with LEP and persons with disabilities. Some organizational commenters added that when the 2016 Rule's notice requirement, former 45 CFR 92.8, was removed by the 2020 Rule, many people did not know their rights, how to access interpreters or auxiliary aids and services, or how to file a grievance. Several commenters added that a clear explanation of rights and contact information for the Section 1557 Coordinator, as set forth in § 92.10(a)(1)(v), is crucial. Some disability rights groups commented that not only should the Section 1557 Coordinator's contact information be included, but also that of the ADA Coordinator.

Response: The Notice of Nondiscrimination is a critical means by which to inform individuals of their civil rights, which is part of a proactive civil rights compliance structure that functions—in part—through grievances and complaints raised by individuals. We decline to require inclusion of contact information for an ADA

[84] 45 CFR 80.6(d) (title VI); 84.8 (section 504, federally assisted); 85.12 (section 504, federally conducted); 86.9 (title IX); 91.32 (Age Act).

Coordinator as this regulation is limited to section 1557; further, not all covered entities under this rule are subject to the ADA.

Comment: Various covered entities commented that the burden of the notice provisions is compounded by the complexity of having two separate notices (*i.e.,* the Notice of Nondiscrimination and the Notice of Availability) and the requirements to provide information in 15 languages.

Response: OCR takes seriously the concerns raised by some commenters regarding burden. In crafting the two distinct notice requirements, OCR considered comments received in response to the 2015 and 2019 NPRMs regarding the burden of a notice requirement. The provisions in the final rule reflect careful consideration of what must be included in each notice, and they include substantially more clarity regarding when and where each notice must be provided compared to the 2016 Rule.

We note that there is not a requirement that ''all information'' be provided in multiple languages; the requirement is that the Notice of Availability required by § 91.11 be provided in 15 non-English languages to inform individuals of the availability of language assistance services and auxiliary aids and services. Further discussion of this requirement can be found in our discussion related to the Notice of Availability (§ 92.11).

Comment: Many commenters noted that the parenthetical for sex discrimination included in proposed § 92.10(a)(1)(i) differs from the language of § 92.101(a)(2) and that it should be consistent, such that it should include sexual orientation and gender identity as well as pregnancy-related conditions.

Response: OCR appreciates the need for consistency across the regulation, and to ensure that the public is aware of the various bases for discrimination included under the umbrella of sex discrimination. As such, OCR has revised the parenthetical in § 92.10(a)(1)(i) to directly cite to § 92.101(a)(2), rather than listing examples of discrimination on the basis of sex. This is consistent with edits made to the Nondiscrimination Policy required by § 92.8(b).

Comment: Various commenters requested that OCR require any entity receiving a religious exemption to include notice of the exemption in the Notice of Nondiscrimination; they said it would be misleading to have a notice stating that the entity does not discriminate if it has been granted permission to do so in certain circumstances. They stated that the information is needed for LGBTQI+ persons seeking health care.

Response: OCR appreciates these comments. OCR declines to revise § 92.10 to impose an affirmative obligation on a recipient to identify any exemptions it has received under applicable Federal religious freedom and conscience laws. OCR additionally notes that it is a best practice for a recipient to include in its Notice of Nondiscrimination language when it has received a temporary exemption or an assurance of exemption. OCR is also subject to the Freedom of Information Act (FOIA), and information may be released to a requestor or made available for public inspection consistent with the agency's obligations under that statute and its implementing regulations.

Comment: Several commenters stated that the Notice of Nondiscrimination should be provided in the same non-English languages required by § 92.11 (Notice of Availability). Several commenters urged OCR to create a model Notice of Nondiscrimination, and to issue translations of this notice.

Response: The Notice of Nondiscrimination is among the materials that must be accompanied by a Notice of Availability, per § 92.11(c)(5)(i), which must be provided in multiple languages. While we have declined to require translation of the Notice of Nondiscrimination into a set number of languages, covered entities may still be required to provide translations when necessary to ensure meaningful access as required under § 92.201. OCR will provide a sample Notice of Nondiscrimination and may provide translations of the sample Notice of Nondiscrimination.[85]

Comment: Some commenters argued that the requirement for when and where the Notice of Nondiscrimination must be provided, § 92.10(a)(2), is too burdensome; others commented that it eases financial burdens compared to the 2016 Rule requirements, while also ensuring that people receive information about the covered entities' civil rights obligations. Some commenters supported the requirement of prominent posting on websites, including because of the low cost, while another commenter observed that poor and rural areas sometimes cannot be reached by internet and described the need to reach historically underserved and marginalized populations.

Various commenters agreed with the proposal to provide the Notice of Nondiscrimination annually and upon request as opposed to the 2016 Rule's ''significant communications'' [86] requirement, including because the current proposal is clearer than the 2016 Rule requirement. Others stated that OCR should require the Notice of Nondiscrimination in all significant communications, such as Explanations of Benefits and patient intake forms. Some opposed annual notices as costly and annoying to patients, recommending that notice instead be upon enrollment, upon request, and prominently in health care plan documents. Others argued for using the HIPAA model, which requires notice at first point of service and then upon request only.

Response: In developing the points of contact at which a Notice of Nondiscrimination must be provided, OCR considered the concerns raised by covered entities regarding burden, consumer fatigue, and lack of clarity and specificity in prior requirements. However, we also considered comments that stated the Notice of Nondiscrimination is important to ensure that persons are informed of their civil rights and without this knowledge, including the right to language assistance services and effective communication, health disparities may continue to increase as they did during the COVID–19 pandemic. The provision is a reasonable and balanced approach that reduces the number of communications in which this essential notification is required compared to the 2016 Rule requirements,[87] while preserving its necessary function.

While OCR appreciates that many individuals lack internet access, we note that the regulation as drafted requires posting in physical locations, as well as being provided upon request, § 92.10(a)(2)(ii) and (iv); therefore, access to the Notice of Nondiscrimination is not dependent on internet access.

Comment: Various commenters recommended that the Notice of Nondiscrimination be posted prominently where frontline employees can see it, and that it be in large sans serif font (at least 18-point font).

Response: OCR appreciates these comments and the importance of ensuring that the Notice of Nondiscrimination posted in physical

[85] U.S. Dep't of Health & Hum. Servs., Off. for Civil Rts., *Translated Resources for Covered Entities, https://www.hhs.gov/civil-rights/for-individuals/section-1557/translated-resources/index.html* (translated Notice of Nondiscrimination. Statement of Nondiscrimination, and Taglines required by the 2016 Rule).

[86] 87 FR 47852–53 (discussion in 2022 NPRM); 85 FR 37161–62, 37175 (discussion in 2020 Final Rule).

[87] *Id.*

locations can be seen and is accessible to individuals who may have low vision. For this reason, we are finalizing § 92.10(a)(2)(iv) to require that posted notices be in a sans serif font, no smaller than 20-point font.[88]

Comment: Several commenters argued that the Notice of Nondiscrimination and Notice of Availability must be provided together, because they are so intertwined, adding that this may also reduce the burden for covered entities.

Response: OCR appreciates this comment and directs commenters to the requirement at § 92.11(c)(5)(i), which requires that the Notice of Availability be provided with the Notice of Nondiscrimination. Covered entities may choose to integrate the Notice of Availability into its Notice of Nondiscrimination.

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 § 92.10, with modifications. OCR is revising the explanatory parenthetical for sex at § 92.10(a)(1)(i) to read ''consistent with the scope of sex discrimination described at § 92.101(a)(2).'' We are also providing a technical revision to § 92.10(a)(1)(iii) to replace ''necessary'' with ''a reasonable step'' for consistency with the standard articulated in § 92.201(a), that ''[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.'' We are revising § 92.10(a)(2)(iv) to require that posted notices be provided ''in no smaller than 20-point sans serif font.'' Finally, we are making a technical revision to replace ''limited English proficient individual'' with ''individual with limited English proficiency,'' consistent with modifications elsewhere.

Notice of Availability of Language Assistance Services and Auxiliary Aids and Services (§ 92.11)

In § 92.11, we proposed requiring covered entities to notify the public of the availability of language assistance services and auxiliary aids and services for their health programs and activities (''Notice of Availability'').

In § 92.11(a), we proposed requiring a covered entity to provide a notice that, at minimum, states that the covered entity provides language assistance services and appropriate auxiliary aids and services free of charge in its health programs and activities, when necessary for compliance with section 1557 or the part. This notice must be provided to participants, beneficiaries, enrollees, and applicants of the covered entity's health program or activity, and members of the public.

In § 92.11(b), we proposed requiring the Notice of Availability to be provided in English and at least the 15 most common languages spoken by individuals with LEP of the relevant State or States, and in alternate formats for individuals with disabilities who require auxiliary aids and services to ensure effective communication.

In § 92.11(c), we proposed requiring the notice be provided on an annual basis to participants, beneficiaries, enrollees (including late and special enrollees), and applicants, and upon request at any time; we also proposed that the notice be provided online (when applicable) and in a clear and prominent physical location where it is reasonable to expect individuals seeking services from the health program or activity to be able to read or hear the notice. In § 92.11(c)(5), we proposed a list of specific electronic and written communications that the Notice of Availability must accompany. We invited comment as to whether requiring a Notice of Availability for all Explanation of Benefit (EOB) documents is the most appropriate approach, balancing the burden of providing Notices of Availability with all EOBs against the burdens associated with determining which EOBs must include the notice.

In § 92.11(d), we proposed alternative, optional methods by which a covered entity may be deemed in compliance with proposed § 92.11(a).

We sought comment on whether the Notice of Availability requirement as proposed is practical and responsive to concerns raised regarding the 2016 and 2020 Rules, including the sufficiency of the content of the Notice of Availability and requirements for when and where covered entities must provide the notice. We also invited comment as to whether the proposed requirements adequately address the specific concerns raised regarding the burdens associated with the 2016 Rule requirements by providing a list of specific documents with which the Notice of Availability must be provided. Additionally, we invited comment on how to best provide the Notice of Availability to individuals with disabilities to ensure they know how to request and receive relevant materials and documents in formats that meet their disability-related needs, and whether covered entities should be required to provide the Notice of Availability in sign language. Similarly, we sought comment on how to best provide the Notice of Availability to individuals with LEP, including individuals with LEP with disabilities, to ensure they know how to request and receive language assistance services and auxiliary aids and services to provide meaningful access to relevant materials and documents. We also sought comment on whether the proposed list of electronic and written communications that the Notice of Availability must accompany adequately captures the documents for which individuals with LEP and individuals with disabilities should receive the Notice of Availability. We further invited comment on the anticipated costs to covered entities of various sizes to comply with the proposed requirements.

The comments and our responses regarding § 92.11 are set forth below.

Comment: Many commenters stated that the Notice of Availability is needed because people are unaware of their rights to language assistance and auxiliary aids and services, leaving them unable to advocate for themselves and leading to health disparities. Commenters agreed that the 2019 NPRM and 2020 Rule fail to address the costs borne by participants, beneficiaries, and enrollees in the absence of notice, and the additional costs to the health care system that could result. 87 FR 47853. Many commenters provided examples of how individuals with LEP experience disparities in health care, including poor care and outcomes; higher uninsured status; lower health literacy; longer hospital stays; greater difficulty understanding health instructions; and general health care underuse. The commenters emphasized that providing Notice of Availability is the most essential element to decreasing language barriers and that with proper notice of their rights, health disparities for individuals with LEP would be reduced.

Response: OCR appreciates commenters highlighting the importance of providing individuals with LEP notice of their right to receive language assistance services, and the negative consequences of failure to do so. As discussed, OCR considered the concerns raised in response to the 2019 NPRM and 2020 Rule's failure to include a similar notice provision, as well as concerns raised in response to the 2016 Rule's notice provision. As proposed and finalized, § 92.11 provides

[88] *See* Am. Council of the Blind, *Best Practices and Guidelines for Large Print Documents Used by the Low Vision Community* (2011), *https://archive.org/details/bestpracticesgui00coun.*

an appropriate balance between the approaches of these prior rules and is an important tool for combatting and preventing health disparities based on communication barriers.

Comment: Numerous commenters stated that the requirement to provide the Notice of Availability in 15 non-English languages was too many, providing examples of places in which they believe fewer languages were needed. For example, one provider commented that in California, 95 percent of their communications were requested in the top five languages in the State, therefore translations into the top five languages would be sufficient. Other commenters noted that smaller entities would be particularly burdened by the proposed standards. One commenter stated that requiring pediatric dental offices to offer the Notice of Availability as proposed would be burdensome and cause confusion.

Conversely, many other commenters stated that 15 languages is too few and that, under the proposed requirements, the Notice of Availability would not reach enough individuals with LEP, giving examples of language populations that would not be reached. Some commenters expressed a belief that covered entities should ensure each individual with LEP receives information about their rights in their preferred language, and that a 15-language requirement would not adequately provide that assurance. Some commenters stated that the identification of languages required should not be determined at the State level but should instead be based on the covered entity's entire program area in various states. On the other hand, some commenters expressed that the required languages should always be determined at the State level only, rather than ''State or States.''

Commenters said that because OCR will provide model notices translated into the required languages, and because of the need for meaningful notice of auxiliary aids and language assistance services, the burden for providing notices in the top 15 languages per State is lessened and reasonable. A few local government commenters stated that their jurisdiction currently requires translation in more than 100 languages and recommended that this rule incorporate State and local norms.

Response: In determining the formula for the Notice of Availability translation requirement, OCR considered the 2016 Rule requirement, evaluated national- and State-level language proficiency data issued by the U.S. Census Bureau (Census), as well as potential the costs and burdens for covered entities.

The need to provide individuals with LEP notice of the availability of language assistance services remains clear and there is ample evidence that failure to provide meaningful language access in a health care setting can lead to higher costs to the health care system and have grave consequences to individuals with LEP. 87 FR 47853–54. Since the ACA was enacted, the percentage of the U.S. population with LEP (defined as those who speak English less than ''very well,'' as collected by the Census) has remained at roughly 10 percent.[89]

OCR has received complaints and entities have sued the Department for rescinding the 2016 Rule's notice requirements.[90] Litigants in *Chinatown Services Center* v. *U.S. Department of Health & Human Services* raised specific concerns that older members of the Asian American, Native Hawaiian, and Pacific Islander community, who have high rates of limited English proficiency, experienced disparities because they are not aware of their right to receive language assistance services or how to raise a concern when such services are not provided.[91] Although one Federal court ultimately held that a plaintiff health system was not likely to prevail on the merits of its Administrative Procedure Act challenge to the 2020 Rule's repeal of the 2016 Rule's notice requirements, the court notably acknowledged that a consequence of the 2020 Rule was that the plaintiff health system provided ''costlier and more difficult treatment'' because patients with LEP likely received inadequate health care elsewhere and arrived to their system sicker than they otherwise may have.[92]

OCR appreciates concerns regarding proposed § 92.11, which would require a covered entity operating in all 50 States to aggregate the populations with LEP across those States to determine the top 15 languages spoken by individuals with LEP in its service area. While this may result in a failure to reach some in-State LEP populations due to geographical variances, no single formula, including a State-level formula, will cover all individuals with LEP. However, this formula would cover a significant majority (over 93 percent) of individuals with LEP, even for covered entities that operate on a national level.[93]

Thus, while OCR appreciates the request to increase the number of languages into which the Notice of Availability must be translated, we have determined that this would likely increase burdens while yielding additional coverage of marginally few individuals with LEP. However, covered entities are reminded that they must still take reasonable steps to provide meaningful access to *all* individuals with LEP, regardless of whether the individual's primary language is one of the 15 most frequently spoken non-English languages in their State or States, per § 92.201. Further, nothing in this rule prevents jurisdictions from requiring that the Notice of Availability be translated into more languages; covered entities wishing to provide more languages may also do so.

OCR recognizes concerns raised in the comments regarding the potential cost of translating the Notice of Availability into the required languages. To offset this concern, OCR has provided translations of the model Notice of Availability in the top 15 languages in each State, at *www.hhs.gov/1557*. Additionally, § 92.11(c) reduces the number of documents for which provision of the translated notices is required from the 2016 Rule, and § 92.11(d) provides two options for how a covered entity may otherwise meet the requirements of this provision. OCR anticipates that efficiencies created by this formula—complemented by the availability of OCR-translated Notices of Availability—will benefit covered entities and the communities they serve. These benefits will reduce harmful impacts of the failure to take reasonable steps to provide meaningful access—such as unnecessary hospital readmissions, lower rates of outpatient follow up, limited use of preventive services, poor medication adherence, and lack of understanding of discharge

[89] U.S. Bureau of Census, Sandy Dietrich & Erik Hernandez, *Language Use In the United States: 2019, Am. Community Survey Reports,* p. 4 (2022), *https://www.census.gov/content/dam/Census/library/publications/2022/acs/acs-50.pdf.*

[90] *See* Compl., *Chinatown Serv. Ctr.* v. *U.S. Dep't of Health & Hum. Servs.,* No. 1:21–cv–00331 (D.D.C. Feb. 25, 2021), Compl., *Whitman-Walker Clinic* v. *U.S. Dep't of Health Hum. Servs.,* No. 1:20–cv–01630 (D.D.C. June 22, 2020) and *see* 87 FR 47853–54.

[91] Compl., *Chinatown Serv. Ctr.* v. *U.S. Dep't of Health & Hum. Servs.,* No. 1:21–cv–00331, 22–35 (D.D.C. Feb. 25, 2021).

[92] *Whitman-Walker Clinic* v. *U.S. Dep't of Health & Hum. Servs.,* 485 F. Supp. 3d 1, 30 (D.D.C. 2020).

[93] U.S. Census Bureau, *Am. Community Survey 5-Year Estimates Public Use Microdata Sample 2020 for the 50 States and DC* (2000), ACS 5-Year Estimates Public Use Microdata Sample 50 States & DC; *https://data.census.gov/mdat/#/search?ds=ACSPUMS5Y2020&cv=ENG&rv=ucgid,LANP&wt=PWGTP&g=0400000US01,02,04,05,06,08,09,10,11,12,13,15,16,17,18,19,20,21,22,23,24,25,26,27,28,29,30,31,32,33,34,35,36,37,38,39,40,41,42,44,45,46,47,48,49,50,51,53,54,55,56.*

instructions [94]—thereby alleviating burdens on community organizations that have been providing notice of language access as well as providers who have seen negative impacts such as increased costs and sicker patients since the repeal of the 2016 Rule's notice requirements. *See* 87 FR 47853–54. Given these efforts, the requirement of providing notice of language access rights is not overly burdensome when balanced with the need to provide notice of the availability of language assistance services to individuals with LEP.

Comment: A few commenters suggested that a hybrid method should be used to calculate which languages are required for translation under this provision, such as the higher or lower of a percentage or absolute number (for example, a threshold of five percent or 1,000 individuals with LEP, whichever is lower). Some commenters recommended OCR adopt the standard found in Tri-Departmental regulations at 26 CFR 54.9815–2719(e), 29 CFR 2590.715–2719(e), and 45 CFR 147.136(e), which applies a county-level formula and is applicable to the internal claims and appeals and external review processes for group health plans and health insurance issuers in the group and individual health insurance markets, to decrease costs and avoid confusion. Some added that a hybrid method, such as allowing for calculations at the county- instead of State-level, is especially critical for small practices operating at only the county level. They stated these practices may not have resources to translate the Notice of Availability into the top 15 languages spoken in the State and may serve language communities that are different from those represented by the top 15 languages at the State-level.

Response: OCR appreciates these suggestions but, as we discussed in the Proposed Rule, OCR declined to adopt a population threshold due to variances among urban and rural communities. 87 FR 47855. We are concerned about similar results if a percentage threshold is used, and we decline to adopt this approach.

While OCR appreciates that some covered entities will have to comply with both OCR and Tri-Departmental regulations, we decline to adopt the county-level formula found in the referenced Tri-Departmental regulations, 26 CFR 54.9815–2719(e), 29 CFR 2590.715–2719(e), and 45 CFR 147.136(e), which provides that a non-English language is an applicable non-English language if ten percent or more of the population residing in the county is literate only in the same non-English language, as section 1557 applies to a wider range of covered entities, communications, and individuals with LEP. We will continue to monitor issues related to this area and work with CMS as appropriate in the future to ensure compliance.

Comment: Some commenters suggested that OCR work with covered entities and community groups to develop additional effective ways to inform individuals with LEP about their language access rights. A health insurance entity suggested convening a stakeholder process to develop and test a pilot with easy-to-understand, universal language access symbols to connect persons with LEP to language assistance services.

Response: OCR appreciates this recommendation and welcomes the opportunity to collaborate with covered entities and community groups to develop effective means for informing individuals with LEP of their language access rights.

Comment: Many commenters supported the list of documents requiring a Notice of Availability in § 92.11(c), emphasizing the critical importance of clear communications in health care settings. Some commenters noted the provision fills information gaps and that receiving information multiple times is sometimes needed for effective notice, particularly for older adults. Others expressed support for the balanced approach of including opt-out provisions so that covered entities are not overly burdened, but participants and beneficiaries know their rights. Several commenters urged OCR to add medical bills to the list, providing examples of negative impacts of bills being sent without notice of how to access effective communication.

Many other commenters expressed concerns about administrative burdens and costs of notice in relation to the number of communications in which the Notice of Availability would be required under § 92.11(c), while others pointed out that the list is effectively shorter than in the past.

Several commenters wrote generally about language assistance services and auxiliary aids and services, with some asking for flexibility in the language access rules to allow for translation of the most important documents with the provision of oral interpretation for other information. Another argued that translation and interpretation as well as auxiliary aids and services rules should not apply to physician practices or health centers. Others requested that health insurance issuers or the Federal Government reimburse providers for disseminating these items.

Response: We appreciate the comments and believe that the list of documents identified in § 92.11(c), which provides clarity and prioritizes inclusion of the Notice of Availability in critical health care documents, strikes the appropriate balance between potential burdens to covered entities and the benefits to individuals with LEP and individuals with disabilities. OCR appreciates commenters raising concerns regarding the accessibility of medical billing, which can have long-term negative financial impacts on patients.[95] Similarly, accessible notices of expected costs and benefits, such as the good faith estimate, can help patients make informed, cost-conscious decisions about their care and reduce the risk of unexpected medical bills.[96] The potential financial impact of making these estimates accessible is particularly significant for individuals with LEP and individuals with disabilities who are uninsured (or self-pay), because these individuals have the right to dispute medical bills that are substantially in excess of the expected charges on their good faith estimate [97] and exercise of this right depends on the ability of such individuals to understand both their good faith estimates and their medical bills. For these reasons, we are adding § 92.11(c)(5)(ix), which requires a covered entity to provide its Notice of Availability along with billing-related documents and reads: ''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.''

Comment: Regarding an alternative, optional means of compliance at § 92.11(d), one covered entity commenter requested that OCR specify that entities in compliance with other

[94] *See* Neelam H. Ahmed et al., *Moderation of the Association Between Primary Language and Health by Race and Gender: An Intersectional Approach,* 19 Int. J. Environ. Rsch. Pub. Health 7750 (2022), *https://www.mdpi.com/1660-4601/19/13/7750.*

[95] *See* NPR, Lauren Weber & Hannah Recht, *Medical Bills Remain Inaccessible for Many Visually Impaired Americans,* Health, Inc. (Dec. 1, 2022), *https://www.npr.org/sections/health-shots/2022/12/01/1139730806/blind-disability-accessibility-medical-bills* (discussing an investigative news report and including an OCR investigation).

[96] Internal Revenue Code section 9816(f), ERISA section 716(f), and PHS Act section 2799A–1(f), as added by section 111 of title I of division BB of the Consolidated Appropriations Act, 2021 (CAA); PHS Act section 2799B–7, as added by section 112 of title I of division BB of the CAA; 45 CFR 149.610.

[97] PHS Act section 2799B–6, as added by section 112 of title I of division BB of the CAA; 45 CFR 149.620.

Department requirements related to language access and auxiliary aids are deemed to have complied with section 1557. One commenter stated that the Notice of Availability should be combined with the Notice of Nondiscrimination, as well as HIPAA notices; another suggested OCR work with CMS and other HHS agencies to leverage existing practices and make these requirements technically operational.

Response: As discussed elsewhere, OCR appreciates that covered entities may have compliance requirements under other Department regulations similar to those found in this provision. However, given the range of health programs and activities to which section 1557 and the part apply—including those where inaccessible communication can have life-or-death consequences—it is imperative to have an independent requirement. Covered entities' compliance with § 92.11(b) will increase the likelihood of compliance with similar Department translation requirements. While we appreciate commenters' suggestion to combine the Notice of Availability with the Notice of Nondiscrimination and the HIPAA notices, § 92.11(c)(5) requires the Notice of Availability to additionally be included with a list of important health care documents because the ability of patients to avail themselves of language access services is foundational to improving health outcomes for individuals with LEP. OCR will therefore maintain this requirement under § 92.11(c)(5) for covered entities.

Comment: Various commenters expressed support for the alternate compliance provisions found in § 92.11(d). One group raised the idea of an ''opt-in'' provision, in which individuals with LEP would have to state that they want Notice of Availability, in lieu of the proposed opt-out provision, and sought clarification about whether the opt-out provision can be combined with Notice of Availability.

Some commenters argued that the alternate compliance options could be difficult to implement and lead to additional costs, cause confusion, or be generally burdensome, with one commenter stating they would be more burdensome than the 2016 Rule requirements because they require customizing documents. One commenter requested OCR delay implementation of the opt-out provision until 2024; other commenters suggested replacing the option with a less burdensome approach, asking that it be only electronic.

On the other hand, commenters stated that the opt-out provision strikes a reasonable balance that is effectively narrower than the 2016 Rule's ''significant communications'' requirement. Another commenter agreed, commenting that the proposal could be both more consumer friendly and helpful, as well as less duplicative and costly than the 2016 Rule. One commenter encouraged OCR to provide robust oversight of opt-out processes in order to protect civil rights.

Response: OCR appreciates the range of comments received on this new provision. We emphasize that the options included in § 92.11(d) are options, and not requirements. Thus, we appreciate that covered entities may wish to have a delayed applicability date, to pursue these options only through electronic means, or not pursue them at all. OCR is not requiring any actions under § 92.11(d) be taken; rather, OCR is providing alternate means to satisfy the requirements of § 92.11 without including the full Notice of Availability with all communications listed at § 92.11(c).

OCR declines to make further changes clarifying that a person should only be asked about their language needs once, because § 92.11(d)(1) permits this if the individual exercises the option to opt-out. Moreover, § 92.11(d)(2) allows a covered entity to document an individual's primary language, any appropriate auxiliary aids and services, and to communicate with them in that manner.

OCR intends to provide robust review of opt-outs, as well as technical assistance, to ensure that covered entities that choose to exercise this option do so in a manner consistent with the requirements at § 92.11(d).

Comment: Many commenters submitted recommendations to increase guarantees of accessibility of the Notice of Availability for individuals with disabilities, such as requiring that: (1) notices be provided in large sans serif print, at a minimum of 18-point font; (2) notices be on the first page or otherwise at the beginning of documents or publications; (3) the needs of persons who are illiterate be taken into account through provision of audio or video notices; (4) all written notices be in plain language (fourth grade reading level), accompanied by visual aids when practicable; and (5) notice should be provided via audio, video, and American Sign Language. A coalition also discussed recommendations to ensure effective communication. Other accommodations recommended included: (1) screen readers and audio/video accessibility; (2) alternatives to braille (*e.g.,* large print, qualified reader) because braille may not be economically feasible for all entities; (3) accessible tagline requirements or cross-references to language access rights; and (4) ''Easy Read'' text, images, brief sentences, large and simple fonts, and location on the first page.

Many also commented that the Notice of Availability should be posted where frontline employees can readily see it, that employees should be trained to provide it, and that it be available upon request. Various commenters urged that covered entities must proactively ask people if they have communications barriers. Further, commenters stated that primary consideration should be given to what a person with a disability asks for in terms of auxiliary aids or services. Another commenter added that provision of the notice should be clarified so it applies to listening devices and the other range of auxiliary aids.

Response: OCR appreciates all the suggestions and reminds commenters and others that the meaningful access and effective communication requirements (§§ 92.201 and 92.202, respectively) regarding the provision of language access and auxiliary aids apply to the Notice of Availability. Covered entities have existing effective communication obligations under section 504 and section 1557, which may include providing the notice in an alternate format or providing another auxiliary aid or service. Thus, if an individual is in need of the notice in an alternate format or through another auxiliary aid or service, that would likely already be required when it is necessary to ensure effective communication. We decline to affirmatively require the notice be provided in any additional formats at this time. However, OCR agrees that larger print should be required to ensure the accessibility of the Notice of Availability when posted in physical locations, and that this requirement is relatively straightforward to implement; accordingly, § 92.11(c)(4) has been amended to require print no smaller than 20-point in a sans serif font.

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 § 92.11, with modifications. We are revising § 92.11(b) to clarify the relevant State or States are those ''in which a covered entity operates.'' We are modifying § 92.11(c)(4) to clarify that posted notices be provided ''in no smaller than 20-point sans serif font.'' We are adding

§ 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

---

[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/.*

comment on the use of machine translation in health programs and activities generally, other possible approaches to address this issue, and whether there should be an exception to this provision to allow for the limited use of machine translation in exigent circumstances.

In § 92.201(d), we addressed how the Director will evaluate compliance with this section. In § 92.201(d)(1), we proposed that the Director shall 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 LEP. Proposed § 92.201(d)(2) provides that the Director shall 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 proposed § 92.8(d).

In § 92.201(e), we proposed restrictions on the use of certain persons to provide language assistance services for individuals with LEP. In § 92.201(e)(1), we proposed prohibitions on covered entities from requiring individuals with LEP to provide, or pay for, their own interpreters. Proposed § 92.201(e)(2) provided for very limited situations in which an adult, not qualified as an interpreter, accompanying an individual with LEP can serve as an interpreter. Section 92.201(e)(3) proposed to prohibit a covered entity from relying 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 LEP immediately available. In § 92.201(e)(4), we proposed prohibiting reliance on staff other than qualified interpreters, qualified translators, or qualified bilingual or multilingual staff to communicate directly with individuals with LEP.

In § 92.201(f), we proposed standards for video remote interpreting (VRI).

In § 92.201(g), we proposed standards for audio remote interpreting services.

In § 92.201(h), we proposed that nothing in this section shall be construed to require an individual with LEP to accept language assistance services.

The comments and our responses regarding § 92.201 are set forth below.

Comment: Many commenters were very supportive of § 92.201(a)'s requirement that covered entities must take reasonable steps to provide meaningful access to ''each'' individual with LEP eligible to be served or likely to be directly affected by its health programs and activities. Commenters also supported OCR's revision concerning individuals with LEP ''likely to be directly affected'' by a health program or service, as opposed to the previous ''likely to be encountered,'' as it provides greater clarity about the applicability of this rule and reduces some burden on health care practices. Commenters maintained that this standard provides a better description for providers to understand. Other commenters supported inclusion of ''eligible to be served or likely to be directly affected'' because they believe it expands the definition of who can receive language access and better reflects how language service needs are experienced by people seeking health care. Many commenters recommended that OCR clarify that companions are expressly included, noting that this is especially important for caretakers of minor children or those accompanying older adults.

Response: OCR appreciates commenters' thoughts on the language at § 92.201(a) and confirms that covered entities' language access obligations also apply to companions (defined in § 92.4), as companions are ''directly affected by [a covered entity's] health programs and activities'' by virtue of their relationship with the person whom they are accompanying. For example, a covered entity will need to take reasonable steps to provide meaningful access to a parent with LEP whose minor child is being treated or an individual with LEP who may be assisting their spouse with post-operative care. To reinforce this requirement, OCR is adding a parenthetical to the text of § 92.201(a) to clarify that individuals with LEP who are covered under this part include companions with LEP. This language is consistent with the requirement to provide effective communication for companions with disabilities under § 92.202.

Comment: Various commenters appreciated OCR providing clarity on the terms ''reasonable steps'' and ''meaningful access,'' noting that the 2020 Rule's deletion of meaningful access requirements was detrimental to the health of communities with LEP. A few commenters recommended that clearer directives should be included as to what types of services constitute ''reasonable steps,'' suggesting this could be clarified by providing examples of ''reasonable steps,'' or by adding definitions of ''reasonable steps'' and ''meaningful access'' to § 92.4 (Definitions). Another commenter cautioned that the lack of clarity could result in covered entities coming to the determination that no services are required of them. Others stated that additional guidance is needed specifically for providers and payers.

Response: OCR appreciates the request for additional definitions; however, we decline to provide a definition for ''reasonable steps'' or ''meaningful access,'' as these terms are not unique to section 1557 and reflect longstanding requirements under title VI. OCR will consider developing additional guidance on this topic but also refers commenters to the Department's longstanding HHS LEP Guidance, 67 FR 47311, as well as the Department's 2023 Language Access Annual Progress Report. The 2023 Progress Report describes the Department's reconstituted Language Access Steering Committee based on the HHS Equity Action Plan issued under E.O. 13985, clarifies benchmarks for meaningful language access in key areas such as developing best practices for oral interpretation and internet-based access to written translation, and sets forth current plans to update the Department's Language Access Plans and issue related guidance.[128]

Comment: A number of commenters stated that failure to provide meaningful access may violate both section 1557's national origin prohibition and the prohibition on race discrimination. Several commenters stated that there are instances in which an individual experiences discrimination based on their limited English proficiency, in addition to another protected characteristic. For example, a person who is Black and has limited English proficiency is more likely to experience discrimination in health care settings than an individual who is Black but does not have limited English proficiency or an individual with limited English proficiency but who is not Black.[129] Commenters stated that this type of discrimination may deter patients from seeking critical health care services, leading to adverse health outcomes and decreased trust in the health care system.[130] Commenters also

[128] U.S. Health & Hum. Servs., Off. for Civil Rts., *2023 Language Access Annual Progress Report* (2023), *https://www.hhs.gov/sites/default/files/language-access-report-2023.pdf.*

[129] Neelam H. Ahmed et al., *Moderation of the Association Between Primary Language and Health by Race and Gender: An Intersectional Approach,* 19 Int. J. Environ. Rsch. Pub. Health 7750 (2022), *https://www.mdpi.com/1660-4601/19/13/7750.*

[130] Neelam H. Ahmed et al., *Moderation of the Association between Primary Language and Health by Race and Gender: An Intersectional Approach,* 19 Int. J. Environ. Rsch. Pub. Health 7750 (2022),

Continued

provided data showing that almost one in four health center patients communicate in a language other than English;[131] 63 percent of individuals with LEP identify as Hispanic/Latino;[132] language barriers have been proven to contribute to health inequities for Asian American, Native Hawaiian, and Pacific Islander individuals in particular;[133] and people with LEP are less likely to receive primary care and preventive care, such as breast and cervical cancer screenings.[134]

Some commenters also specifically addressed the importance of language assistance services for older individuals with LEP. These commenters submitted research demonstrating that it is especially difficult for older adults with LEP to communicate with providers because of limited English proficiency, low health literacy, and lack of translators and interpreters.[135] Many commenters argued that to ensure access to quality care, covered entities must have translators and interpreters available at all points of contact at no cost to an individual. This is because older adults may be less inclined to ask for language assistance or may rely on family members who are not qualified to interpret health information. Additionally, the commenters noted that language assistance services are critical for people at the end of life who, absent these services, cannot give true informed consent or thoroughly understand their end-of-life care options.

Response: OCR appreciates these comments and the data submitted. As discussed elsewhere in this preamble, section 1557's language access requirements derive from the statute's prohibition on discrimination against national origin. OCR also appreciates, and agrees with, comments highlighting the ways in which individuals may experience discrimination on multiple grounds as well as comments about the importance of language assistance services for older individuals with LEP. The provisions for § 92.201(a) enhance health access and reduce discrimination by requiring covered entities to take reasonable steps to provide meaningful access to each individual with LEP.

Comment: Many commenters stated that language assistance has often been costly to the individuals with LEP, and translations have often been inaccurate, incomplete, or both. Commenters additionally noted that language assistance has often been provided later in time than other services and that interpretation has not been done in a way that protects patient privacy. Other commenters submitted examples of individuals with LEP being provided with incomplete information, such as being told of only one treatment option, rather than be told of other available treatment options.

Response: We appreciate concerns raised regarding cost, timeliness, and privacy concerns, which we address in § 92.201(b). Consistent with language access requirements in the 2016 and 2020 Rules, required language assistance services must be provided free of charge, be accurate and timely, and protect the privacy of the individual with LEP. Inaccurate or incomplete translations or interpretation may violate the accuracy standard found in this provision and the overarching requirement to take reasonable steps to provide meaningful access. Accuracy issues are further addressed by requiring covered entities to use the services of qualified interpreters and translators, at § 92.201(c).

Comment: Commenters noted a lack of definition for timeliness in § 92.201(b), and one recommended OCR establish time, distance, and wait time standards. Another commenter suggested that the timeliness standard take into account the geographic location of the covered entity and the hour of the day when the need for language assistance services arises.

Response: As OCR discusses in the HHS LEP Guidance, timeliness may depend on multiple variables and so no one definition would be reasonable or applicable to ''all types of interactions at all times by all types of recipients.'' 68 FR 47316. However, language assistance should be provided at a time and place that avoids the effective denial of the service, benefit, or right at issue or the imposition of an undue burden on or delay in important rights, benefits, or services to the person with LEP. 68 FR 47316. When evaluating a complaint, OCR will consider the context, including the urgency and importance of many health care services. We encourage covered entities to review the HHS LEP Guidance for additional guidance.

Comment: Several commenters stated that language assistance services should be required to include cultural competency and that providers should reflect the community around them in order to build trust. One commenter noted that during listening sessions they conducted, participating health centers emphasized the important role that bilingual and bicultural staff who represent the community served to provide accurate and culturally comprehensible interpretation. A few commenters recommended requiring covered entities to ensure sufficient staff with appropriate training and to administer language proficiency assessments to confirm competency of bilingual and multilingual staff.

Some commenters urged that translators and interpreters be from or a part of the impacted community in which they serve, with some suggesting that community-based interpreters and translators may be more qualified for a number of reasons, including familiarity with local dialect and cultural competency. Others, however, stated that family members and community service providers or other external groups should not have to bear the burden of interpreting.

Response: OCR generally agrees that cultural competency is essential for

---

https://www.mdpi.com/1660-4601/19/13/7750: Francisco Ramos-Gomez et al., *Addressing Social Determinants of Oral Health, Structural Racism and Discrimination and Intersectionality among Immigrant and Non-English Speaking Hispanics in the United States,* 82 J. Pub. Health Dentistry 133 (2022), *https://doi.org/10.1111/jphd.12524.*

[131] Kathryn Pitkin Derose et al., *Limited English Proficiency and Latinos' Use of Physician Servs.,* 57 Med. Care Rsch. Rev. 76 (2000), *https://doi.org/10.1177/107755870005700105.*

[132] Jie Zong & Jeanne Batalova, Migration Pol'y Inst., *The Limited English Proficient Population in the United States in 2013* (2015), *https://www.migrationpolicy.org/article/limited-english-proficient-population-united-states-2013.*

[133] Gilbert C. Gee et al., *Associations Between Racial Discrimination, Limited English Proficiency, and Health-Related Quality of Life Among 6 Asian Ethnic Groups in California,* 100 Am. J. of Pub. Health 891 (2010), *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2853608/.*

[134] Elizabeth A. Jacobs et al., *Limited English Proficiency and Breast and Cervical Cancer Screening in a Multiethnic Population,* 95 Am. J. Pub. Health, 1410 (2005), *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1449374/*; Israel De Alba et al., *English Proficiency and Physicians' Recommendation of Pap Smears Among Hispanics,* 30 Cancer Detection & Prevention 292 (2006), *https://pubmed.ncbi.nlm.nih.gov/16844320/*; Lisa Diamond et al., *A Systematic Review of the Impact of Patient–Physician Non-English Language Concordance on Quality of Care and Outcomes,* 34(8) J. Gen. Internal Med. 1591 (2019), *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6667611/*; Kelly H. Bruce et al., *Barriers and Facilitators to Prevent Cancer Screening in Limited English Proficient (LEP) Patients: Physicians' Perspectives,* 11 Commc'ns. Med. 235 (2014), *https://journal.equinoxpub.com/CAM/article/view/8592.*

[135] U.S. Dep't of Health & Hum. Servs., Ctr. for Disease Control, *Adults with Disabilities: Ethnicity and Race, https://www.cdc.gov/ncbddd/disabilityandhealth/materials/infographic-disabilities-ethnicity-race.html* (citing Elizabeth A. Courtney-Long et al., *Socioeconomic Factors at the Intersection of Race and Ethnicity Influencing Health Risks for People with Disabilities,* 4 J. Racial and Ethnic Health Disparities 213 (2017), *https://pubmed.ncbi.nlm.nih.gov/27059052/*); Francisco J. Medrano et al., *Limited English Proficiency in Older Adults Referred to the Cardiovascular Team,* 136 Am. J. of Med. 466 (2023); Terceira A. Berdahl et al., *Patient-Provider Communication Disparities by Limited English Proficiency (LEP): Trends from the US Medical Expenditure Panel Survey, 2006–2015,* 34 J. Gen. Internal Med. 1434 (2019), *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6667581/.*

equitable language access and communications.[136] This is especially important considering variations in dialects, expressions, or ''regionalisms.'' For example, a Spanish word that may be understood to mean something for someone from Puerto Rico may mean something else for someone from Mexico. Thus, cultural competency is a key factor in providing accurate interpretation and translation, and accuracy is a necessary component of meaningful access.

OCR recognizes that community members may be more likely to be culturally competent but declines to include in the regulatory text a requirement that translators and interpreters be from the community they serve. Covered entities are free to determine their own hiring and contracting processes for utilizing the services of qualified interpreters and translators, and hiring bilingual/multilingual staff, as long as these individuals meet the requirements for their respective positions as provided in § 92.4 (Definitions).

Comment: Many commenters supported the novel proposal to address machine translation in this regulation, with some requesting that machine translation *always* be checked by a qualified human translator and that patients be advised when a translation has been completed by machine translation due to high error rates. One commenter specified that covered entities should not use Google Translate as the only resource for translations as it generates errors, pointing to a State Department of Health website translating ''the vaccine is not required'' for COVID–19 to ''the vaccine is not necessary'' in Spanish (since corrected). Other commenters stated that the rule does not adequately account for future innovations and that the final rule should include an exception for exigent circumstances. Insurance entities and other providers commented that machine translation is a viable option to reduce costs in some instances.

Response: OCR recognizes that machine translation is an evolving technology. However, given that it still carries significant potential for error, we believe this provision strikes an appropriate balance between the convenience some may find in this technology and the critical nature of communications in the health care context. We appreciate commenters' concerns regarding exigent circumstances, where use of machine translation technology may provide immediate language assistance capabilities in very urgent circumstances. As provided under § 92.201(a), ''[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.'' For example, if an emergency medical technician must provide urgent medical care to an individual with LEP, and no other language assistance services are available, it may be reasonable to use machine translation technology to communicate with that person while a qualified interpreter is identified. We note that the definition for machine translation found at § 92.4 under this final rule ''means automated translation . . . that is text based and provides instant translations between various languages,'' which includes automated translation covers speech as well as written communications. However, given the importance of communication and understanding in the health care and services setting, OCR requires that in such circumstances, the machine translation must be subsequently checked by a qualified human translator as soon as practicable. OCR also recommends that, if machine translation is used in circumstances that do not require human review (*i.e.,* those circumstances that do not meet the criteria set forth in § 92.201(c)(3)), the patients should be warned that it may contain errors. OCR directs commenters to § 92.4 (Definitions) for further discussion on machine translation and future technology.

Comment: OCR received limited comments on our proposed revisions to the factors the Director will take into account when evaluating compliance with language access obligations (proposed § 92.201(d)). Several commenters supported discontinuing the 2020 Rule's use of the ''four-factor analysis,'' 45 CFR 92.101(b)(1), found in the HHS LEP Guidance, 68 FR 47314–16, to determine compliance with a covered entity's language access requirements under section 1557. These commenters stated that the four-factor analysis is too vague to be useful for oversight of compliance and does not provide direction on how each of the factors would be weighed against each other. Conversely, a few commenters recommended that OCR retain the four-factor analysis since it provides covered entities more flexibility. These commenters noted that recipients must have flexibility in achieving compliance with requirements for language access because of their limited resources and patient populations.

A few commenters noted that the phrase ''other relevant factors'' in § 92.201(d) is vague and should either be removed or clarified. Specifically, they said that compliance has been an ongoing problem and more information is needed to help covered entities understand the factors that will be used for evaluation of compliance. Additionally, one commenter recommended that the final rule include the geographic location of the covered entity and the hour of the day when the need for language assistance services arises as one of the factors for OCR to consider in evaluating compliance. For example, the ability of a small, rural provider to find an interpreter for an individual with LEP at midnight on a Saturday is going to be substantially more challenging than it would be for a provider in an urban setting.

Response: As discussed in the 2022 NPRM, 87 FR 47862, after additional consideration OCR determined that the four-factor test was not a sufficiently precise or flexible compliance tool. Section 92.201(d)(1) provides flexibility that allows the Director to take into account a range of relevant factors, including the ''nature and importance of the health program or activity and the particular communication at issue, to the individual with limited English proficiency.'' Additionally, § 92.201(d)(2) allows for the consideration of ''other relevant factors,'' including those that relate to whether ''reasonable steps'' were taken in a given situation. Thus, the Director may take into account the geographic location and timing considerations posed by the commenter's example in evaluating whether ''reasonable steps'' were taken.

Comment: Many commenters supported the inclusion of an explicit prohibition on the use of certain persons to interpret or facilitate communication, including the expectation that in an emergency situation, reliance on an accompanying adult or minor should be ''a temporary measure'' at § 92.201(e).

[136] *See* U.S. Dep't of Health & Hum. Servs., Off. of Minority Health, *Think Cultural Health, National Standards for Culturally and Linguistically Appropriate Services (CLAS) in Health and Health Care, https://thinkculturalhealth.hhs.gov/assets/pdfs/EnhancedNationalCLASStandards.pdf* (recommending that health organizations: ''[p]rovide effective, equitable, understandable, and respectful quality care and services that are responsive to diverse cultural health beliefs and practices, preferred languages, health literacy, and other communication needs,'' through providing language assistance and ''[e]stablish[ing] culturally and linguistically appropriate goals, policies, and management accountability, and infuse them throughout the organization's planning and operations'').

Commenters stated that children oftentimes are asked to interpret medical information for which they do not have the vocabulary or content knowledge. Some also stated that older adults with LEP may feel pressure to rely on family members as interpreters, even if those family members are not qualified to interpret health information, which can inhibit the older adult's understanding of their health status and instructions from their provider.

Response: We appreciate the commenters' support and underscore that untrained ''interpreters'' are more likely to make errors, violate confidentiality, and increase the risk of poor outcomes. Research has shown that the ability of a provider to accurately diagnose a patient's condition can be jeopardized by untrained interpreters, such as family and friends, and especially minor children who are prone to omissions, additions, substitutions, volunteered opinions, semantic errors, and other problematic practices.[137] Additionally, the use of children as interpreters raises not only the same concerns as those of an accompanying adult who is not qualified as an interpreter, but also poses other problems including exposing children to complex health care interactions for which they are not developmentally prepared, upsetting a family power dynamic, causing embarrassment, and conveying incorrect or incomplete information. 87 FR 47863.

Comment: Some commenters requested that OCR provide emergency exceptions for using bilingual/multilingual staff as interpreters. These commenters noted that covered entities should be able to use their staff's skills in different languages when needed in emergency situations.

Response: We appreciate commenters' concerns regarding obtaining the services of a qualified interpreter in emergency situations. Under § 92.201(e)(2) introductory text, a covered entity may ''[r]ely on an adult, not qualified as an interpreter, accompanying a limited English proficient individual to interpret or facilitate communication'' as a temporary measure in an emergency pending the retention of a qualified interpreter. OCR has revised § 92.201(e)(2) introductory text to remove references limiting reliance on a non-qualified interpreter to only an adult ''accompanying an individual with LEP.'' This provision now allows for a covered entity to rely on a bilingual/multilingual staff member—or other adult not accompanying an individual with LEP—to serve as an interpreter as a temporary measure in such emergency situations. Furthermore, the interpreter services of bilingual/multilingual staff who are also qualified interpreters may be utilized in any situation, including emergency situations. However, covered entities should consider how to obtain the services of a qualified interpreter as quickly as possible in emergency and exigent circumstances, and only rely upon other persons in highly exceptional circumstances.

Comment: A couple of commenters recommended that OCR revise § 92.201(e)(2)(ii) to allow a covered entity to use a qualified interpreter even in situations where the patient has requested that a family member or friend interpret or facilitate communication. These commenters explained that if a provider believes that the family member or friend may not be accurately communicating with the patient or appears to be struggling when interpreting or if a health provider suspects in good faith that an individual may be a victim of trafficking or abuse, then the health provider should be able to utilize a qualified interpreter.

Another commenter recommended that OCR clarify that an accompanying adult may only facilitate communication at the request of an individual with LEP when the request is made in private, without the adult present. The commenter expressed concern that the exception as written could interfere with the autonomy of the individual with LEP seeking sexual or reproductive health services, especially if the individual is accompanied by an abusive partner that objects to certain sexual and reproductive health services.

Additionally, one commenter noted that the prohibition of an accompanying adult acting as an interpreter—absent the individual with LEP's consent or in the case of an emergency—is particularly important for survivors of domestic and sexual violence. The commenter stated that without such a restriction, victims and survivors are faced with situations where their abuser, child, or family member may be used to interpret traumatic and sensitive information, compounding the risk to victims and trauma to themselves as well as their children. Another commenter recommended OCR specify that if an individual with LEP requests an accompanying adult to facilitate one time, this does not mean the covered entity can assume the individual with LEP will continue to bring that same adult or choose to use that adult as an interpreter for future interactions. The covered entity must offer language services each and every time it encounters an individual with LEP.

One commenter requested OCR also address nonemergency situations where the patient does not ''specifically request'' that an accompanying adult interpret or facilitate communication, but where, despite best efforts to find a qualified interpreter, it is not possible to find a qualified interpreter for the individual with LEP, such as when a patient speaks a rare dialect of a language.

Response: We appreciate the commenters' concerns regarding when it may or may not be appropriate to grant an adult with LEP's request for an individual not qualified as an interpreter to interpret or facilitate communication. When considering reliance on an accompanying adult to interpret, the covered entity must consider whether that reliance is appropriate—this includes whether the covered entity believes the accompanying adult can adequately convey the information being discussed and whether they may have a conflict or bias, as in the case of intimate partner violence. Any agreement by a covered entity to allow an accompanying adult to interpret or facilitate communication may only be at the affirmative and independent request of the individual with LEP so as to protect individuals in situations such as intimate partner violence, abuse, or trafficking. We clarify that OCR appreciates the critical role parents and guardians play in medical decision-making for their children and that the rule does not prevent parents from being involved in their children's health care decisions. To address the concern of coercion and the like, we are finalizing § 92.201(e)(2)(ii) to include a requirement that the individual with LEP make their request without the accompanying adult present and with the services of a qualified interpreter, which does not include the exigent circumstances exception found at § 92.201(e)(2)(i).

Comment: One commenter encouraged OCR to include a specific provision at § 92.201(e) ensuring privacy and confidentiality for individuals with LEP, such as not having sensitive discussions in waiting rooms and other public spaces.

Response: We appreciate the commenter's concern regarding privacy and confidentiality for individuals with

[137] Joseph R. Betancourt et al., The Disparities Solutions Ctr., *Mongan Inst. for Health Pol'y, Mass. Gen. Hosp., Improving Patient Safety Systems for Patients with Limited English Proficiency: A Guide for Hospitals,* pp. 3–5, 10–11, 14–16 (2012), *https://www.ahrq.gov/sites/default/files/publications/files/lepguide.pdf.*

LEP and restate that one of the key components of the definition of ''qualified interpreter for an individual with limited English proficiency'' is that they must adhere to generally accepted interpreter ethics principles, including client confidentiality. Additionally, covered entities that are subject to both HIPAA and section 1557 must comply with the requirements of both laws.[138]

Comment: Several commenters supported the restoration of requirements related to video remote interpreting (VRI) for individuals with LEP. Commenters noted that the 2020 Rule removed requirements related to VRI for individuals with LEP, yet many covered entities use video interpreting not only for deaf or hard of hearing patients but also patients with LEP. Further, these commenters noted that the quality of video interpreting should be the same for all individuals who use it. A couple of commenters specifically noted the importance of high-quality picture, video, and transmissible audio for all parties in order for interpreters to perform their job effectively. For example, one commenter noted the importance of restoring VRI standards for individuals with LEP given frequent concerns about the poor quality of interpreter services using VRI. A couple of other commenters mentioned that the use of such technology will facilitate discussion between qualified interpreters and individuals with LEP and will also assist individuals who may have disabilities who are aided by using such technology. One commenter, who supported inclusion of VRI standards, recommended in-person interpretation should be sought as a first step because it is more responsive than VRI.

Response: We agree with commenters that it is important to have parity in VRI quality standards for all individuals who use it. The final rule reinstates the VRI standards from the 2016 Rule, former 45 CFR 92.201(f), which were based on standards found in the implementing regulations for title II of the ADA.[139] This provision is designed to achieve parity with the VRI requirements found in § 92.202 regarding effective communication for people with disabilities.

We recognize that VRI is not always the most appropriate method for providing language assistance services. This provision does not require a covered entity to provide VRI but rather ensures that when such services are used, they meet a minimum quality standard. To also clarify that the language assistance services delivered via VRI must provide meaningful access, we are revising § 92.201(f) to require that when a covered entity uses VRI services, it ''must ensure the modality allows for meaningful access.''

Comment: A few commenters raised concerns with the proposed technical requirements for VRI services. A couple of commenters requested OCR provide emergency exceptions for performance standards for video remote interpreting. These commenters also expressed concern with the requirement that VRI must be over a dedicated high-speed, wide-bandwidth video connection or wireless connection since it may be difficult to meet that standard in an emergency, such as a natural disaster that disrupts access to the high-speed connection.

Another commenter suggested revising the rule to require covered entities to use audio and video communications for interpretation services that are consistent with those available in the community served by the health program or activity. The commenter explained the communications framework in a community, such as a rural community, may not fully meet the standards proposed.

Response: We appreciate commenters' concerns regarding the ability to meet the VRI standards proposed. In the event of a natural disaster or locations where high-speed wide-bandwidth video capabilities may not be available, covered entities may not be able to meet the required standards. In these circumstances, a reasonable step to achieving meaningful access may be through using the services of a qualified interpreter via telephone (or in-person, if available). As in all circumstances, OCR will consider the specific facts of whether a covered entity has taken reasonable steps to provide meaningful access under the circumstances.

Comment: A couple of commenters recommended that VRI requirements be reflective of and adaptable to the specific community or individual. One organizational commenter recommended that the rule clarify that covered entities should follow an individual's preference with respect to interpreter services where appropriate. The commenter noted that the majority of their members and patients with LEP communicate through telephonic interpretation services and that there are also situations where a member or patient may express a preference to use an audio interpreter service rather than be required to participate in a video session.

Response: We appreciate commenters' suggestions regarding prioritizing an individual with LEP's preference when determining the manner in which interpreting services will be provided. However, we decline to revise the requirements for VRI standards. These standards set minimum requirements for when language assistance services are provided via VRI; they do not, however, *require* a covered entity to use such technology. Covered entities are free to use audio-only interpretation if that is a reasonable step to provide meaningful access to an individual with LEP, including if it is the expressed preference of an individual with LEP.

Comment: A few commenters recommended OCR establish further requirements with respect to VRI. These commenters suggested OCR specify that the covered entity should be held responsible for ensuring that the VRI device connects to a qualified interpreter within five minutes of the arrival of the VRI device in the room and ensure that there are no interruptions in communication, such as disconnections or screensavers. Further, commenters recommended that health care entities should have personnel available on a 24-hour basis who are trained and able to operate the VRI system efficiently. These commenters stressed that hospitals are already responsible for the maintenance and upkeep of multiple types of equipment necessary for health care and, as such, the same strict standards for optimal operation and upkeep should apply to VRI technology as well. A few commenters stated that covered entities should have policies and procedures in place to procure video remote interpretation.

Response: OCR appreciates the commenters' recommendations for providing further requirements related to VRI. The rule requires that language assistance services be provided in a timely manner. We decline to mandate a specific time period in which an interpreter must be made available once

[138] Determining the relationship between the interpreter and the covered entity is a covered entity's HIPAA obligation and is unchanged by section 1557 or the part. We encourage covered entities to review OCR's HIPAA Frequently Asked Questions (FAQ) regarding business associates. *See* U.S. Health & Hum. Servs., Off. for Civil Rts., *Health Information Privacy FAQs, https://www.hhs.gov/hipaa/for-professionals/faq/760/must-a-covered-provider-obtain-individual-authorization-to-disclose-to-an-interpreter/index.html.*

[139] *See* 28 CFR 35.160(d)(1)–(4). In contrast to 28 CFR 35.160(d)(2), which regulates the size of the video image to ensure that the screen shows one's face, arms, hands, and fingers, § 92.201(f)(2) in this final rule does not regulate the size of the video image because this component is less relevant for oral interpretation between English and non-English languages or two non-English spoken languages.

a VRI device is present, as it does not allow for the necessary flexibility that may be required to account for the specific circumstances giving rise to the interaction, such as whether it is scheduled or unscheduled. We agree it is important to ensure a covered entity has personnel who can maintain and efficiently set up and operate VRI technology. To this end, the rule requires covered entities to maintain language access procedures per § 92.8(d), and to provide adequate training to users of the technology and other involved persons so that they may quickly and efficiently set up and operate the VRI device per § 92.201(f)(4). Although we support covered entities having policies and procedures in place related to the procurement of video remote interpretation, we decline to require them to do so because we do not believe imposing such a requirement is warranted at this time.

Comment: OCR received a few comments on the standards for audio remote interpreting services at § 92.201(g), which were generally supportive. One commenter expressed that audio-only interpretation is often a poor substitute for video remote or in-person interpretation and recommended OCR consider audio-only interpretation to be a last resort.

Response: We appreciate the commenter's concern and recognize that audio remote interpreting may not be adequate to provide meaningful access to an individual with LEP. However, there are situations in which audio remote interpreting may be the only option available to a covered entity and so we decline to place further restrictions on its use. To address concerns that audio remote interpreting may fail to provide meaningful access, we are revising § 92.201(g) to require that when a covered entity uses audio remote interpreting services, it ''must ensure the modality allows for meaningful access.''

Comment: One commenter recommended OCR explicitly prohibit covered entities from coercing individuals with LEP to decline language assistance services, which was stated in the preamble to the 2015 NPRM. 80 FR 54185. The commenter noted that the 2022 NPRM did not capture this important concept and covered entities should be prohibited from discouraging individuals with LEP from exercising their rights, which may be a form of discrimination.

Response: We appreciate the commenter's concern and reiterate that a covered entity may not coerce an individual with LEP to decline language assistance services. In the same way that a covered entity is prohibited from requiring an individual with LEP to accept language assistance services, § 92.201(h), a covered entity similarly cannot require or coerce an individual to decline such services.

Summary of Regulatory Changes

For the reasons set forth in the Proposed Rule and considering the comments received, OCR is finalizing the provisions as proposed in § 92.201, with modifications. In § 92.201(a), we are adding ''(including companions with limited English proficiency)'' after the term ''individual with limited English proficiency.'' In § 92.201(e)(2), we are deleting the clause ''accompanying a limited English proficient individual.'' In § 92.201(e)(2)(i), we are replacing ''the accompanying adult'' with ''an initial adult interpreter.'' In § 92.201(e)(2)(ii) we are adding the phrase ''in private with a qualified interpreter present and without an accompanying adult present,'' after ''where the individual with limited English proficiency specifically requests.'' In § 92.201(f), we are adding the phrase ''ensure the modality allows for meaningful access and must . . .'' after ''through video remote interpreting services in the covered entity's health programs and activities must . . .'' In § 92.201(g), we are adding the phrase ''ensure the modality allows for meaningful access and must . . .'' after ''through audio remote interpreting services in the covered entity's health programs and activities must . . .''

We are also making technical revisions. Throughout § 92.201, we are replacing the term ''limited English proficient individual'' with ''individual with limited English proficiency.'' In § 92.201(c)(2), we are replacing the phrase ''a covered entity must use a qualified translator'' with ''a covered entity must utilize the services of a qualified translator.'' In § 92.201(e)(2)(ii), we are replacing the word ''the'' in the phrase ''by the accompanying adult is documented'' with ''by an accompanying adult is documented.'' In § 92.201(e)(4) we are striking the word ''directly'' as technically incorrect to describe the manner in which a covered entity communicates to an individual with LEP via the services of a qualified interpreter or qualified translator.

Effective Communication for Individuals With Disabilities (§ 92.202)

Proposed § 92.202 addressed requirements related to providing effective communication for individuals with disabilities.

In § 92.202(a), we proposed requiring a covered entity to take appropriate steps to ensure that communications with individuals with disabilities, and companions with disabilities, are as effective as communications with individuals without disabilities in its health programs and activities, incorporating the standards found at 28 CFR 35.130 and 35.160 through 35.164 of the regulation implementing title II of the ADA.

In § 92.202(b), we proposed to require covered entities to provide appropriate auxiliary aids and services to individuals with impaired sensory, manual, or speaking skills, where necessary to afford such individuals an equal opportunity to benefit from the service in question.

The comments and our responses regarding § 92.202 are set forth below.

Comment: While commenters generally expressed support for § 92.202, many discussed the extensive lack of compliance with current effective communication requirements under section 1557, section 504, and title II of the ADA by covered entities. Some referenced costs as the key issue, and one commenter stated that some providers have a policy of only providing an interpreter if the cost is covered by the patient's health insurance. Another commenter stated that even when the State has a Medicaid billing code, the patients still are faced with the burden of having to educate prospective providers about the availability of the code and the provider's obligation to provide auxiliary aids and services.

Other commenters mentioned that compliance will require implementing programs to develop, maintain, and communicate clear policies, and train on the provision of language assistance services and auxiliary aids and services for effective communication.

Response: OCR is aware that some covered entities fail to comply with their responsibility to ensure effective communication with individuals with disabilities, including through requiring an individual to bring their own interpreter, only providing interpreter services when covered by the individual's health insurance coverage or other health-related coverage, or incorrectly citing health privacy laws as a reason to not provide interpreter services.

In an effort to proactively address compliance concerns and resulting lack of access to covered health programs and activities, we are requiring all covered entities to develop and

maintain effective communication procedures, per § 92.8(e). OCR encourages covered entities to include any necessary billing codes in such procedures. We are further requiring covered entities to train relevant employees on these procedures, per § 92.9.

Comment: A patient advocacy group recommended requiring that states establish a medical communication access fund that pools fees from State-mandated medical licenses to pay for effective communication. The commenter expressed that this method spreads out the costs of auxiliary aids and services so that no single covered entity bears the costs.

Response: All covered entities must provide auxiliary aids and services when needed to communicate effectively with people with disabilities. OCR encourages covered entities to develop creative approaches to support the provision of these required aids and services. OCR declines to include a specific requirement for states to establish mandatory medical communication access funds in this rulemaking as such a requirement would exceed the authority granted to OCR for this rulemaking.

Comment: Some commenters expressed appreciation and support for the inclusion of ''companions'' in the text of § 92.202. One commenter added that doctors and hospitals have told patients that their legal counsel informed them that they are not obligated to provide communication access to anyone who is not a patient. One commenter recommended that OCR include that the selection of ''appropriate'' companion(s) be made by the individual not the provider.

Response: Section 1557 requires that covered entities ensure effective communication for individuals with disabilities, including companions. The definition in § 92.4 is consistent with the definition of ''companion'' from the implementing regulations for title II of the ADA, which similarly requires that a public entity ''take appropriate steps to ensure that communications with . . . companions with disabilities are as effective as communications with others.'' 28 CFR 35.160(a).

Comment: A couple of commenters mentioned that patients are sometimes told that due to confidentiality they cannot have a friend, family member, advocate, or attorney be present for an appointment for effective communication purposes. One commenter provided the following example: An individual with Autism Spectrum Disorder (ASD) was required to enter the hospital without his mom, who could assist him in communicating, and likely because of that he was misdiagnosed and required to return to the emergency room within a week.

Response: Unless a covered entity has a specific confidentiality concern regarding the presence of a specific companion, the individual with a disability should be permitted to select a companion and have them present when accessing a covered health program or activity. Further, and consistent with instruction under the ADA, a companion may need to help the patient with information or instructions given by hospital personnel.[140] Companions may be an essential part of ensuring an individual with a disability is afforded effective communication and should not be separated from an individual with a disability outside of extenuating circumstances. However, we note that a covered entity may not rely on a person accompanying an individual with a disability to interpret or otherwise facilitate communication; this is only permitted when the individual with a disability specifically requests that an accompanying adult interpret or facilitate communication, the accompanying adult agrees to provide such assistance, and reliance on that adult for such assistance is appropriate under the circumstances. *See* 28 CFR 35.160(c)(2)(ii), incorporated by § 92.202.

Comment: Several commenters thanked OCR for proposing to restore the requirements for quality measures in VRI, while some raised concerns regarding the appropriateness of VRI in various circumstances. They shared that, for example, VRI may not be effective for a person lying on their back for a medical procedure due to challenges with viewing the screen and that VRI has been inappropriately used during high-risk childbirth. Yet another commenter mentioned that VRI is not appropriate for individuals who are deafblind (*i.e.,* individuals who have combined hearing and vision loss that limit access to both auditory and visual information). One commenter expressed concern that a provider made it a policy that their facility only uses VRI and never uses the services of in-person interpreters.

Response: We acknowledge the concerns with VRI and note that it may not provide effective communication for all individuals in all situations. Covered entities are required to take appropriate steps to ensure that communications with individuals with disabilities are as effective as communications with individuals without disabilities in their health programs and activities. If the use of VRI does not provide an individual equal opportunity to participate in or benefit from the service in question, then the communication is ineffective and does not meet section 1557 requirements.

Several cases have found that VRI was ineffective due to hospital staff's lack of knowledge about how to operate the VRI equipment or technology issues with the equipment itself, including the attempted use of VRI during labor.[141] Settlement agreements with the United States have similarly found concerns with VRI, including one settlement decree that specified that VRI would not be considered effective in specific situations, including situations due to: ''(1) a patient's limited ability to move his or her head, hands or arms; vision or cognitive issues; or significant pain; (2) space limitations in the room; (3) the complexity of the medical issue; or (4) any other time when there are indicators that VRI is not providing effective communication.'' [142]

This enforcement activity suggests that VRI may not always afford a person with a disability an equal opportunity to participate in and enjoy the benefits of the program or activity of a covered entity. Thus, policies that require the exclusive use of VRI, or the exclusive use of any particular auxiliary aid or service, are likely to result in the eventual failure to provide effective communication and therefore should not be adopted.

Comment: One patient advocacy group recommended that OCR emphasize that family members should not act as interpreters for a deaf or hard of hearing patient, except in certain exigent circumstances.

[140] 75 FR 56183, 56223–24 (Sept. 15, 2010).

[141] *Sunderland* v. *Bethesda Hosp., Inc.,* 686 F. App'x 807 (11th Cir. 2017); *Silva* v. *Baptist Health S. Fla., Inc.,* 303 F. Supp. 3d 1334 (S.D. Fla. 2018), *aff'd in part, vacated in part, remanded,* 838 F. App'x 376 (11th Cir. 2020); *Juech* v. *Children's Hosp. & Health Sys., Inc.,* 353 F. Supp. 3d 772 (E.D. Wis. 2018); Settlement Agreement Between the United States of America and Floyd Medical Center (2016), *https://archive.ada.gov/floyd_sa.html*; *see also* Manako Yabe, *Healthcare Providers' and Deaf Patients' Interpreting Preferences for Critical Care and Non-Critical Care: Video Remote Interpreting,* 13.2 Disability and Health J. 100870 (2020), *https://pubmed.ncbi.nlm.nih.gov/31791822/*; Nat'l Ass'n for the Deaf, *Minimum Standards for Video Remote Interpreting Services in Medical Settings, https://www.nad.org/about-us/position-statements/minimum-standards-for-video-remote-interpreting-services-in-medical-settings/.*

[142] Settlement Agreement Between the U.S. and Swedish Edmonds Hospital (2014), *https://archive.ada.gov/swedish_edmonds_sa.htm*; Settlement Agreement Between the U.S. and Grady Memorial Hospital (2016), *https://archive.ada.gov/grady_sa.html.*

Response: Covered entities are responsible for providing effective communication, including through utilizing the services of a qualified interpreter, and cannot require an individual to bring someone to interpret for them. Persons with disabilities can, however, bring an interpreter of their choosing, including a family member, and OCR declines to add the suggested language prohibiting this choice. This approach is consistent with existing ADA title II regulations, 28 CFR 35.160(c), and with the approach OCR has followed in the section 504 proposed rule. 88 FR 63392, 63508 (Sept. 14, 2023) (proposed 45 CFR 84.77(c)(2)(ii)).

Comment: One group recommended that the final rule include language that requires health care entities to consider a patient's preference for gender of the interpreter as a means of ensuring more effective communication. This group noted that given the intimate nature of medical assessments and treatments, patients may not be comfortable with an interpreter of a different gender than themselves, particularly in settings that involve nudity such as in an obstetrics and gynecology appointment.

Response: While OCR appreciates that a patient may prefer an interpreter of a particular gender and recommends consideration of a patient's preference for a particular gender whenever possible, including when the request is made based on an individual's religious practices and beliefs, we decline to include such language in the rule regarding the gender of a qualified interpreter for an individual with a disability. OCR notes that some organizations, such as the National Association of the Deaf and Deaf Seniors of America, have issued position statements to guide providers in adopting internal VRI policies, and have stated that medical providers ''shall honor the preference of the deaf or hard of hearing patient and/or companion with respect to the gender of video interpreter.'' [143] However, OCR notes that whether a covered entity has ensured their communication is effective for an individual with disability does not inherently depend on whether the covered entity is able to satisfy a patient's preference regarding the interpreter's gender.

Comment: An organizational commenter said that providers should be required to ''affirmatively ask'' patients what they need to make documents accessible and should document that requirement so that it does not need to be repeatedly asked and answered.

Response: OCR understands the frustration experienced by individuals who have to inform their providers of their need to receive communication in accessible formats multiple times. We note that the Department has implemented a process by which Medicare beneficiaries who are blind or have low vision can request Medicare Summary Notices in an accessible format, and following the initial request, the required accessible format will be the default format of the document mailed to the beneficiary.[144] We recognize this as a best practice, and while we decline to require that such need be documented, we encourage covered entities to implement such a practice in the written effective communication procedures required under § 92.8(e).

Comment: Some organizational commenters urged OCR to incorporate the following OCR guidance documents directly into the final regulations, as well as all subsequent similar guidance, technical assistance, and enforcement activities: enforcement efforts related to support persons in hospital settings[145] and Bulletin on Civil Rights, HIPAA, and the Coronavirus Disease 2019.[146]

Response: OCR thanks commenters for their suggestion to incorporate guidance and enforcement materials into the final rule. Guidance documents advise members of the public how an agency understands its legal authorities.[147] Similarly, covered entities and others may be able to look to OCR's enforcement to gain clarity regarding regulatory requirements. As guidance, technical assistance, and enforcement activities are constantly evolving, we decline to codify the referenced materials in this rule.

Comment: Multiple commenters, including organizations, recommended that § 92.202(b) explicitly parallel the language in § 92.201(b) by stating that auxiliary aids and services must be provided free of charge, be accurate and timely, and protect the privacy and the independent decision-making of the individual with a disability. The commenters noted that while this section adopts by reference 28 CFR 35.160 through 35.164 (ADA title II communication requirements), some covered entities may simply read the regulatory language and note the difference in language between §§ 92.201 and 92.202. Noting this difference, several commenters also requested that OCR develop technical assistance materials on 28 CFR 35.160 through 35.164 in plain language.

Response: Like multiple places in this regulation, the text of § 92.202 adopts ADA title II standards by reference, including the requirements related to auxiliary aids and services. OCR appreciates the concerns raised by commenters regarding the apparent lack of parity between §§ 92.201(b) and 92.202(b), and how this may lead to confusion on behalf of covered entities and the public and may increase the likelihood that individuals with disabilities may either not receive or may be required to pay for auxiliary aids and services. Therefore, in light of comments received and continued compliance concerns, we are revising § 92.202(b) as follows.

First, OCR is revising the text, consistent with 28 CFR 35.160(b)(1), to clarify that all individuals with disabilities must be afforded appropriate auxiliary aids and services and an equal opportunity to ''participate in and enjoy the benefits of'' the health program or activity in question.

Further, OCR agrees with commenters that it is important that those reading this regulation can immediately identify that appropriate auxiliary aids and services must be provided free of charge. Some commenters and our enforcement experience demonstrate that this requirement, similar to that in the ADA and section 504, is not always clear or adhered to by covered entities. Thus, OCR is adding a sentence to § 92.202(b) stating that auxiliary aids and services must be provided free of charge. OCR notes that this is similar to the approach taken in DOJ's implementing regulations for title II and title III of the ADA, which forbid surcharges on persons with disabilities or groups of persons with disabilities to

[143] Nat'l Ass'n of the Deaf, *Minimum Standards for Video Remote Interpreting Services in Medical Settings, https://www.nad.org/about-us/position-statements/minimum-standards-for-video-remote-interpreting-services-in-medical-settings/.*

[144] Beneficiaries can find information on how to request Medicare Summary Notices in accessible formats at Medicare.gov, *Accessibility & Nondiscrimination Notice, https://www.medicare.gov/about-us/accessibility-nondiscrimination-notice*; *see also* 88 FR 22120, 22122 (April 12, 2023).

[145] U.S. Dep't of Health & Hum. Servs., Off. for Civil Rts., *OCR Resolves Complaints after State of Connecticut and Private Hospital Safeguard the Rights of Persons with Disabilities to Have Reasonable Access to Support Persons in Hospital Settings During COVID–19* (June 9, 2020), *https://public3.pagefreezer.com/content/HHS.gov/31-12-2020T08:51/https://www.hhs.gov/about/news/2020/06/09/ocr-resolves-complaints-after-state-connecticut-private-hospital-safeguard-rights-persons.html.*

[146] U.S. Dep't of Health & Hum. Servs., Off. for Civil Rts., *March 28, 2020 BULLETIN: Civil Rights, HIPAA, and the Coronavirus Disease 2019 (COVID–19)* (Mar. 28, 2020), *https://www.hhs.gov/guidance/document/march-28-2020-bulletin-civil-rights-hipaa-and-coronavirus-disease-2019-covid-19.*

[147] *Kisor* v. *Wilkie,* 139 S. Ct. 2400, 2420 (2019) (plurality opinion) (quoting *Perez* v. *Mortgage Bankers Ass'n,* 575 U.S. 92, 97 (2015)).

cover the provision of auxiliary aides and services. 28 CFR 35.130(f) (title II), 36.301(c) (title III). For parity with 28 CFR 36.160(b)(2) and 45 CFR 92.201(b), we are also revising the text to clarify that auxiliary aids and services must be provided 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.

OCR appreciates commenters' suggestion to develop technical assistance materials regarding effective communication under 28 CFR 35.130 and 35.160 through 35.164. These are regulations promulgated and enforced by DOJ, and we will continue to coordinate and collaborate with DOJ to develop technical assistance materials related to effective communication requirements under our respective authorities.[148]

Comment: A few organizational commenters argued that the provision of auxiliary aids and services is necessary but not a sufficient tool for avoiding and remedying effective communication discrimination. The commenters said that individuals who cannot rely on natural speech for effective communication require ''effective access to the robust language-based alternative and augmentative communication they need to express themselves and be understood.'' Another group said that OCR should expand on the definition of ''auxiliary aids and services'' to include plain language and screen reader capabilities.

Response: Covered entities are required take appropriate steps to ensure effective communication. Though the provision of appropriate auxiliary aids and services is addressed in § 92.202(b), the examples of auxiliary aids and services provided at § 92.4 (Definitions) is non-exhaustive and covered entities may use additional auxiliary aids and services to achieve effective communication.

Effective communication for patients with cognitive, neurological, and psychiatric disabilities may require auxiliary aids and services or strategies different from those employed with patients with other disabilities. For example, while an individual who is deaf or hard of hearing may require an ASL interpreter to effectively communicate with a provider, an individual with a cognitive disability may require additional time with the provider to ask questions and receive plain language answers about a specific health care decision.

In addition, one type of auxiliary aid or service that may be required is the acquisition or modification of equipment or devices, including for augmentative and alternative communication, and the provision of training and assistance to the individual with a disability on how to use them. Augmentative and alternative communications devices include, but are not limited to, speech generating devices, single-message devices, computers, tablets, smartphones, amplification devices, telecommunications devices, voice amplifiers, artificial phonation devices, picture and symbol boards, paper-based aids, and other equipment or devices used to compensate for impairments to speech-language production or comprehension, including spoken and written modes of communication. In some instances, the use of augmentative and alternative communication is necessary for individuals with certain disabilities that impair speech production and comprehension to access vital health and human services programs and activities. Often, the most effective way for recipients to ensure effective communication is to provide training on the use of this equipment.

Comment: A health care organization requested that this provision should be modified to state that covered entities ''must make a reasonable attempt'' to provide auxiliary aids and services, ''unless the covered entity can demonstrate that providing such auxiliary aids or services would fundamentally alter the nature of the service in question or result in an undue burden, *i.e.,* significant difficulty or expense.''

Response: OCR declines to modify the standard for effective communication, which requires that covered entities ensure that communications with people with disabilities are as effective as communications with others. The language on fundamental alteration or undue burden related to the provision of communications, found in 28 CFR 35.164, is already adopted into this section by reference.

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 § 92.202, with modification. We are revising § 92.202(b) to read: ''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.''

Accessibility for Buildings and Facilities (§ 92.203)

In § 92.203, we proposed adding a general provision establishing that 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, consistent with OCR's section 504 regulation. OCR also proposed incorporating the identical language found in the 2020 Rule at § 92.103, except that the definitions for 1991 Americans with Disabilities Act Standards for Accessible Design (1991 ADA Standards), 2010 ADA Standards for Accessible Design (2010 ADA Standards), and Uniform Federal Accessibility Standards (UFAS), Public Law 90–480; 42 U.S.C. 4151 *et seq.,* are now located in § 92.4.

OCR also notes that the section 504 regulatory provisions incorporated into subpart B in this regulation contain program accessibility requirements that apply to existing facilities as well as new construction and alterations. Title II of the ADA and section 504 require that covered entities operate their programs and activities so that, when viewed in their entirety, they are readily accessible to individuals with disabilities; neither statute has been interpreted to require that each existing facility be made accessible.[149] Nearly all of the entities subject to the facility access requirements in the final rule are also subject to facility access requirements under section 504 and the ADA. Section 92.203 establishes specific accessibility standards for new construction and alterations under section 1557.

The comments and our responses regarding § 92.203 are set forth below.

Comment: Some commenters emphasized the importance of a

[148] U.S. Dep't of Health & Hum. Servs., Off. for Civil Rts., *Disability Resources for Effective Communication, https://www.hhs.gov/civil-rights/for-individuals/special-topics/hospitals-effective-communication/disability-resources-effective-communication/index.html; see also Medicaid.gov, Unwinding Documents, https://www.medicaid.gov/resources-for-states/coronavirus-disease-2019-covid-19/unwinding-and-returning-regular-operations-after-covid-19/state-letters/index.html.*

[149] *See* 28 CFR 35.150(a); 45 CFR 84.22(a); *Bird* v. *Lewis & Clark Coll.,* 303 F.3d 1015, 1021 (9th Cir. 2002) (''the central inquiry [under the ADA and section 504] is whether the program, when viewed in its entirety is readily accessible to and usable by individuals with disabilities'').

continued push towards universal compliance with the 2010 ADA Standards. Many commenters also noted how critical it would be for OCR to provide oversight to ensure that covered entities' buildings and facilities come into compliance with the 2010 ADA Standards. These commenters also noted that the uniform application of the 2010 ADA Standards will also enable greater consistency among implementing agencies.

Response: OCR appreciates the comments regarding the existing standards and the push towards universal compliance with the 2010 ADA Standards and will continue to retain the requirement that new construction or alteration of buildings or facilities must comply with the 2010 ADA Standards.

Comment: Some commenters did not support the incorporation of 45 CFR 84.23(c) at § 92.101(b) because they stated it would allow facilities to only conform with UFAS instead of the more recent 1991 ADA Standards or 2010 ADA Standards. They also expressed concern that the application of the UFAS to new facilities would be outdated. These commenters believe that the UFAS permits facilities to maintain barriers that exclude people with disabilities that impact their mobility or strength.

Response: OCR appreciates the commenters concerns regarding the incorporation of the UFAS. However, this rule does not allow UFAS to be used as the accessibility standard for new facilities. UFAS is only used to determine if a building built before July 18, 2016, was designed and constructed in accordance with the standards at the time. Any alteration or addition of any building or facilities built after July 18, 2016, must follow the 2010 ADA Standards.

Comment: Some commenters also recommend incorporating existing standards relating to accessible Medical and Diagnostic Equipment (MDE) that were developed by the U.S. Access Board. 82 FR 2810 (Jan. 9, 2017), codified at 36 CFR part 1195 (U.S. Access Board 2017 Standards for MDE). Commenters also noted that the lack of access to MDE should constitute both a discriminatory benefit design and network inadequacy.

Response: On September 14, 2023, OCR published a NPRM proposing modifications to the implementing regulations for section 504. The NPRM proposes adopting the U.S. Access Board 2017 Standards for MDE used by recipients of Federal financial assistance to ensure accessibility for patients with disabilities. 88 FR 63450–55, 63511 (proposed 45 CFR 84.92). OCR will continue to address accessible MDE in that rulemaking.

Summary of Regulatory Changes

For the reasons set forth above and considering the comments received, we are finalizing the provisions as proposed in § 92.203 with modification. We are making two technical corrections to add ''or alteration'' after ''construction'' in § 92.203(b) and (c) for consistency with the description of the 2010 Standards elsewhere in the provision. We have replaced the phrase ''and such facility was not covered by the 1991 Standards or 2010 Standards'' in § 92.203(c) with ''and such facility would not have been required to conform with a different accessibility standard under 28 CFR 35.151'' for clarity and consistency. We have also added language clarifying the timeframes for compliance with either the 2010 Standards or the UFAS standards for existing facilities where construction or alteration was begun on or after July 18, 2016, and on or before January 18, 2018, in conformance with UFAS but the facility or part of the facility was not covered by the 2010 Standards. That addition reads, ''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 this section requirements of this section and with 45 CFR 84.23(a) and (b).''

Accessibility of Information and Communication Technology for Individuals With Disabilities (§ 92.204)

Proposed § 92.204 addressed the accessibility of information and communication technology (ICT) for individuals with disabilities.

In § 92.204(a), OCR proposed requiring covered entities to ensure that their health programs and activities provided through ICT 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 subpart would result in such an alteration or burdens, a covered entity is required to take any other action that would not result in such an alteration or burdens but would nevertheless enable, to the maximum extent possible, individuals with disabilities to receive the benefits or services of the health program or activity provided by the covered entity.

In § 92.204(b), OCR proposed requiring recipients and State Exchanges to ensure that their health programs and activities provided through websites and mobile applications comply with the requirements of section 504 as interpreted in a manner consistent with title II of the ADA.

Given the crucial role that ICT can play for individuals with disabilities accessing health programs and activities, OCR sought comment on whether the section 1557 rule should include a provision requiring covered entities to comply with specific accessibility standards, such as the Web Content Accessibility Guidelines (WCAG) developed by the Web Accessibility Initiative. Additionally, OCR invited comments on whether to adopt a safe harbor provision under which covered entities that are in compliance with established specific accessibility standards are deemed in compliance with proposed § 92.204(a) and (b); whether OCR should require covered entities to comply with the most recent edition of a published standard; and the timeline necessary for covered entities to come into compliance with a new standard.

The comments and our responses regarding § 92.204 are set forth below.

Comment: Many commenters, including civil rights groups, health care organizations, and a group of Federal elected officials, expressed general support for the ICT requirements for people with disabilities in the Proposed Rule. Several commenters said they are concerned that this section only focuses on accessibility for individuals with disabilities, saying that this section should be applicable to all individuals covered by section 1557. These commenters noted that section 1557's nondiscrimination mandate guards against discrimination on the basis of race, color, national origin, sex, and age, as well as disability. Therefore, these commenters recommended that § 92.204 provide that covered entities must ensure that their health programs or activities provided through ICT are accessible to individuals on all protected bases, not just disability.

Response: Section 92.204 prohibits discrimination based on disability in health programs and activities provided through ICT because individuals with certain disabilities are often unable to access certain aspects of ICT when that ICT is not developed to be accessible. For example, OCR has received complaints from people with disabilities, including those who are blind or have low vision, alleging that the ICT of covered entities is

inaccessible to them and not compatible with screen reader software, resulting in a denial of access to health programs and activities. While § 92.204 addresses ICT accessibility issues for individuals with disabilities, it does not limit the application of general nondiscrimination principles found throughout section 1557 regulations to the accessibility of health programs and activities offered through ICT to other groups. Thus, the general prohibition against discrimination set forth in § 92.101(a) requires the accessibility of health programs and activities offered through ICT, without discrimination on the basis of race, color, national origin, sex, age, or disability.

Comment: Several groups recommended adding that ''covered entities must procure, design, maintain and use accessible ICT in all aspects of providing health programs and activities'' to remind covered entities that their civil rights obligations apply in procurements. One group said that OCR should clarify that covered entities should be aware that third-party providers of ICT are not directly covered by this regulation, and that covered entities are obligated to ensure that they procure ICT that is accessible. Several commenters suggested the use of a Voluntary Product Accessibility Template,[150] a document that indicates compliance with section 508 standards,[151] should be completed by the third-party vendors.

Response: Regardless of the method that a covered entity uses to acquire ICT, the health programs and activities it provides through that ICT must be accessible to individuals with disabilities. Due to the increasing importance of ICT in the provision of health care, health insurance coverage, and other health-related coverage, OCR will continue to closely monitor this area. Both OCR and DOJ recently issued NPRMs addressing the accessibility of web content and mobile apps used by recipients of Federal financial assistance and public entities, respectively.[152] Those rulemakings provide greater clarity on obligations to ensure that web content and mobile applications are accessible.

Comment: An organizational commenter asked OCR to provide more guidance on what constitutes undue burden or fundamental alteration.

Response: This rulemaking does not create a different standard for fundamental alteration or undue burden beyond the standards in section 504 and the ADA. As DOJ noted in its August 4, 2023 NPRM, Nondiscrimination on the Basis of Disability; Accessibility of Web Information and Services of State and Local Government Entities, there are current undue burden and fundamental alteration limitations in the ADA title II regulation that are familiar to public entities. 88 FR 51948, 51978. The current limitations are in the ADA title II implementing regulation at 28 CFR 35.150(a)(3) (program accessibility) and 35.164 (effective communication) for fundamental alteration and undue burden limitations and 28 CFR 35.130(b)(7) (reasonable modifications in policies, practices, or procedures) for fundamental alteration limitations. DOJ also provides additional context for fundamental alteration and undue burden on its ADA.gov website.[153] Additionally, DOJ's technical assistance manual on title III of the ADA provides guidance on what constitutes fundamental alteration and undue burden for public accommodations under title III.[154]

Comment: A professional association asked OCR to work with small, independent, and under-resourced physician practices to ensure they have the resources, tools, and financial assistance necessary to ensure ICT accessibility for patients with disabilities.

Response: OCR will continue to develop technical assistance and educational materials to assist covered entities' compliance with section 1557 and this regulation. However, we are unable to provide other resources or financial assistance to ensure ICT accessibility.

Comment: One organizational commenter said that OCR should provide technical assistance to covered entities servicing populations with digital inequities, such as populations of older adults that may not be as digitally savvy or individuals who do not have stable internet connections.

Response: OCR recognizes that many people lack internet connectivity and may therefore be unable to access web-based tools and resources provided by covered entities, and OCR encourages entities to develop creative means to meet the needs of these individuals. However, though this issue may raise civil rights concerns in some contexts, it is outside the scope of this regulation.

Covered entities have general nondiscrimination obligations under § 92.101(a), including that a covered entity may not discriminate based on age. Accordingly, covered entities that use web-based health programs and activities must ensure that older adults are not denied participation, denied benefits, or otherwise discriminated against in the provision of those web-based health programs and activities. For example, a covered entity may not decline to provide an electronic appointment reminder to an older individual because of a stereotype that older individuals may experience difficulties using such technology.

Comment: One organizational commenter recommended extending the full ICT requirements to recipients and State exchanges.

Response: Recipients and State Exchanges are required to comply with both § 92.204(a) and (b), per the text of the section.

Comment: Multiple commenters requested the explicit inclusion of mobile applications within this section. They stated that it would spur greater awareness among software developers of the need for fully accessible mobile applications that are also compatible with mobile devices and internet platforms. One organizational commenter warned that there could be privacy concerns with certain mobile apps used for substance use disorder treatment and recommended that OCR collaborate with the Substance Abuse and Mental Health Services Administration (SAMHSA) to determine if Federal privacy laws apply to mobile application health information, and communicate that information to consumers.

Response: OCR appreciates these comments. Mobile applications are a form of information and communication technology and are explicitly included in the regulatory text under § 92.204(b); thus, to the extent covered entities use mobile applications as part of their health programs and activities they must be accessible for individuals with disabilities. Though privacy protections are outside of the scope of this rulemaking, OCR reminds commenters

[150] Section508.gov, *Voluntary Product Accessibility Template (VPAT), https://www.section508.gov/sell/vpat/.*

[151] 36 CFR part 1194, appendix A. Section 508 of the Rehabilitation Act imposes accessibility requirements for information and communication technology that Federal departments and agencies develop, procure, maintain, or use.

[152] 88 FR 63392 (Sept. 14, 2023) (HHS) and 88 FR 51948 (Aug. 4, 2023) (DOJ).

[153] *See* U.S. Dep't of Justice, *State and Local Governments, https://www.ada.gov/topics/title-ii/.*

[154] *See* U.S. Dep't of Justice, ADA Title III Technical Assistance Manual, *https://www.ada.gov/resources/title-iii-manual/.* This guidance document on title III of the ADA defines fundamental alteration as ''a modification that is so significant that it alters the essential nature of the goods, services, facilities, privileges, advantages, or accommodations offered.'' It defined undue burden as a ''significant difficulty or expense'' that can be determined based on the nature and cost of the action, the overall financial resources of the site involved, geographical separateness, overall financial resources of the parent entity, and the type of operation of the parent entity.

that it has issued guidance on the application of the HIPAA Privacy, Security, and Breach Notification Rules to mobile health apps.[155]

Comment: Many commenters recommended OCR require covered entities to comply with specific accessibility standards, such as section 508 standards, the WCAG 2.0 standards, the WCAG 2.1 standards, or other standards that provide equal or greater accessibility. Several commenters, including organizations, recommended requiring covered entities to comply over time with the latest WCAG as they are updated by the Web Accessibility Initiative of the World Wide Web Consortium (W3C). The commenters also said that a requirement to adhere to the latest standards could offer a range of time for compliance, with larger entities that have more resources being required to comply with a new WCAG standard within a shorter timeline than smaller entities. A technology company said that OCR should not establish a requirement to conform to the latest standard, but rather a requirement to conform to technical specifications that are proven and generally accepted for achieving and maintaining reasonable levels of accessibility; currently that is WCAG 2.1 levels A and AA.

Some organizational commenters suggested that OCR should incorporate a functional, evergreen standard for accessibility that will adapt to changes in technology and accessibility practices. Such a standard would require the ICT to be perceivable, operable, understandable, and robust, and ''enable individuals with disabilities to access the same information as, to engage in the same interactions as, to communicate and to be understood as effectively as, and to enjoy the same services offered to other individuals with the same privacy, same independence, and same ease of use as, individuals without disabilities.''

Several commenters, including health care organizations, advocacy groups, and a trade association, offered suggestions for the timeline for compliance with new standards. These included 60 days, 12 months, 18 months, and 2 years. A health care organization recommended that OCR only require initial compliance in fields that are ''critical to utilizing telehealth services'' and that covered entities be required to meet the minimum conformance levels of the two most recent versions of the W3C guidelines.

Some commenters supported compliance with accessibility standards, provided that OCR conducts real-world testing with successful results across a variety of physician offices before requiring compliance. The commenter also suggested that OCR work with the Office of the National Coordinator for Health Information Technology and vendors to ensure that compliance does not place an undue financial or administrative burden on physician practices. Expressing concern about the cost of compliance, a professional association requested an exemption for businesses classified as small businesses by the Small Business Administration.

A few commenters, including a trade association, health care organizations, and health insurance entities, suggested that OCR establish a safe harbor by which covered entities compliant with WCAG 2.1 Level AA are deemed in compliance with the section 1557 requirements. Other commenters argued that OCR should not establish a safe harbor because compliance with a set of accessibility standards is not necessarily evidence of compliance with accessibility requirements; there may be ICT that meets published standards but remains inaccessible. Another commenter said OCR should not establish a safe harbor because the ADA, the Rehabilitation Act, and other Federal laws must continue to provide standalone protections.

Response: OCR appreciates commenters' input on this important topic but has decided not to adopt specific accessibility standards or a safe harbor at this time. This is in part due to OCR and DOJ recently publishing NPRMs proposing specific accessibility requirements for section 504 and title II of the ADA, respectively.[156] Those NPRMs propose to require that recipients of Federal financial assistance and public entities must ensure that their web content and mobile applications comply with set accessibility standards. In this rulemaking, OCR continues to require covered entities to ensure that health programs and activities provided through ICT are accessible to individuals with disabilities sufficient to provide equal access to the health program or activity, unless doing so would impose undue financial and administrative burdens or would result in a fundamental alteration in the nature of the entity's health program or activity. OCR strongly encourages covered entities that offer health programs and activities through ICT to incorporate current WCAG standards as they take steps to ensure that those programs and activities comply with requirements of this regulation and other Federal civil rights laws.

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 § 92.204, without modifications.

Requirement To Make Reasonable Modifications (§ 92.205)

In § 92.205, we proposed requiring covered entities to make reasonable modifications to policies, practices, or procedures 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. Section 92.205 is the same as § 92.205 in the 2016 Rule and § 92.105 in the 2020 Rule. The term ''reasonable modifications'' will be interpreted as set forth in the regulation implementing title II of the ADA at 28 CFR 35.130(b)(7), such that ''[a covered entity] shall make reasonable modifications in policies, practices, or procedures when the 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] service, program, or activity'' and ''[a covered entity] is not required to provide a reasonable modification to an individual who meets the definition of 'disability' solely under the 'regarded as' prong of the definition of 'disability' at § 35.108(a)(1)(iii).''

The comment and our response regarding § 92.205 are set forth below.

Comment: One commenter urged OCR to strengthen the section by adding language to clarify that a modification to add something that is medically necessary for individuals with disabilities, or to eliminate exclusions related to medically necessary services, are not considered fundamental alterations to the nature of the health program.

Response: OCR appreciates the commenter's request for clarifying language related to fundamental alterations. In promulgating this rule, OCR cannot address how the requirements of section 1557 apply to every scenario that may arise. OCR also

[155] U.S. Dep't of Health & Hum. Servs., Off. for Civil Rts., *Resources for Mobile Health Apps Developers, https://www.hhs.gov/hipaa/for-professionals/special-topics/health-apps/index.html*; U.S. Dep't of Health & Hum. Servs., Off. for Civil Rts., *Protecting the Privacy and Security of Your Health Information When Using Your Personal Cell Phone or Tablet, https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/cell-phone-hipaa/index.html.*

[156] *See* 88 FR 63392 (Sept. 14, 2023) (section 504) and 88 FR 51948 (Aug. 4, 2023) (ADA title II).

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/.*

facts and circumstances that must be independently investigated on a case-by-case basis before OCR can determine whether a challenged action is considered discriminatory under this section, particularly considering that each covered entity's reason for engaging in the challenged action may be specific to that covered entity and the circumstances surrounding its decision process. For example, when determining whether a challenged design feature is discriminatory, OCR considers the benefit design of the plan as a whole, whether similar limitations or restrictions are placed on other types of health services, and whether the covered entity consistently relies on neutral, nondiscriminatory criteria when developing the design feature, among other things. Therefore, OCR reaffirms the investigative approach set forth in the Proposed Rule, 87 FR 47875, whereby OCR's determination of whether a challenged action is discriminatory is necessarily a fact-specific, case-by-case analysis dependent on the facts of the particular situation. When analyzing whether an action violates this section, OCR will apply basic nondiscrimination principles to the facts of the particular health insurance coverage or other health related coverage, consistent with civil rights case law. This includes the opportunity for covered entities to articulate a legitimate, nondiscriminatory justification for an alleged discriminatory action, which OCR will scrutinize to ensure it is not a pretext for discrimination. Where a covered entity's justification relies upon medical standards or guidelines, we note that such standards or guidelines may be subject to additional scrutiny if they are not based on clinical, evidence-based criteria or guidelines. For more information related to OCR's consideration of a covered entity's legitimate, nondiscriminatory reason, please see previous discussion under § 92.207(c).

OCR reiterates that this rule does not require a covered entity to provide coverage for any particular health service in its health insurance coverage or other health-related coverage when provided in a nondiscriminatory manner; 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.

Regarding our analysis when investigating potential discrimination in the benefit design of excepted benefits and short-term, limited duration insurance (STLDI), we provide additional information below in the discussion under this section on *Scope of Application to Health Insurance and Health-Related Coverage (Including Excepted Benefits and STLDI).*

OCR acknowledges that the nature of our complaint-driven investigative process results in OCR reviewing existing plans and making determinations on the benefit designs of existing plans. However, OCR's case-by-case analysis is necessary in order to consider the fact-specific nature of each challenged action and to apply relevant case law to each situation. OCR investigates each allegation in a consistent manner and treats all complainants and covered entities evenly.

We appreciate commenters' suggestions to provide more information to educate covered entities about what OCR interprets to be best practices; OCR will consider issuing such guidance in the future. To educate both the public and covered entities, OCR posts its resolution agreements on its website and issues press releases when cases are resolved, and we intend to continue this practice.

Comment: Commenters recommended that OCR specify in the final rule that a nondiscriminatory benefit design is one that is clinically based. While expressing support for OCR considering clinical guidelines and standards of care when evaluating plan benefit designs, these same commenters also cautioned that OCR should not exclusively rely on clinical guidelines and journal articles in its analysis of discriminatory design because clinical guidelines may perpetuate racial bias and health disparities, and entities could cite a single peer-reviewed article as a shield to escape valid claims of discriminatory benefit design.

Response: An analysis of whether a benefit design is discriminatory under this rule is a fact-specific inquiry that will be made in accordance with general civil rights principles and applicable case law. As discussed under § 92.207(c), covered entities may provide a legitimate, nondiscriminatory reason as a defense to a potentially discriminatory coverage determination. A covered entity has latitude to submit any legitimate reason for its actions as long as it is not discriminatory or pretext for discrimination. However, if the justification given is not based on clinical, evidence-based criteria or guidelines, OCR will consider that evidence of pretext. When a covered entity submits a justification that relies upon medical standards or guidelines, OCR may conduct additional investigation to ensure the justification is not pretextual, including a review on whether the standards or guidelines are or are not based on clinical, evidence-based criteria or guidelines. OCR's review of a covered entity's justification will not rely solely on a covered entity's provision of one piece of literature but will consider a variety of factors, as discussed in detail above under §§ 92.206(c) and 92.207(c). We further note that OCR will not conduct a general medical review of the medical judgment undergirding the determination.

Comment: Commenters noted that OCR could ensure higher quality health care for all enrollees through stronger oversight and regulation. These commenters urged OCR not to rely solely on complaints and to engage in proactive oversight by affirmatively reviewing covered entities' plan designs.

Response: We agree that robust enforcement of section 1557 is critical to ensure individuals' ability to receive medically necessary health services, unencumbered by discriminatory conduct. OCR will employ all available means of investigating health insurance coverage and other health-related coverage under this rule, including through compliance reviews and complaint investigations.

Comment: Commenters requested that OCR clarify how it will coordinate with State and Federal agencies that establish specific plan requirements and approval processes. Commenters noted that many facets of benefit design are heavily regulated by other agencies within the Department, including CMS' regulation of nondiscriminatory plan design in EHB and qualified health plans, retail pharmacy network adequacy of Medicare Part D plans, and benefit coverage requirements under Medicare Advantage and Medicaid. Commenters suggested that OCR should not enforce a discrimination claim if the underlying design is accepted by the plan's regulator and should defer enforcement action to existing review processes where appropriate. Some commenters also suggested that the Department should establish a safe harbor for health insurance issuers to comply with section 1557 in cases where there are State law interactions to avoid creating multiple or duplicative standards.

Response: OCR acknowledges commenters' concerns about harmonization in the regulation and enforcement of benefit design requirements across State and Federal laws. We note that covered entities offering health insurance coverage and other health-related coverage, such

Medicaid or qualified health plans in the Exchanges, are subject to a host of other laws and regulations, at both the State and Federal level. OCR does not view a covered entity's compliance with other State or Federal laws, which were adopted under different requirements and for different purposes, to be determinative in all cases of a covered entity's compliance with section 1557, unless otherwise specified in this rule.[226] OCR commits to coordinating with other Federal agencies as appropriate to avoid inconsistency and duplication in enforcement efforts and will consider issuing guidance in coordination with other agencies, such as CMS, after publication of the rule. We will give consideration to a covered entity's compliance with other Federal laws when those requirements overlap with section 1557's requirements and will work closely with covered entities when compliance with this final rule requires additional action. That said, as the lead enforcement agency for section 1557, OCR maintains sole authority to determine a covered entity's compliance with this final rule.

Comment: Commenters requested clarity on which covered entity is liable for potentially discriminatory plan benefit designs when several covered entities provide or administer elements of the benefit design. Commenters requested that OCR state that all entities, including third party administrators, benefits advisers, and consultants, that participate in discriminatory plan design with respect to group or individual insurance plans are covered entities under section 1557. A commenter requested that benefits advisers or consultants working with employers to design self-funded group health plans specifically should be considered a covered entity presumptively where the employer, the plan, or the third party administrator receives Federal financial assistance. The commenter noted concern that such advisers and consultants are a driving force behind discriminatory plan design and should be put on notice that their conduct is subject to section 1557 in many circumstances. A commenter requested that OCR make clear that any entity itself covered by section 1557 violates the statute by outsourcing the implementation or design of discriminatory plans to entities that might themselves not be covered by the statute.

Response: OCR clarifies that in situations where multiple covered entities provide or administer elements of a discriminatory benefit design, all of the entities may be found liable under section 1557. In the discussion of the definition of ''Federal financial assistance'' in § 92.4, we explained that both the direct recipient and subrecipient (or subcontractor) are responsible for complying with applicable civil rights laws. We also note that covered entities are responsible for the conduct of their subcontractors and cannot outsource or contract away their civil rights obligations by entering into contractual arrangements with subcontractors. The responsibility of third party administrators is discussed later in this section. As noted, this final rule does not apply to employment practices. *See* § 92.2(b).

Comment: Commenters expressed concern that the proposed regulation may unintentionally limit covered entities' ability to develop effective programs and initiatives to close care gaps and address unique needs to reduce health disparities. Commenters explained that they currently conduct individual outreach to members of a subgroup through care management processes, invest in social determinants of health interventions, tailor marketing to subgroups to address particular health concerns, provide plans that restrict enrollment to special needs individuals with specific chronic conditions, and develop targeted quality programs and chronic care management programs to reduce health disparities for their members. A commenter noted that issuers take those actions to more efficiently provide care to particularly vulnerable populations without an intent to discriminate. Another commenter noted that if health plans are required to provide services that address chronic care, social determinants of care, or other similar programs ''equally'' to all enrollees rather than ''equitably'' target services to those in need based on health or socioeconomic condition, plans will be limited in their ability to provide appropriate services and scale and sustain these programs. To address these concerns, commenters requested that OCR clarify in the final rule that actions taken to reduce health disparities and those designed to improve health for specific populations are not discriminatory for purposes of section 1557. Commenters also recommended that OCR consider an approach similar to language in the Department's Group Health Insurance Market regulations prohibiting prohibition on discrimination based on health status that explicitly permits group health plans and health insurance issuers to treat individuals with adverse health conditions more favorably. 45 CFR 146.121(g).[227]

Response: We appreciate commenters raising this concern and applaud efforts to mitigate and address health disparities. Nothing in this rule prohibits programs designed to improve health outcomes for specific populations so long as the programs do not discriminate on the basis of race, color, national origin, age, sex, or disability. For example, programs could be developed using social determinants of health or other metrics that serve to identify underrepresented individuals that are not based on protected bases under section 1557. To illustrate, a ''Special Needs Plan'' is a specialized Medicare Advantage coordinated care plan that exclusively enrolls ''special needs individuals,'' who are not limited to individuals with disabilities, and do not violate section 1557.[228] In addition, covered entities are permitted and encouraged to develop programs that address health disparities related to a person's age. Under the Age Act and section 1557, age distinctions in programs that provide special benefits to older adults or children are permitted. 45 CFR 91.17 (Age Act); 92.101(b)(1) (section 1557, incorporating 45 CFR 91.17).

Scope of Application to Health Insurance Coverage and Other Health-Related Coverage (Including Excepted Benefits and STLDI)

In the 2022 NPRM, we sought comment on excepted benefits and short-term, limited-duration health insurance (STLDI), and the Proposed Rule's application to these products. Consistent with the definition of ''health program or activity'' under § 92.4, we proposed that the rule would apply to all the operations of any covered entity principally engaged in the provision or administration of health insurance coverage or other health-related coverage. 87 FR 47875–76.[229] As an example, we explained that an issuer participating in the Exchange and thereby receiving Federal financial assistance would be covered by the rule for its qualified health plans offered on the Exchange, as well as for its health

[226] *E.g.,* 45 CFR 92.203, which requires covered entities to comply with certain accessibility requirements in the ADA.

[227] In this final rule, we cite to HHS regulations, but note that the Departments of Labor and the Treasury have parallel regulatory citations.

[228] *See* sections 1859(b)(6), 1859(f)(2)–(4) of the Social Security Act (42 U.S.C. 1395w–28(b)(6), (f)(2)–(4)).

[229] However, per § 92.2(b), this rule does not apply to employers with regard to their employment practices, including the provision of employee health benefits.

plans offered outside the Exchange, including, for example, large group market plans,[230] grandfathered plans,[231] grandmothered plans,[232] excepted benefits,[233] and STLDI,[234] as well as for its operations related to acting as a third party administrator for self-insured group health plans. 87 FR 47876.

The comments and our responses regarding the scope and application to all operations of a covered health insurance issuer and to excepted benefits and STLDI specifically are set forth below.

Comment: Several commenters, including those representing the health insurance industry and some State insurance regulators, raised concerns about how the Proposed Rule's application to all operations of a recipient health insurance issuer would result in covering an issuer's other operations and lines of business that do not receive Federal financial assistance, including, for example, plans sold off the Exchange, grandfathered plans, grandmothered plans, employer plans, excepted benefits, STLDI, third party administrator activities and pharmacy benefit manager activities. Commenters noted that these plans are treated separately under the ACA and are not subject to some or all of the ACA's health insurance market reforms. Commenters suggested that plans that do not receive Federal financial assistance should not be subject to section 1557. Comments about particular types of plans are discussed in turn below.

Commenters argued the Proposed Rule's application was too broad and went beyond Congressional intent and urged OCR to retain the 2020 Rule's approach that the rule cover a health insurance issuer's operations only to the extent the operations directly receive Federal financial assistance.

In addition, commenters argued that applying the rule to a covered issuer's operations that do not receive Federal financial assistance would create an unlevel playing field among health insurance issuers that accept Federal funding and those that do not, placing those that receive Federal funding at a competitive disadvantage. For example, commenters stated that issuers that do not receive Federal financial assistance may underwrite excepted benefits or STLDI by age or sex, or exclude higher cost health care services, which may result in non-covered entities offering lower-cost coverage to a pool of individuals whose coverage is less costly, while the pool of individuals under a covered entity's coverage could be costlier, leading to higher premiums. Commenters also argued that covered entities would be subject to increased compliance costs to which competitors are not subject. For example, these commenters stated that compliance with the rule's nondiscrimination notices would result in tremendous costs to which non-covered entities are not subject. Some commenters argued that this competitive disadvantage could discourage issuers from participating in the Exchanges.

A few commenters that supported the proposed application to all an issuer's operations also raised concerns that the rule would create an unlevel playing field that would disadvantage plans that support Federal programs like Medicare and Medicaid while giving an unfair competitive advantage to competitors that are not required to comply with nondiscrimination requirements. To level the playing field, these commenters and others suggested that OCR work with other Federal agencies and develop a tri-Department rule with the Departments of Labor and the Treasury to subject all health plans to similar nondiscrimination and accessibility requirements.

A number of commenters, including some members of Congress, supported the broad application of the rule to an issuer's other operations and argued the 2020 Rule's approach is contrary to Congress's intent in passing the ACA to prohibit discrimination in health care. Commenters argued that a private insurance company receiving financial assistance from the Federal Government should not be allowed to engage in discriminatory practices in its other lines of business. Commenters observed that issuers offering plans that receive Federal financial assistance, such as qualified health plans or Medicare Advantage plans, often also offer plans that do not receive Federal financial assistance. Noting that many of these other types of plans are not currently subject to any or all nondiscrimination requirements under the ACA's health insurance market reforms, these commenters argued that the Proposed Rule's broad application will increase protections from discriminatory practices for individuals enrolled in those plans.

Response: OCR appreciates the concerns raised by some commenters regarding the Proposed Rule's application to all operations of a recipient health insurance issuer; however, these concerns do not abrogate a recipient's obligation to comply with section 1557. Under the definition of ''health program or activity'' at § 92.4, a recipient of Federal financial assistance that is principally engaged in the provision or administration of health insurance coverage or other health-related coverage is covered under this rule for all of its operations. Section 1557 applies to ''any health program or activity, *any part of which* is receiving Federal financial assistance,'' 42 U.S.C. 18116(a) (emphasis added). As we explain in detail under the discussion of the definition of ''health program or activity'' in § 92.4, it is reasonable to infer that Congress intended the term ''health program or activity'' to be interpreted broadly and to include all of that entity's operations if the entity that receives Federal funding is principally engaged in the provision or administration of health insurance coverage or other health-related coverage.[235]

[230] 42 U.S.C. 300gg–91(e)(3); 45 CFR 144.103.

[231] 42 U.S.C. 18011; 45 CFR 147.140.

[232] Grandmothered plans are certain non-grandfathered health insurance coverage in the individual and small group market that are not considered to be out of compliance with certain specified market reforms under certain conditions. *See* U.S. Dep't of Health & Hum. Servs., Ctrs. for Medicare & Medicaid Servs., *Extended Non-Enforcement of Affordable Care Act-Compliance With Respect to Certain Policies* (Mar. 23, 2022), *https://www.cms.gov/files/document/extension-limited-non-enforcement-policy-through-calendar-year-2023-and-later-benefit-years.pdf.*

[233] 42 U.S.C. 300gg–21(b), 300gg–63, and 300gg–91(c); 45 CFR 144.103, 146.145(b), and 148.220(b). The Departments of HHS, Labor, and the Treasury share interpretive jurisdiction over the definition of ''excepted benefits''. We cite to HHS regulations but note that the Departments of Labor and the Treasury have parallel statutory and regulatory citations.

[234] Short-term limited duration insurance is a type of health insurance coverage that is generally exempt from the provisions of title XXVII of the PHS Act because it is specifically excluded from the definition of ''individual health insurance coverage'' in the PHS Act. See 42 U.S.C. 300gg–91(b)(5). Short-term limited duration insurance is currently defined in Federal regulations as health insurance coverage issued under a contract that is effective for less than 12 months, and, taking into account renewals or extensions, has a duration of no longer than 36 months in total. 45 CFR 144.103. Short-term limited duration insurance is defined by the Departments of HHS, Labor, and the Treasury (Tri-Departments). The Tri-Departments issued a Notice of Proposed Rulemaking on Short-Term, Limited-Duration Insurance; Independent, Noncoordinated Excepted Benefits Coverage; and Tax Treatment of Certain Accident and Health Insurance that would revise the definition of ''Short-Term Limited-Duration Insurance'' to limit the length of the initial contract period to no more than three months and the maximum coverage period to no more than four months, taking into account any renewals or extensions. 88 FR 44596 (July 12, 2023). In this final rule, we cite to HHS regulations, but note that the Departments of Labor and the Treasury have parallel regulatory citations.

[235] *See, e.g., Fain* v. *Crouch,* 545 F. Supp. 3d 338, 342–43 (S.D.W. Va. 2021) (finding '''health program or activity' under Section 1557 necessarily includes health insurance issuers'' and holding that defendant health plan was, ''by virtue of its acceptance of federal assistance under its Medicare Advantage program,'' required to comply with section 1557 ''under its entire portfolio''), *rehearing*

In response to comments that this obligation might cause a competitive disadvantage with entities that do not accept Federal funds, this obligation is consistent with statutory text as set forth by Congress, as discussed above. Further, the risk of competitive disadvantage is low given that the majority of health insurance issuers offer some type of product that receives Federal financial assistance, such as Medicare Advantage plans, Medicare Part D prescription drug plans, Medicaid managed care plans, and qualified health plans through the Exchanges.[236] In any event, by accepting the benefit of Federal funds, a recipient is prohibited from discriminating in its health programs and activities under section 1557, as discussed previously under the definition of ''health program or activity.'' Any recipient of Federal financial assistance from the Department is subject to this same requirement and prohibited from discriminating in its health programs and activities, including all of its operations when principally engaged, as set forth in this final rule.

Section 1557 does not authorize OCR to require a health plan or insurance issuer not otherwise subject to section 1557 to comply with the statute. Whether the Department could issue a rule, under different authority, with the Departments of Labor and the Treasury, to apply similar nondiscrimination and accessibility standards to all health plans or health insurance issuers, is outside the scope of this rule.

We further address comments about particular types of plans and their coverage under this final rule in various comment responses below.

Comment: Some commenters requested that grandfathered and grandmothered plans should be exempt from the rule because they are not subject to many of the ACA's provisions. These plans benefit consumers, commenters stated, by allowing them to maintain affordable existing coverage as long as it continues to meet their needs. Commenters argued that applying section 1557 to these plans would be inconsistent with the longstanding regulatory treatment of the plans. Further, commenters argued that the costs of complying with section 1557, including but not limited to notice and tagline requirements, could result in increased costs for issuers, which would be passed on to consumers, and could lead to a decision to discontinue plans.

Response: OCR understands commenters' concerns and acknowledges that grandfathered and grandmothered plans are not subject to many of the ACA's provisions. However, the statutory text of the grandfathered health plan provision [237] indicates that Congress did not intend to exclude them from dection 1557. The statute sets forth the specific provisions of the PHS Act that apply to grandfathered plans and then provides that except for those provisions, ''this subtitle and subtitle A (and the amendments made by such subtitles) shall not apply'' to grandfathered plans. 42 U.S.C. 18011(a)(2). ''This subtitle'' refers to subtitle C of title I of the ACA, while ''subtitle A'' refers to subtitle A of title I of the ACA, both of which contain market reforms. Section 1557 is in subtitle G of title I of the ACA and therefore is not one of the subtitles that Congress specified should not apply to grandfathered health plans.

Grandmothered plans [238] were not established in the ACA or the PHS Act; they are not exempt from the ACA or the PHS Act by statute or regulation. Rather, CMS specified that it will not take enforcement actions against grandmothered plans that are out of out of compliance with certain specified ACA market reforms under certain conditions (CMS Non-Enforcement Policy).[239] The CMS Non-Enforcement Policy has been in place since 2013 [240] and has provided relief from the same ACA market reform provisions continuously since that time.[241] Section 1557 has never been one of the provisions for which enforcement relief was provided; therefore, grandmothered plans are not exempt from section 1557.

When offered by a recipient health insurance issuer, grandfathered and grandmothered plans would be covered under the rule as part of the issuer's operations when the issuer is principally engaged in the business of providing or administering health insurance coverage or other health-related coverage. If OCR were to receive a complaint about a grandfathered plan or grandmothered plan, OCR would carefully consider the facts and circumstances of the challenged action or practice. As discussed throughout this section, the health insurance issuer may provide a legitimate, nondiscriminatory reason for the action or practice. Further, in cases of alleged disability discrimination, covered entities may also prove that modifying a plan to comply with section 1557 would result in a fundamental alteration to their health program or activity.

Comment: A commenter requested clarification on how the rule would apply to Medicare Employer Group Waiver Plan (EGWP) participants.

Response: EGWPs are types of Medicare Part C (Medicare Advantage) plans [242] or Medicare Part D prescription drug plans [243] that qualify for waivers of certain Medicare regulations because they are offered exclusively to the employees, former employees, members or former members of an employer, union or labor organization, or the trustees of a fund established by one or more employers or labor organizations (or combination thereof). Entities that receive funding through the Department's Medicare Part C or Medicare Part D program are subject to the rule as recipients of Federal financial assistance. This includes entities providing Medicare

en banc granted, No. 22–1927 (4th Cir. Apr. 12, 2023) (oral argument held Sept. 21, 2023) (argued with *Kadel* v. *Folwell,* No. 22–1721).

[236] U.S. Dep't of Health & Hum. Servs., Ctrs. for Medicare & Medicaid Servs., *Medical Loss Ratio Data and System Resources* (2022), *https://www.cms.gov/CCIIO/Resources/Data-Resources/mlr.*

[237] Grandfathered health plans were established by Congress in title I of the ACA to permit the continuation of coverage for certain plans in effect as of the date of enactment of the ACA (March 23, 2010) in which individuals were enrolled at that time. 42 U.S.C. 18011; 45 CFR 147.140. Grandfathered health plans are statutorily subject to only certain market reforms in the ACA, 42 U.S.C. 18011(a)(3)–(5), and thus are not subject to certain market reforms related to nondiscrimination, such as fair health insurance premiums and EHB. To maintain grandfathered status, plans cannot make certain changes to the terms of the plan or coverage. Specifically, certain changes to benefits, cost-sharing requirements, and contribution rates will cause a plan or coverage to relinquish its grandfather status.

[238] Grandmothered plans are certain non-grandfathered health insurance coverage in the individual and small group market that are not considered to be out of compliance with certain specified market reforms under certain conditions, including those related to nondiscrimination, such as fair health insurance premiums, the prohibition of preexisting condition exclusions or other discrimination based on health status with respect to adults (except with respect to group coverage), the prohibition of discrimination based on health status (except with respect to group coverage), and EHB.

[239] *See* U.S. Dep't of Health & Hum. Servs., Ctrs. for Medicare & Medicaid Servs., *Extended Non-Enforcement of Affordable Care Act-Compliance With Respect to Certain Policies* (Mar. 23, 2022), *https://www.cms.gov/files/document/extension-limited-non-enforcement-policy-through-calendar-year-2023-and-later-benefit-years.pdf.*

[240] *See* Letter from Gary Cohen, Director, Ctr. for Consumer Info. & Ins. Oversight, Ctrs. for Medicare & Medicaid Servs., to Insurance Commissioners (Nov. 14, 2013), *https://www.cms.gov/cciio/resources/letters/downloads/commissioner-letter-11-14-2013.pdf.*

[241] *See* U.S. Dep't of Health & Hum. Servs., Ctrs. for Medicare & Medicaid Servs., *Extended Non-Enforcement of Affordable Care Act-Compliance With Respect to Certain Policies* (Mar. 23, 2022), *https://www.cms.gov/files/document/extension-limited-non-enforcement-policy-through-calendar-year-2023-and-later-benefit-years.pdf.*

[242] 42 U.S.C. 1395w–27(i); 42 CFR 422.106.

[243] 42 U.S.C. 1395w–132(b); 42 CFR 423.458.

Advantage plans or Medicare Part D plans, including EGWPs, or qualified retiree prescription drug plans (as defined at 42 CFR 423.882) (also known as RDS plans). Because employers and other plan sponsors are not subject to this rule with regard to their employment practices, pursuant to § 92.2(b), an employer or other plan sponsor would not be liable for discrimination related to these plans under this rule. This applies even if an employer directly contracts with CMS to offer a Medicare Advantage or Part D plan as an EGWP and receives Federal financial assistance for that EGWP.[244] In circumstances where an employer offers an ''800 series'' EGWP through a Medicare Advantage organization or Part D plan sponsor,[245] the health insurance issuer or entity offering the EGWP would be subject to the rule for the EGWP plan due to receipt of either Medicare Part C or Part D funding.

Comment: One commenter requested clarification as to whether self-funded non-Federal Governmental plans, such as municipal plans, that opt out of certain Federal market reforms are covered under this rule if they receive funds from the Department directly or indirectly.

Response: A self-funded non-Federal Governmental plan is a governmental plan established or maintained by a non-Federal Governmental agency, such as a State, county, school district, or municipality, for its employees.[246] As with any other type of group health plan coverage, a non-Federal Governmental plan would be subject to this rule if it directly or indirectly receives Federal financial assistance from the Department. The non-Federal Governmental agency sponsoring the employee health benefit plan would be excluded from liability under this rule an employer or plan sponsor, as applicable, pursuant to § 92.2(b).

Comment: Commenters requested that the rule clarify when group health plans are subject to the rule.

Response: A group health plan is subject to this rule if it is a recipient (or subrecipient) of Federal financial assistance as set forth under § 92.2(a)(1). We address the rule's applicability to group health plans in more detail in the discussion above under §§ 92.1 (Applicability) and 92.4 (definition of ''health program or activity'').

Comment: Several commenters expressed concerns with the rule's proposed application to excepted benefits as part of a covered health insurance issuer's operations and urged OCR to exclude excepted benefits from the rule. Commenters argued that the rule's coverage of excepted benefits is inconsistent with Congressional intent and likely subject to legal challenge. These commenters explained that excepted benefits are statutorily defined benefits that Congress has long recognized as distinct from traditional health insurance coverage by excluding them from health insurance and group health plan coverage mandates under the PHS Act, ERISA, and the Internal Revenue Code, as long as they meet certain requirements.[247] Commenters argued that the ACA retained this exclusion and that Congress therefore intended excepted benefits to be excluded from the ACA. To further demonstrate Congressional intent to exclude excepted benefits, commenters stated that since Congress first recognized excepted benefits in 1996 as part of HIPAA by incorporating their provisions into the PHS Act, ERISA, and the Internal Revenue Code, Congress has had several opportunities to redefine excepted benefits or to impose new requirements on them in subsequent laws, including the ACA, but it has not chosen to do so.[248]

While acknowledging that section 1557 does not explicitly exclude excepted benefits, commenters asserted that OCR cannot use its regulatory authority to impose new requirements that are inconsistent with the carefully crafted statutory provisions governing excepted benefits where Congress has clearly chosen not to do so. As support, commenters cited to *Central United Life* v. *Burwell,* 827 F.3d 70 (D.C. Cir. 2016). Commenters stated the court in *Central United* struck down a Department rule that revised the requirements related to fixed indemnity excepted benefit insurance in the individual market as an unconstitutional exercise of regulatory authority because the ACA maintained the HIPAA excepted benefit exemption for these benefits and the law did not authorize the Department's proposed requirement. *Central United,* commenters argued, illustrates that nothing in the ACA changes the excepted benefits governing statutes and demonstrates that agencies must adhere to the boundaries set forth in Federal statute.

Commenters stated that the ACA is entirely focused on comprehensive medical coverage, while excepted benefits are not intended to serve as such coverage. They maintained that excepted benefits are not used to finance the delivery of health care services but are meant to provide benefits for a wide variety of costs associated with accidents or illnesses not covered by comprehensive medical insurance, or to defray costs that are not fully covered by comprehensive medical coverage. For example, commenters stated that some of these products, such as dental and vision plans and Medicare supplemental insurance (Medigap), can cover additional benefits not included in comprehensive medical plans. Commenters stated that noncoordinated excepted benefits, such as fixed indemnity excepted benefits and specified disease excepted benefits coverage, must pay benefits regardless of whether the medical event triggering benefits is covered under another plan. Commenters stated that while comprehensive medical insurance coverage is regulated through HIPAA or the ACA, excepted benefits are subject to separate long-standing and extensive State regulatory regimes whereby Congress and State policymakers have consistently maintained excepted benefits are not meant to be a type of comprehensive health insurance that pays for medical benefits, and therefore, commenters argue, should not be within the purview of the ACA, including section 1557.

Commenters further expressed concerns that applying the rule to excepted benefits could severely disrupt the market for these benefits and may drive competitors out of the market,

---

[244] CMS may contract directly with an employer, union or labor organization, or the trustees of a fund established by one or more employers or labor organizations (or combination thereof) for the entity to offer a Medicare Advantage plan or Part D plan to its employees, former employees, members or former members. 42 U.S.C. 1395w–28(i) and 1395w–132(b); 42 CFR 422.106(d) and 423.458(c).

[245] In these situations, a Medicare Advantage organization or a Part D plan sponsor contracts with CMS to offer the Medicare health or drug plan and separately contracts with the employer, union or labor organization, or trustee of a fund established by one or more employers or labor organizations (or combination thereof) for the Medicare Advantage organization or Part D plan sponsor to offer an EGWP. For more information about direct contract and ''800 series'' EGWPs, *see generally* U.S. Dep't of Health & Hum. Servs., Ctrs. for Medicare & Medicaid Servs., *Medicare Managed Care Manual, Chapter 9—Employer/Union Sponsored Group Health Plans* (2013), *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/mc86c09.pdf.*

[246] 42 U.S.C. 300gg–91(d)(8)(A)–(C); 45 CFR 144.103. For more information on self-funded, non-Federal Governmental plans, *see* U.S. Dep't of Health & Hum. Servs., Ctrs. for Medicare & Medicaid Servs., *Self-Funded, Non-Federal Governmental Plans, https://www.cms.gov/CCIIO/Programs-and-Initiatives/Health-Insurance-Market-Reforms/nonfedgovplans.*

[247] Title XXVII of the PHS Act; part 7 of ERISA; chapter 100 of the Internal Revenue Code.

[248] For example, the Mental Health Parity Act of 1996; Newborns' and Mothers' Health Protection Act of 1996 (NMHPA); Genetic Information Nondiscrimination Act of 2008 (GINA); Paul Wellstone and Pete Domenici Mental Health Parity and Equity Additional Act of 2008 (MHPAEA); Michelle's Law (2008); ACA (2010); and No Surprises Act (2020).

ultimately increasing health care costs and premiums and reducing product choice for consumers and employers, and thereby reducing access to care. Commenters also asserted that applying the rule to excepted benefits could result in increased costs that are passed onto consumers as increased premiums, which could result in individuals dropping coverage due to lack of affordability and thereby result in reducing access to care, particularly in dental plans where consumers are highly price sensitive when selecting coverage.

Conversely, many other commenters supported applying the rule to excepted benefits as part of an issuer's operations. Commenters noted that excepted benefits are under-regulated and not otherwise subject to nondiscrimination requirements. Commenters argued this would provide comprehensive nondiscrimination protections for individuals enrolled in excepted benefits, particularly individuals with disabilities who face barriers to accessing care.

Response: OCR appreciates the breadth of comments received and the concerns raised. Excepted benefits are statutorily defined benefits that are exempt from the Federal consumer protection and market reforms applicable to comprehensive coverage under title XXVII of the PHS Act, part 7 of ERISA, and Chapter 100 of the Internal Revenue Code (hereinafter the Federal consumer protections and market reform requirements applicable to comprehensive coverage). Some excepted benefits are exempt from the Federal consumer protection and market reform requirements applicable to comprehensive coverage in all circumstances, such as coverage only for accident, workers' compensation or similar coverage, disability income coverage, and coverage for on-site medical clinics. 42 U.S.C. 300gg–21(b), 300gg–63(a), and 300gg–91(c)(1).

Other types of coverage, known as limited excepted benefits, are exempt from the Federal consumer protection and market reform requirements applicable to comprehensive coverage when the benefits are offered under a separate policy, certificate or contract of insurance, or are otherwise not an integral part of the plan. 42 U.S.C. 300gg–21(c)(1), 300gg–63(b), and 300gg–91(c)(2). Examples of limited excepted benefits include certain limited scope vision insurance and limited scope dental insurance (though stand-alone dental plans sold through the Exchange are subject to certain qualified health plan requirements),[249] and long term care insurance.

Another type of coverage, known as independent, noncoordinated excepted benefits, are exempt from the Federal consumer protection and market reform requirements applicable to comprehensive coverage when certain conditions are met. 42 U.S.C. 300gg–21(c)(2), 300gg–63(b), and 300gg–91(c)(3). This category of excepted benefits includes coverage only for a specified disease or illness (such as cancer-only policies) and hospital indemnity or other fixed indemnity insurance.

The final type of excepted benefit coverage is supplemental excepted benefits. Benefits are supplemental excepted benefits only if they are provided under a separate policy, certificate, or contract of insurance and are Medicare supplemental health insurance (also known as ''Medigap''), coverage supplemental to the coverage provided under 10 U.S.C. chapter 55 (also known as TRICARE supplemental programs), or similar supplemental coverage provided to coverage under a group health plan. 42 U.S.C. 300gg–21(c)(3), 300gg–63(b), and 300gg–91(c)(4).

Excepted benefits offer more limited coverage than, and are generally not intended to be an alternative to or replacement for, comprehensive coverage. These products are not subject to the Federal consumer protections and market reform requirements applicable to comprehensive coverage when applicable criteria are met. As we stated in the 2016 Rule, 81 FR 31431, and the 2022 NPRM, 87 FR 47875, and restate here, the fact that excepted benefits are exempt from the Federal consumer protections and market reform requirements applicable to comprehensive coverage, including the ACA's consumer protections and market reforms, and are not intended to serve as comprehensive coverage does not justify their exclusion from section 1557.[250] In addition, section 1557 does not limit its protections only to health programs and activities that are themselves subject to other provisions of the ACA or that are comprehensive coverage, but also applies to all operations of any covered entity that is principally engaged, as defined under the term ''health program or activity'' in § 92.4. Further, section 1557 is an independent provision, which Congress did not codify in the PHS Act or co-locate in the ACA with the ACA's market reforms. Further, section 1557 uses the broad term ''health program or activity,'' in contrast to elsewhere in the ACA where Congress specifically made distinctions between various types of insurance. If Congress had intended to limit section 1557's reach to only certain types of insurance in the PHS Act or to carve out excepted benefits from the scope of section 1557, it could have done so.

OCR is mindful of comments raised about potential market disruption and reduced health care options for the public. However, as we discussed previously in the definition of ''health program or activity'' under § 92.4, commenters did not provide sufficient evidence to support this contention. Further, we note that when OCR has determined that a particular plan is discriminatory under this final rule, a covered entity may provide a legitimate, nondiscriminatory reason for the plan's benefit design. This could include evidence that compliance with § 92.207 would result in making the plan unaffordable to the extent the covered entity could no longer offer the plan. When such a reason is proffered, OCR will carefully consider the evidence presented by the covered entity in making our determination as to whether the reason is legitimate and not pretext for discrimination. In the case of alleged disability discrimination, covered entities may also prove that modifying a plan to comply with section 1557 would result in a fundamental alteration to their health program or activity.

For these reasons, we are not excluding excepted benefits from requirements established in this final rule. If a recipient health insurance issuer is principally engaged in the provision or administration of health insurance coverage or other health-related coverage, all of its operations are covered, including its provision of excepted benefits. Further, we note that a principally engaged issuer would not be covered under this rule for its excepted benefits subsidiary if the issuer can prove that the subsidiary is legally separate from its federally funded activities.[251]

Commenters' reliance on *Central United* to argue that this rule exceeds OCR's regulatory authority by imposing new requirements that are inconsistent

[249] *See, e.g.,* 45 CFR 155.1065 and 156.150.

[250] We further note that none of the statutory provisions that establish the exemption for these products from the PHS Act Federal consumer protections and requirements applicable to comprehensive coverage extend beyond the requirements in title XXVII of the PHS Act. *See* 42 U.S.C. 300gg–21(b)–(c), 300gg–63, and 300gg–91(c).

[251] For more information on how OCR will analyze such claims, see discussion of subsidiary liability under the definition of ''health program or activity'' in § 92.4 and under the *Application to Third Party Administrators* in this section.

with statutory provisions regarding excepted benefits is misplaced. In *Central United,* the court invalidated the requirement at 45 CFR 148.220(b)(4)(i) that an individual must attest to having minimum essential coverage prior to purchasing fixed indemnity excepted benefits coverage in the individual market. The court held that imposing that requirement went beyond what Congress required under the PHS Act. 827 F.3d at 74. The PHS Act statutes at issue in *Central United* contain statutory language specifically addressing excepted benefits, while section 1557 does not expressly mention or address excepted benefits. Further, Congress could have but did not extend the exemption under the PHS Act for these products to section 1557.[252] OCR therefore maintains that this rule's interpretation and application to all operations of a recipient health insurance issuer when principally engaged, including an issuer's excepted benefits, is the best reading of the section 1557 statutory language, which applies to ''any health program or activity, *any part of which is receiving Federal financial assistance.*'' 42 U.S.C. 18116(a) (emphasis added).

Comment: A few commenters raised concerns with the sufficiency of the Proposed Rule's discussion on excepted benefits. These commenters asserted the Proposed Rule did not adequately explain why subjecting excepted benefits to the rule is necessary or appropriate. Commenters stated that the regulatory text does not address excepted benefits and that the preamble discussion does not explain how the rule would apply to excepted benefits. Thus, according to commenters, there was insufficient notice for public comment, which they assert would likely subject the final rule to legal challenge as violative of the Administrative Procedure Act. These commenters argued OCR should issue a new Proposed Rule with comment period that explains how OCR intends to address excepted benefits and provides additional clarity on how the rule will apply to excepted benefits, taking into account the specific nature and legal structure of such products that Congress made statutorily distinct from major medical products. Commenters also objected to the Proposed Rule's investigative approach to evaluate claims of discrimination on a case-by-case basis, with one commenter arguing the case-by-case approach indicated a ''regulation-by-audit scheme.''

Response: We disagree that the Proposed Rule failed to adequately provide notice and opportunity to comment on OCR's reasoning regarding the applicability of section 1557 to all operations of a recipient health insurance issuer that is principally engaged in the provision or administration of health insurance coverage or other health-related coverage. We fully discussed OCR's legal authority and reasoning regarding this scope of coverage in the Proposed Rule's discussion of the definition of ''health program or activity'' under § 92.4. 87 FR 47844–45. We also disagree that the Proposed Rule did not provide notice to the public of the terms or substance of how OCR intends to address excepted benefits for purposes of applying section 1557. In the preamble to the Proposed Rule, we clearly stated that all operations of a covered issuer principally engaged would include its other plans, explicitly mentioning excepted benefits. 87 FR 47875–76. Further, in the Proposed Rule, 87 FR 47875, we described the subject and the issues involved in how OCR will analyze claims of discriminatory benefit design by specifically stating that we acknowledged the unique nature of these products as being exempt from the Federal consumer protections and market reform requirements applicable to comprehensive coverage, and discussed how OCR proposes to investigate such plans by considering the nature, scope, and contours of the specific plan at issue and evaluating on a case-by-case basis an alleged discriminatory design feature in light of the entity's stated coverage parameters.[253] We also reiterated that covered entities have the opportunity to articulate a legitimate, nondiscriminatory basis for their challenged action or practice. As discussed throughout this section and in the Proposed Rule, OCR's analysis for investigating a potentially discriminatory benefit design—as well as for all OCR investigations—is necessarily a fact-specific, case-by-case analysis. This is true for allegations related to benefit design features in all plans, including major medical coverage as well as excepted benefits.

Comment: Some commenters raised concerns specific to Medicare supplemental health insurance (known as ''Medigap''), which is an excepted benefit, and requested that the rule not apply to such plans.

Commenters argued that applying section 1557 to Medigap plans would be inconsistent with Congress's intent and the interlocking Federal-State regulatory framework set forth by Congress. A commenter noted that when Congress wants to alter this regulatory scheme, it speaks clearly,[254] and because Congress made no such specific reference to Medigap when enacting section 1557, Congress intended Medigap to be beyond the scope of section 1557. Commenters discussed that Medigap is highly standardized coverage comprehensively regulated under both Federal and State law over which issuers have little discretion with respect to plan benefit design.[255] Commenters explained that Federal law prescribes ten different types of Medigap benefit packages, with each offering a different set of standardized benefits.[256] Commenters noted that Congress established a Federal-State regulatory framework that prescribes the benefits, eligibility, and rating methodologies permissible for Medigap plans, with States establishing State-specific requirements for Medigap policies sold in their State. For example, a commenter noted that State laws may regulate Medigap plans in several ways, such as premium rating based on age, sex/gender, or medical underwriting, with some states requiring sex/gender rating; Medigap eligibility criteria based on an individual's age, disability, or end-stage renal disease, with some States specifying that Medigap plans are not available to such individuals; and State-specific standardized Medigap plans over which issuers have no control with respect to benefit design, communications, or other factors.

Commenters stated that Medigap is commonly underwritten after an initial open enrollment period to prevent adverse selection, and that Medigap

[252] *See* 42 U.S.C. 300gg–21(b)–(c) and 300gg–63. *See also* the conforming amendments in section 1563(a) of the ACA.

[253] *Cf. Easley by Easley* v. *Snider,* 36 F.3d 297, 301–05 (3d Cir. 1994) (examining the ''essential nature of the program'' as intended by the state when determining that a state's Attendant Care Program did not discriminate against individuals with mental disabilities under the ADA by excluding adults with disabilities who were not mentally alert).

[254] For example, the commenter noted that Congress revised the Medigap statute when it wanted to expressly apply section 104 of the Genetic Information Nondiscrimination Act to Medigap. Public Law 100–360, 102 Stat. 683, sec. 221 (1988) (codified in 42 U.S.C. 1395ss).

[255] *See* 42 U.S.C. 1395ss, 42 CFR 403.200 through 403.258; *see also* Nat'l Ass'n of Ins. Comm'rs, *NAIC Model Regulation to Implement the NAIC Medicare Supplement Insurance Minimum Standards Model Act, MO–651–1* (2022), *https://content.naic.org/sites/default/files/model-law-651.pdf.*

[256] *See* 42 U.S.C. 1395ss. *See also* U.S. Dep't of Health & Hum. Servs., Ctrs. for Medicare & Medicaid Servs., *Choosing a Medigap Policy: A Guide to Health Insurance for People with Medicare,* 11 (2023), *https://www.medicare.gov/publications/02110-medigap-guide-health-insurance.pdf.*

issuers are generally limited to competing along two dimensions: price and customer service.[257] Commenters argued that subjecting Medigap to section 1557 could result in adverse selection that could force covered issuers to leave the Medigap market, resulting in reduced consumer choice, higher Medigap premiums, and lower quality of service for seniors.

If the final rule does not exclude Medigap from section 1557, commenters requested at minimum that the rule specify that covered issuers are not responsible for possible discriminatory benefit designs, decisions, or actions that are a result of complying with a Federal or State requirement, including State-approved commercial underwriting practices.

Response: OCR appreciates the concerns raised by commenters about Medigap, which is a statutorily defined excepted benefit.[258] Medigap is a type of private supplemental health insurance coverage designed to cover cost-sharing gaps in original Medicare, such as deductibles, coinsurance, and copayments.[259] Medigap is regulated by both Federal and State law. 42 U.S.C. 1395ss. Congress standardized Medigap plans to establish standard plan designs.[260] While the plan benefits are standardized, the premiums and availability of the plans may vary by issuer depending on Federal and State law requirements. Medigap plans are statutorily prohibited from medical underwriting based on health status or imposing preexisting condition exclusions under certain circumstances, including during a six-month Medigap open enrollment period that begins when an individual turns 65 and enrolls in Medicare Part B and other specific times when guaranteed issue rights are available, 42 U.S.C. 1395ss(s), after which they are generally not prohibited from such practices under Federal law. States may enact their own State-specific requirements on Medigap, including whether the plans are guaranteed issue and whether the premiums may be rated based on age, health status, sex, or other factors.[261] In addition, while there generally is no Federal Medigap open enrollment period during which time Medigap plans must be sold to individuals with disabilities under the age of 65, some States may require it.[262]

Like other excepted benefits, Medigap is not designed to serve as comprehensive coverage and does not receive Federal financial assistance. As an excepted benefit, Medigap plans would be subject to the rule in the same fashion as other excepted benefits: if a Medigap plan is offered by a recipient health insurance issuer that is principally engaged in the provision or administration of health insurance coverage or other health-related coverage as specified under the definition of ''health program or activity'' in § 92.4, the Medigap plan would be subject to the rule as part of the issuer's operations.

That said, we acknowledge commenters' concerns about State law requirements that might result in benefit design features that could violate section 1557. When investigating a discriminatory design feature in a Medigap plan, OCR will evaluate the covered entity's legitimate, nondiscriminatory reason for the challenged feature. If the reason is based on a Federal or State law requirement, OCR will take this information into account when evaluating the context of the challenged design feature and will work with the covered entity to achieve compliance to help ensure that issuers do not leave the Medigap market or lower quality of products for consumers; however, section 1557 would preempt a State law Medigap requirement—or any other excepted benefit requirement—that compelled conduct prohibited by section 1557 as applied to a recipient health insurance issuer subject to section 1557.

Comment: Many commenters supported the Proposed Rule's application to STLDI as part of a principally engaged covered entity's operations. Commenters argued that the proposed broad application is crucial to protect against discrimination in these products.

Commenters stated that STLDI plans are marketed, often misleadingly and fraudulently, as an alternative to comprehensive coverage, but have significant gaps that lead to high out-of-pocket costs and little financial protection for consumers.[263] Commenters stated that STLDI plans are under-regulated and use a lax regulatory environment to market and sell products that can harm individuals, especially those with complex health needs. For example, a commenter stated that a person with cancer would pay anywhere from $23,000 to $100,000 in out-of-pocket expenses during the first six months following diagnosis under an STLDI plan.[264]

Commenters discussed that STLDI plans charge higher prices based on an applicant's age, sex, or disability and exclude or severely limit coverage for benefits related to preexisting conditions, prescription medications, mental health, and preventive services for women, contraception, and maternity care, all of which adversely impact individuals with disabilities, women, and individuals who are or who may become pregnant.[265] Commenters suggested that the plans appear to be designed to discourage enrolling women of child-bearing age and that one study revealed that all plans reviewed discriminated against women through various practices, including gender rating and coverage exclusions.[266] Commenters stated that including

[257] U.S. Dep't of Health & Hum. Servs., Ctrs. for Medicare & Medicaid Servs., *Medigap (Medicare Supplement Health Insurance), https://www.cms.gov/Medicare/Health-Plans/Medigap* (stating that ''the only difference between medigap policies sold by different insurance companies is the cost.'').

[258] Referred to as ''Medicare supplemental health insurance'' under 42 U.S.C. 300gg–91(c)(4); 45 CFR 144.103, 146.145(b)(5), and 148.220(b)(5).

[259] Cong. Rsch. Serv., R47552, *Medigap: Background and Statistics,* 2 (2023), *https://sgp.fas.org/crs/misc/R47552.pdf.*

[260] Omnibus Budget Reconciliation Act of 1990, H.R. 5835, Pub. L. 101–508, pt. 5, Nov. 5, 1990, 104 Stat. 1388, *https://www.congress.gov/bill/101st-congress/house-bill/5835. See also* Cong. Rsch. Serv., R47552, *Medigap: Background and Statistics,* 5–7 (2023), *https://sgp.fas.org/crs/misc/R47552.pdf.*

[261] *See, e.g.,* Cristina Boccuti et al., Kaiser Family Found., *Medigap Enrollment and Consumer Protections Vary Across States,* pp. 8–13 (2018), *https://files.kff.org/attachment/Issue-Brief-Medigap-Enrollment-and-Consumer-Protections-Vary-Across-States.*

[262] *See* 42 U.S.C. 1395ss(s)(2)(A). *See also* Cong. Rsch. Serv., R47552, *Medigap: Background and Statistics,* 3 (2023), *https://sgp.fas.org/crs/misc/R47552.pdf.*

[263] *See, e.g.,* Sabrina Corlette et al., *Urban Inst., The Marketing of Short-Term Health Plans: An Assessment of Industry Practices and State Regulatory Responses* (2019), *https://www.urban.org/sites/default/files/publication/99708/moni_stldi_final_0.pdf.*

[264] *See, e.g.,* Gabriela Dieguez & Dane Hansen, Milliman, *The Impact of Short-Term Limited-Duration Policy Expansion on Patients and the ACA Individual Market,* p. 13 (2020), *https://www.lls.org/sites/default/files/National/USA/Pdf/STLD-Impact-Report-Final-Public.pdf.*

[265] *See, e.g.,* H.R. Comm. on Energy & Com., 116th Cong., *Shortchanged: How the Trump Administration's Expansion of Junk Short-Term Health Insurance Plans is Putting Americans at Risk* (2020), *https://drive.google.com/file/d/1uiL3Bi9XV0mYnxpyaIMeg_Q–BJaURXX3/view*; Dania Palanker & Emily Curran, Commonwealth Fund, *Limitations of Short-Term Health Plans Persist Despite Predictions That They'd Evolve* (2020), *https://www.commonwealthfund.org/blog/2020/limitations-short-term-health-plans-persist-despite-predictions-theyd-evolve*; JoAnn Volk et al., Commonwealth Fund, *Trump Administration Promotes Coverage That Fails to Adequately Cover Women's Key Health Care Needs* (2020), *https://www.commonwealthfund.org/blog/2020/trump-administration-promotes-coverage-that-fails-to-cover-womens-key-health-care-needs.*

[266] H.R. Comm. on Energy & Com., 116th Cong., *Shortchanged: How the Trump Administration's Expansion of Junk Short-Term Health Insurance Plans is Putting Americans at Risk,* 61, 74 (2020), *https://drive.google.com/file/d/1uiL3Bi9XV0mYnxpyaIMeg_Q–BJaURXX3/view.*

coverage under section 1557 for these plans is particularly important for individuals with disabilities, including those with HIV, hepatitis, and mental health and substance use disorder disabilities who are harmed by discriminatory practices, such as including more frequent application of prior authorization and fail-first protocols and denials of medically necessary services.

Because STLDI plans are not subject to traditional oversight of their provider networks, commenters stated that the plans may be designed in a way that limits care for LGBTQI+ people, individuals with disabilities, older individuals, individuals with LEP, or people of color.[267] In addition, commenters observed that STLDI plans retroactively cancel coverage and are not guaranteed renewable, leaving people with serious health conditions without coverage and often unable to enroll if the denial occurred outside of an ACA open enrollment period.[268]

One insurance industry commenter raised detailed concerns about applying the rule to STDLI in its discussion opposing the rule's application to excepted benefits. The commenter argued that similar to arguments above regarding excepted benefits, Congress excluded these products from most of the ACA's requirements and that applying the rule to these products would create a competitive disadvantage for covered entities that must comply with section 1557 as compared to non-recipient competitors that can offer lower-cost coverage due to the ability to vary premium rates on the basis of factors otherwise prohibited under section 1557 or exclude higher cost benefits. The commenter also argued recipients would be subject to greater costs due to compliance with section 1557's procedural requirements.

Response: OCR appreciates commenters' support and shares the concerns raised by commenters about the misleading and deceptive practices of some issuers of STLDI plans. STLDI is excluded from the definition of ''individual health insurance coverage'' under the PHS Act.[269] As a result, it is generally exempt from the Federal consumer protections and market reform requirements applicable to comprehensive coverage offered in the individual market, such as the prohibition on discrimination based on health status, 42 U.S.C. 300gg–4, the prohibition of preexisting condition exclusions, 42 U.S.C. 300gg–3, and the prohibition on lifetime and annual dollar limits on EHB, 42 U.S.C 300gg–11, among others. These plans were traditionally not designed to serve as comprehensive coverage and were intended to fill temporary coverage gaps when an individual was transitioning between comprehensive coverages. *See* 81 FR 38020, 38032 (June 10, 2016).[270]

OCR acknowledges the commenter's concerns about competitive disadvantage and compliance costs. However, as discussed previously, the risk of competitive disadvantage is low given that the majority of health insurance issuers offer some type of product that receives Federal financial assistance, and by accepting the benefit of Federal funds, a recipient is prohibited from discriminating in its health programs and activities under section 1557. For the same reasons set forth above explaining why this rule applies to a principally engaged recipient issuer's excepted benefits, STLDI would be covered under this final rule as part of a recipient issuer's operations if the issuer is principally engaged as set forth in the definition of ''health program or activity'' at § 92.4. That Congress excluded STLDI from the PHS Act definition of individual health insurance coverage does not exclude such coverage from section 1557. Congress could have but did not extend the exemption for these products to section 1557. section 1557 applies to ''health programs or activities'' and contains no exceptions for certain types of plans or coverage, nor is it limited to plans or coverage that are subject to other provisions in the ACA. OCR therefore maintains that this rule's interpretation and application to all operations of a recipient health insurance issuer when principally engaged, including an issuer's products, is the best reading of the section 1557 statutory language, which applies to ''any health program or activity, *any part of which is receiving Federal financial assistance.*'' 42 U.S.C. 18116(a) (emphasis added).

Application to Third Party Administrators

In the Proposed Rule, we discussed that an issuer's or other entity's operations related to third party administrative services also would be subject to the rule when the issuer receives Federal financial assistance and is deemed to be principally engaged in the provision or administration of health insurance coverage or other health-related coverage as set forth in the definition of ''health program or activity'' under § 92.4. 87 FR 47876–77. We stated that we will engage in a fact-specific analysis to evaluate whether a third party administrator is appropriately covered under section 1557 as a recipient of Federal financial assistance in circumstances where the third party administrator is legally separate from the issuer that receives Federal financial assistance.

When investigating complaints relating to third party administrators that are appropriately covered under section 1557, we stated that OCR will determine whether responsibility for the decision or alleged discriminatory action lies with the plan sponsor or with the covered third party administrator. Where the alleged discrimination relates to the administration of the plan by a covered third party administrator, we stated that OCR will process the complaint against the third party administrator because it is the entity responsible for the decision or other action being challenged in the complaint. We also stated that OCR will pursue claims against the covered third party administrator in circumstances where the third party administrator is the entity responsible for developing the discriminatory benefit design feature that was adopted by the employer. Where the alleged discrimination relates to the benefit design of self-insured group health plan coverage that did not originate with the third party administrator, but rather with the plan sponsor, OCR will refer the complaint to the Equal Employment Opportunity Commission (EEOC) or DOJ for potential investigation. We discussed that we would refer complaints related to the Federal Employees Health Benefits (FEHB) Program, the Federal Employees Dental and Vision Insurance Program (FEDVIP), or the Federal Long Term

---

[267] *See, e.g.,* H.R. Comm. on Energy & Com., 116th Cong., *Shortchanged: How the Trump Administration's Expansion of Junk Short-Term Health Insurance Plans is Putting Americans at Risk* (2020), *https://drive.google.com/file/d/1uiL3Bi9XV0mYnxpyaIMeg_Q–BJaURXX3/view.*

[268] *See, e.g.,* Gabriela Dieguez & Dane Hansen, Milliman, *The Impact of Short-Term Limited-Duration Policy Expansion on Patients and the ACA Individual Market,* p. 11 (2020), *https://www.lls.org/sites/default/files/National/USA/Pdf/STLD-Impact-Report-Final-Public.pdf.*

[269] 42 U.S.C. 300gg–91(b)(5) defines ''individual health insurance coverage'' to mean ''health insurance coverage offered to individuals in the individual market, *but does not include short-term limited duration insurance.*'' (Emphasis added.)

[270] *See also,* U.S. Dep't of Health & Hum. Servs., *Short-Term Limited Duration Insurance: Independent, Noncoordinated Excepted Benefits Coverage; Level-Funded Plan Arrangements; and Tax Treatment of Certain Accident and Health Insurance,* Proposed Rule, 88 FR 44596 (July 12, 2023) (proposing to narrow the definition of ''short-term limited duration insurance'' to mean health insurance coverage that has an expiration date that is ''no more than 3 months after the original effective date of the policy, certificate, or contract of insurance, and taking into account any renewals or extensions, has a duration no longer than 4 months in total''.)

Care Insurance Program (FLTCIP) to the Office of Personnel Management (OPM).

The comments and our responses regarding coverage of third party administrator activities are set forth below.

Comment: Several commenters supported the rule's application to third party administrators as part of the operations of a principally engaged recipient health insurance issuer. Commenters stated that issuers often serve as third party administrators and the rule's application to an issuer's third party administrator activities will help achieve health equity, improve health outcomes, and ensure that all individuals can access health care without unnecessary barriers. Commenters stated that third party administrators play an outsized role in administering and designing health coverage for millions of people enrolled in self-funded employer group health plan coverage,[271] which may contain discriminatory provisions prohibited by section 1557.[272] Commenters discussed how third party administrators do more than simply process claims. These commenters stated that, similar to issuers, third party administrators make significant decisions about critical health plan features and often design benefits, formularies, payment structures, and networks; conduct prior authorization; and establish and evaluate other clinical coverage criteria. One commenter stated that third party administrators rely on their own clinical criteria, which may result in discriminatory denials of coverage despite the plan providing coverage generally. For example, the commenter discussed that where a self-funded plan might provide coverage for gender-affirming care, the third party administrator might rely on its own clinical criteria to categorically exclude coverage for certain types of gender-affirming care.

Other commenters opposed the rule covering third party administrators. These commenters argued the rule should exclude third party administrators from the scope of the final rule and that section 1557's application should not extend beyond the legal entity that provides or offers the ''health program or activity.'' Several commenters argued that the rule's coverage of third party administrators would create an unlevel playing field and result in a competitive disadvantage for health insurance issuers that accept Federal financial assistance. For example, commenters argued the administrative costs of complying with section 1557, such as the nondiscrimination notice requirements, would place covered third party administrators at a competitive disadvantage with non-covered third party administrators that are not subject to the same requirements. Commenters asserted that third party administrators generally do not receive Federal financial assistance and argued that applying section 1557 to third party administrators would result in subjecting all their clients to section 1557's requirements when neither the client nor the third party administrator receives Federal financial assistance. Commenters argued this would create a disincentive for clients to engage a third party administrator that is subject to section 1557 and so would create an unlevel playing field between third party administrators covered by section 1557 and those that are not. Commenters further suggested this could result in entities deciding not to participate in federally funded or conducted programs, such as the Exchanges.

One commenter asserted OCR did not explain the need for this proposed change from the 2020 Rule, which does not cover an issuer's third party administrator activities, and that the uncertainty of how the rule will apply to covered third party administrators would likely result in higher third party administrator charges to employers, which would be passed through to enrollees.

Response: We appreciate the diversity of comments received on our proposal to apply section 1557 to third party administrators when certain criteria are met. The final rule applies to all the operations of a recipient principally engaged in the provision or administration of health insurance coverage or other health-related coverage, including its third party administrator activities, as discussed in detail previously under the definition of ''health program or activity'' under § 92.4. This position is also supported by a decision of the District Court for the Western District of Washington, which held that third party administrators operated by health insurance issuers are subject to section 1557 even if the third party administrators do not receive Federal financial assistance.[273] In addition, a third party administrator could be covered under the rule if it is a subrecipient of Federal financial assistance. We also note that where a third party administrator is not covered under section 1557, a covered entity that contracts with a third party administrator, such as a health insurance issuer or group health plan, may be liable for the third party administrator's actions as a subcontractor. Please see the earlier discussion on subrecipients and contractors in the sections on Application, § 92.2, and the definition of ''Federal financial assistance,'' § 92.4.

We acknowledge commenters' concerns that this may result in a competitive disadvantage for health insurance issuers that accept Federal financial assistance. This argument, however, is not unique to health insurance issuers or their third party administrator activities. Any covered entity that accepts Federal funding from the Department knowingly agrees to comply with section 1557 and other civil rights laws that apply to recipients of Federal financial assistance.

Comment: Some commenters were opposed to the rule holding a third party administrator liable for plan benefit designs even if the discriminatory terms originated with the third party administrator. Commenters stated this approach was inconsistent with the 2016 Rule's approach that a third party administrator was liable only where the third party administrator was ''responsible for the decision or action . . . as the decision-making entity.'' 81 FR 31432. These commenters requested that OCR clarify that a third party administrator will be held responsible for actions only when it is the entity that controls whether or not the action must be taken. Commenters argued that third party administrators should not be liable for plan benefit designs simply because a third party administrator suggested or helped develop the benefit design ultimately chosen by the group health plan because the third party administrator is not the decision-making entity that adopted the benefit design. Accordingly, commenters argued that third party administrators should not be held responsible for administering benefits based on benefit design decisions made solely by a plan sponsor and urged OCR to clarify that the rule will not apply to third party

[271] Commenters noted that 64 percent of workers in the United States receive health coverage through self-insured employer plans. Gary Claxton et al., Kaiser Family Found., *Employer Health Benefits 2021 Annual Survey,* p. 9 (2021), *https://files.kff.org/attachment/Report-Employer-Health-Benefits-2021-Annual-Survey.pdf.*

[272] *See, e.g.,* Anna Kirkland et al., *Transition Coverage and Clarity in Self-Insured Corporate Health Insurance Benefit Plans,* 6 Transgender Health 4, 214 (2021), *https://www.liebertpub.com/doi/full/10.1089/trgh.2020.0067* (showing that employer plans had three times as many categorical exclusions for gender-affirming health care).

[273] *See C. P. by & through Pritchard* v. *Blue Cross Blue Shield of Ill.,* No. 3:20–CV–06145–RJB, 2022 WL 17788148, at *8 (W.D. Wash. Dec. 19, 2022).

administrators in cases where a plan sponsor adopts a potentially discriminatory plan design that the third party administrator played no role in selecting.

Commenters also noted that, under ERISA, third party administrators generally must administer self-insured plans according to the plans' terms. 29 U.S.C. 1104(a)(1)(D). These commenters asserted that a third party administrator should not be liable for the benefit design of a plan, including utilization management techniques, when it is administering the plan consistent with the plan terms as adopted by the group health plan or plan sponsor. Otherwise, commenters argued, the rule would effectively hold a third party administrator responsible for decisions made by another entity, namely, the plan's named fiduciary or plan administrator. Commenters further stated that ERISA does not require the third party administrator to be responsible for plan terms, but does require the plan sponsor to have a ''named fiduciary'' that has ultimate control over the plan's operation.[274] A commenter argued it would be unreasonable for OCR to take the position that a third party administrator is legally obligated under section 1557 to violate its obligation under ERISA to honor its contract with the plan sponsor and honor the plan's terms.

Commenters also argued that covering third party administrators is contrary to Congressional intent. Commenters stated that under ERISA, Congress made the group health plan responsible for the benefits it chooses to provide, and that OCR should not shift that responsibility to third party administrators through section 1557. These commenters argued that had Congress intended for third party administrators to be subject to section 1557, it would have said so clearly.

In contrast, several commenters expressed support for the rule that would make a covered third party administrator liable when the discriminatory plan feature originated with the third party administrator. These commenters asserted that third party administrators cannot insulate themselves from liability by arguing that ERISA requires a group health plan to be administered according to its terms (including by a third party administrator contracted by a plan sponsor). ERISA, commenters noted, does not exempt group health plans or their service providers (including third party administrators) from complying with other Federal laws, like section 1557.[275] These commenters, citing to case law,[276] argued that third party administrators should be held liable under section 1557 for discriminatory plan administration and when discriminatory plan terms originate with the third party administrator, even when the plan sponsor subsequently adopts the plan designed by the third party administrator and maintains control over its terms. Commenters noted that many large health insurance issuers design and market self-funded plans to plan sponsors and contract to serve as third party administrators.[277] Commenters noted that third party administrators are largely responsible for designing plans except for those offered by the most sophisticated employers. Commenters stated that issuers administer the self-funded plans using the same coverage policies that they use in their fully insured plans, and therefore the discriminatory terms in self-funded plans are often directly traceable to and redressable by third party administrators.

Some commenters suggested that third party administrators should be liable for administering a plan with discriminatory benefit design features even when the plan design did not originate with the third party administrator. Commenters argued that third party administrators that agree to administer discriminatory plans play a role in discriminating against protected individuals and should not be given immunity when administering plans with discriminatory designs.

Response: OCR carefully considered the variety of views expressed by commenters relating to the liability of a third party administrator covered under this rule. We agree with commenters that a third party administrator should not be held responsible for discriminatory plan design features over which the third party administrator exercised no control.

We disagree with commenters that believe a covered third party administrator should not be liable for discriminatory benefit design features that originated with the third party administrator simply because the plan sponsor is ultimately the entity responsible under ERISA for adopting the plan and maintaining control over its terms. Our interpretation is consistent with case law, which has held that a third party administrator may be liable for discriminatory plan terms that originated with the third party administrator, notwithstanding the fact that the plan sponsor subsequently adopted the plan and maintained control over the terms.[278] Further, as commenters noted, health insurance issuers operating as third party administrators often design the plans that they offer to self-insured group health plans and offer standard plan design options, often to small and midsize employers while only offering flexibility in the plan design to larger employers.[279]

We recognize that ERISA requires group health plans to be administered consistent with the terms governing the plan, as long as the terms are consistent with the provisions of the same

[274] *See, e.g.,* Dep't of Labor, *Meeting Your Fiduciary Responsibilities* (2021), *https://www.dol.gov/node/63375.*

[275] *See* 29 U.S.C. 1144(d) (''Nothing in this subchapter shall be construed to alter, amend, modify, invalidate, impair, or supersede any law of the United States . . . .'').

[276] *Tovar* v. *Essentia Health,* 857 F.3d 771, 778 (8th Cir. 2017).

[277] Blue Cross Blue Shield of N.D., *Self-Funding, Alternative Financial Arrangements for Group Benefit Plans,* p. 1 (2019), *https://www.bcbsnd.com/content/dam/bcbsnd/documents/brochures/employers/29300143_BND-Self-Funding-Brochure.pdf* (''Groups with 26 or more employees enrolled have a choice of several standard design plan options available. There is additional flexibility for custom designed benefit plans for groups with more than 50 employees enrolled.''); UnitedHealthcare, *UMR, https://www.uhc.com/employer/employer-resources/umr* (stating UMR, UnitedHealthcare's third party administrator, ''serve[s] over 5 million members with custom plan designs, cost-containment solutions and innovative services'').

[278] *See, e.g. Tovar* v. *Essentia Health,* 857 F.3d 771, 778 (8th Cir. 2017) (concluding that enrollee in a self-insured employer-sponsored plan could establish Article III standing for a claim of discrimination under section 1557 to sue a third party administrator where ''the plan and its allegedly discriminatory terms originated with [the third party administrator]—not with [the employer],'' and if the third party administrator provided the employer ''with a discriminatory plan document, . . . notwithstanding the fact that [the employer] subsequently adopted the plan and maintained control over its terms''); *C. P. by & through Pritchard* v. *Blue Cross Blue Shield of Ill.,* No. 3:20–CV–06145–RJB, 2022 WL 17788148, at *7, *9 (W.D. Wash. Dec. 19, 2022) (holding that ''third party administrators can be liable under Section 1557 based on discriminatory terms in a self-funded plan even if the third party administrator provided the plan document 'notwithstanding the fact that the [plan sponsor] subsequently adopted the plan and maintained control over its terms''' (quoting *Tovar,* 857 F.3d at 778)); *Tovar* v. *Essentia Health,* 342 F. Supp. 3d 947, 954 (D. Minn. 2018) (holding that a third party administrator may be liable under section 1557 for damages arising from discriminatory terms in a self-insured, employer-sponsored health plan where the harm suffered ''was proximately caused by [the third party administrator's] designing and providing to [the self-insured plan] the discriminatory provisions in the plan'').

[279] *See, e.g.,* Blue Cross Blue Shield of N.D., *Self-Funding, Alternative Financial Arrangements for Group Benefit Plans,* p. 1 (2019), *https://www.bcbsnd.com/content/dam/bcbsnd/documents/brochures/employers/29300143_BND-Self-Funding-Brochure.pdf* (''Groups with 26 or more employees enrolled have a choice of several standard design plan options available. There is additional flexibility for custom designed benefit plans for groups with more than 50 employees enrolled.'').

subchapter in ERISA.[280] ERISA then provides in the same subchapter that it is not to be construed to impair or supersede other Federal laws, including regulations issued under such laws.[281] This rationale finds support in the cases that have held that ERISA's requirement that a plan's terms must be administered as written must not be construed to invalidate or impair section 1557.[282]

For these reasons, we affirm our general approach as discussed in the Proposed Rule at 87 FR 47876–77. When OCR investigates a potentially discriminatory action or plan design related to a self-insured group health plan coverage administered by a covered entity acting as a third party administrator, OCR will take into account the party responsible for the alleged discriminatory conduct. Recognizing that third party administrators might not be responsible for the benefit designs of the self-insured group health plan coverage that they administer, OCR does not intend to enforce this rule against a third party administrator for a plan design that it did not design and over which it has no control. Where the discriminatory terms of the plan originated with the covered third party administrator rather than with the plan sponsor, the third party administrator could be liable for the discriminatory design feature under section 1557.

Accordingly, when analyzing a claim against a covered third party administrator, OCR will determine whether responsibility for the decision or alleged discriminatory action lies with the third party administrator, group health plan, or the plan sponsor. Where the alleged discrimination relates to the administration of the plan by a covered third party administrator, OCR will process the complaint against the covered third party administrator because it is the entity responsible for the decision or other action being challenged. For example, if a covered third party administrator applies a plan's neutral, nondiscriminatory utilization management guidelines in a discriminatory way against an enrollee, OCR will proceed against the covered third party administrator as the entity responsible for the decision. In addition, OCR will pursue claims against a covered third party administrator in circumstances where the third party administrator is the entity responsible for developing the discriminatory benefit design feature that was adopted by the employer. For instance, if a covered third party administrator develops standard plan designs that it offers to employers, the covered third party administrator is liable for any discriminatory design feature in the plans because the plans originated with the third party administrator. Where the alleged discrimination relates to the benefit design of self-insured group health plan coverage that did not originate with the covered third party administrator, but rather with the plan sponsor or the group health plan, and where the third party administrator played no role in the development of the plan's benefit design, OCR will refer the complaint to the EEOC or DOJ for potential investigation.

As discussed in the Proposed Rule at 87 FR 47877, as part of OCR's enforcement authority, OCR has the option of referring or transferring matters to other Federal agencies with jurisdiction over the entity. Accordingly, OCR will transfer matters to the EEOC or DOJ where OCR lacks jurisdiction over an employer responsible for the benefit design of employer-sponsored group health plan coverage. OCR will refer to OPM complaints alleging discrimination in the FEHB Program (including the Postal Service Health Benefits Program), FEDVIP, and FLTCIP. This Rule does not determine how or whether any other agency will investigate or enforce any matter referred or transferred by OCR.

As part of OCR's analysis, we will also engage in a fact-specific inquiry to evaluate whether a third party administrator is appropriately covered under section 1557 in circumstances where the third party administrator is legally separate from the issuer that receives Federal financial assistance, as discussed in more detail below.

Comment: Commenters requested that OCR provide additional clarity on the circumstances under which OCR would hold a third party administrator liable under the rule. Commenters stated that plan sponsors and third party administrators may place blame on each other for the discriminatory features. Another commenter said that a self-insured plan sponsor could direct a third party administrator on the goals or parameters of the design it seeks or refer the third party administrator to other plan designs and request that the third party administrator develop a plan design in accordance with those parameters. The commenter argued that in these cases, where the third party administrator is not the decision-making entity that ultimately controls and determines whether to implement the design or feature, it should not be liable under section 1557 for that design or feature.

Response: If a third party administrator is a covered entity under section 1557, it is responsible for ensuring that its actions do not discriminate on the basis of race, color, national origin, sex, age, or disability. Where a covered third party administrator plays a role in designing benefits for self-insured group health plan coverage, it must not do so in a manner that results in discrimination on a prohibited basis. This is so even if the plan sponsor requests that the covered third party administrator develop a certain plan design that includes a discriminatory feature. For example, if a plan sponsor requested that a covered third party administrator develop a plan design that excluded all enrollees of a certain race, there would be no question that a third party administrator could not design such a plan without violating section 1557. This is true for any other discriminatory design feature that would violate section 1557. In these cases, while the plan sponsor may be the entity requesting the particular design feature for a group health plan, the covered third party administrator would still be liable as the entity that designed such a plan, notwithstanding the plan sponsor's request.

Comment: Several commenters requested that OCR provide clarity on the rule's application to pharmacy benefit managers. Many commenters argued that pharmacy benefit managers, similar to third party administrators, make significant decisions about critical health plan features and should be liable when they are responsible for discriminatory formulary benefit designs. Commenters noted that plan sponsors often defer to the expertise of pharmacy benefit managers. Commenters opposed to the rule's application to third party administrators argued that pharmacy benefit managers similarly should not be liable under the

[280] 29 U.S.C. 1104(a)(1)(D) (''[A] fiduciary shall discharge his duties with respect to a plan solely in the interest of the participants and beneficiaries and . . . in accordance with the documents and instruments governing the plan *insofar as such documents and instruments are consistent with the provisions of this subchapter and subchapter III.*'' (emphasis added)).

[281] 29 U.S.C. 1144(d) (''Nothing in this subchapter shall be construed to alter, amend, modify, invalidate, impair, or supersede any law of the United States (except as provided in sections 1031 and 1137(b) of this title) or any rule or regulation issued under any such law.'').

[282] *See, e.g., C. P. by & through Pritchard* v. *Blue Cross Blue Shield of Ill.,* No. 3:20–CV–06145–RJB, 2022 WL 17788148, at *8, 10 (W.D. Wash. Dec. 19, 2022) (holding that ERISA's requirement at 29 U.S.C. 1104(a)(1)(D) to administer a plan's terms as written ''is subservient to Section 1557, outlawing discrimination, which is dominant''); *Tovar* v. *Essentia Health,* 342 F. Supp. 3d 947, 954 (D. Minn. 2018) (''The Court will not construe ERISA to impair Section 1557. Nothing in Section 1557, explicitly or implicitly, suggests that TPAs are exempt from the statute's nondiscrimination requirements.'').

rule when a pharmacy benefit manager was not responsible for designing the plan benefits that were adopted by the plan sponsor, similar to their arguments above against holding third party administrators liable under the rule.

Response: We discuss the rule's applicability to pharmacy benefit managers in the discussion under § 92.4 regarding the definition of ''health program or activity.'' Pharmacy benefit managers are health programs or activities and would be covered under the rule if they receive Federal financial assistance. A pharmacy benefit manager that does not directly receive Federal financial assistance would also be covered under the rule if it is part of the operations of a recipient that is principally engaged in the provision or administration of health-related services, health-related insurance coverage, or other health-related coverage, as set forth under the definition of ''health program or activity'' at § 92.4.[283]

If a pharmacy benefit manager is subject to section 1557 as part of the operations of a principally engaged recipient, we agree with commenters that the pharmacy benefit manager's liability under the rule would be similar to that of a covered third party administrator. Both entities contract with other parties, such as issuers or sponsors of self-insured group health plan coverage, to administer health benefits to plan enrollees. They may design plan benefits, formularies, payment structures, networks, and conduct utilization management. Therefore, if OCR receives a complaint about a covered pharmacy benefit manager, OCR will evaluate the liability of the pharmacy benefit manager consistent with the analysis set forth above for third party administrators. That is, OCR will determine whether responsibility for the challenged action lies with the covered pharmacy benefit manager or the plan sponsor.

Comment: One commenter requested that OCR clarify that administrative actions such as developing documents or preparing policy booklets for clients, alone, would not constitute third party administrator liability for discriminatory plan design features.

Response: We affirm that such administrative actions would not violate this rule to the extent the covered third party administrator is merely relaying information to enrollees consistent with the underlying plan terms that the third party administrator played no role in developing.

Comment: Some commenters requested that the rule clarify that an entity covered by section 1557 cannot outsource the implementation or design of discriminatory plans to entities that are not covered by the rule. Another commenter requested that OCR clarify that any third-party company may be liable under section 1557 when discriminatory plan terms originate with, or are managed by, the third-party company. For example, the commenter stated that third-party specialty benefits programs may promote or manage discriminatory specialty medication programs.

Response: A covered entity that outsources the implementation or benefit design of discriminatory plans remains liable under this rule for any discriminatory plan terms. Under the discussion of the definition of ''Federal financial assistance'' in § 92.4, we clarify that covered entities are responsible for the conduct of their subcontractors and cannot outsource or contract away their civil rights obligations by entering into contractual arrangements with subcontractors.

A third-party company that develops or manages discriminatory plans on behalf of a covered entity would only be liable under section 1557 to the extent the third-party company is a recipient or subrecipient of Federal financial assistance from the Department, including if the third party is part of a principally engaged recipient's operations.

Comment: Commenters requested that OCR clarify when liability under section 1557 extends across affiliated companies. Some commenters expressed concern that third party administrators and pharmacy benefit managers would automatically be deemed to be covered entities under the rule solely because they are related to an entity that received Federal financial assistance. These commenters requested that the final rule provide the same clarification that was in the 2016 Rule to clarify that a third party administrator (or pharmacy benefit manager[284]) is unlikely to be covered under the rule where they are ''a legal entity that is truly independent of an issuer's other, federally funded, activities.'' 81 FR 31433.

Other commenters expressed concern that third party administrators and pharmacy benefit managers could use complex corporate structures to distinguish separate lines of business to evade compliance with section 1557.[285] These commenters requested that OCR provide greater clarity on when liability under section 1557 extends across affiliated companies.

Response: As discussed in the 2016 Rule, 81 FR 31433, OCR will conduct a case-by-case analysis to determine whether a third party administrator or pharmacy benefit manager is appropriately subject to section 1557 as part of the operations of a recipient covered entity in situations where the third party administrator or pharmacy benefit manager is legally separate from an issuer or other covered entity that receives Federal financial assistance. This fact-specific analysis will rely on principles developed in longstanding civil rights case law, such as the degree of interrelatedness between or among entities, including the degree of common ownership and control between or among entities.[286] OCR will also examine whether the purpose of the legal separation was to avoid liability or avoid the application of civil rights law requirements—that is, whether it is intended to allow the entity to continue to administer discriminatory health insurance coverage or other health-related coverage.[287] As indicated in the 2016 Rule, a third party administrator or pharmacy benefit manager is unlikely to be covered by this final rule where it is a legal entity that is truly independent

[283] *See, e.g., Doe One* v. *CVS Pharmacy, Inc.,* No. 18–cv–01031–EMC, slip op. at 12–23 (N.D. Cal., Aug. 5, 2022) (relying on section 1557, the 2016 Rule, and the incorporated civil rights statutes to conclude that the complaint plausibly alleged that CVS Pharmacy, Inc. is principally engaged in the business of health care and all of its operations are covered by section 1557, including its pharmacy benefit managers Caremark, L.L.C. and Caremark PCS Health, L.L.C.).

[284] The 2016 Rule did not address pharmacy benefit managers.

[285] *Cf., Doe One* v. *CVS Pharmacy, Inc.,* No. 18–cv–01031–EMC, slip op. at 15 (N.D. Cal., Aug. 5, 2022) (''To ignore the overall interrelationship among the entities which, in the case at bar, design and implement the allegedly discriminatory program and permit the CVS interrelated entities to escape responsibility would exalt form over substance and impair the effectiveness of the anti-discrimination provision of the ACA.'').

[286] *See, e.g., Papa* v. *Katy Indus., Inc.,* 166 F.3d 937, 939 (7th Cir. 1999), *cert. denied,* 528 U.S. 1019 (1999) (ADA, ADEA); *Arrowsmith* v. *Shelbourne, Inc.,* 69 F.3d 1235, 1240–42 (2d Cir. 1995) (title VII); *Valesky* v. *Aquinas Acad.,* 2011 U.S. Dist. LEXIS 103791, No. 09–800 (W.D. Pa. Sept. 14, 2011) (title IX); *Russo v Diocese of Greenberg,* 2010 U.S. Dist. LEXIS 96338, No. 09–1169 (W.D. Pa. Sept. 15, 2010) (title IX, section 504); *Margeson* v. *Springfield Terminal Railway Co.,* 1993 U.S. Dist. LEXIS 12243, No. CIV.A. 91–11475–Z (D. Mass. Aug. 24, 1993) (section 504); *See also Doe One* v. *CVS Pharmacy, Inc.,* No. 18–cv–01031–EMC, slip op. at 12–23 (N.D. Cal., Aug. 5, 2022) (relying on section 1557, the 2016 Rule, and the incorporated civil rights statutes to conclude that the complaint plausibly alleged that CVS Pharmacy, Inc. is principally engaged in the business of health care and all of its operations are covered by section 1557, including its pharmacy benefit managers Caremark, L.L.C. and Caremark PCS Health, L.L.C.)

[287] *Papa* v. *Katy Indus., Inc.,* 166 F.3d 937, 941 (7th Cir. 1999), *cert. denied,* 528 U.S. 1019 (1999) (ADA, ADEA).

of an issuer's other, federally funded activities. We also address subsidiary liability under the discussion of § 92.4's definition of ''health program or activity.''

Comment: One commenter urged OCR to consider whether stop-loss coverage sold by a covered third party administrator to an employer results in discrimination on the basis of disability prohibited under section 1557. The commenter stated that stop-loss coverage uses techniques that target group members with high medical needs. The commenter asserted this could result in stop-loss coverage penalizing employers when a covered individual needs intensive treatment for a disabling condition.

Response: Stop-loss insurance provides coverage for the benefit of the employers, plan sponsors, or group health plans to cover financial liability for such entities to provide protection against catastrophic or unpredictable losses, and does not provide coverage for individuals. Stop-loss insurance that does not discriminate against individuals on the grounds protected under section 1557 does not implicate this final rule.

Comment: A few commenters expressed concern that the rule's application to covered third party administrators does not account for situations where the third party administrator is administering plans for religious employers. Commenters argued the rule could impose a burden on an employer's religious beliefs. Another commenter further argued that it could cause the employer to be exposed to liability for a claim of employment discrimination. The commenter explained that § 92.207 prohibits covered entities, such as a covered third party administrator, from providing a health-coverage related product that aligns with the beliefs and practices of religious employers. The commenter argued this results in a burden on the employer's religion because such religious employers cannot obtain a health coverage-related product that is illegal for covered entities to provide. If such an employer were to obtain a group health plan that was consistent with its faith, the commenter argued that the employer is at risk of liability due to OCR's position that it will transfer complaints alleging discrimination by an employer to the EEOC, which will review the employer's plan to determine if it is discriminatory under title VII of the Civil Rights Act.

Response: As discussed throughout this section, a health insurance issuer or third party administrator subject to section 1557 is prohibited from discriminating on the basis of race, color, national origin, sex, age, or disability in its provision or administration of health insurance coverage or other health-related coverage, and is also able to seek assurance of a religious exemption consistent with § 92.302(b). As specified in § 92.2(b), section 1557 does not apply to an employer or a plan sponsor with regard to its employment practices, including the provision of employee health benefits. A religious employer is able to obtain health insurance coverage or administration of its self-funded group health plan coverage from any entity not subject to section 1557, which would fall outside of the application of this rule.

Network Adequacy

The comments and our responses regarding network adequacy are set forth below.

Comment: Commenters appreciated OCR's attention to network adequacy and its acknowledgement that certain provider networks may constitute discriminatory benefit design under section 1557. Commenters stated that discriminatory provider networks profoundly affect the accessibility and quality of care for vulnerable populations. One commenter expressed concern that OCR has limited interest in complaints about access to care stemming from provider networks because the preamble in the Proposed Rule emphasized that health plans have discretion over benefit design and did not explicitly mention provider networks. A commenter recommended that OCR amend the proposed § 92.207(b)(2) to expressly reference provider networks as a type of design feature that falls within the scope of prohibited discriminatory activities.

Response: OCR acknowledges the importance of network adequacy in ensuring nondiscriminatory access to health care while also recognizing covered entities' autonomy in developing their provider networks as part of their benefit design packages, consistent with existing State and Federal network adequacy and other laws, including section 1557.[288] OCR will accept complaints related to provider networks and will investigate allegations of discrimination on a case-by-case basis. OCR declines to amend § 92.207(b)(2) because we believe the regulatory text is clear as written and does not require further clarification. As previously discussed, the term ''benefit design'' encompasses an array of features, including provider networks, and OCR intends to interpret it broadly.

Comment: Commenters urged OCR to include examples of discriminatory network design while articulating several practices that they believed to be violations of section 1557. Some network design practices commenters characterized as discriminatory included low reimbursement rates that lead to lower provider participation, arbitrary limits to in-network providers, limiting the participation of safety-net providers, insufficient providers with accessible medical equipment, narrow pharmacy networks, and performance requirements related to cost or other outcome and quality measures. Commenters argued that all of these practices prevent access and may be used by covered entities to dissuade enrollees with high health needs from enrolling in plans.

Response: OCR appreciates commenters providing examples of how network plan designs might have discriminatory impacts on vulnerable populations. While we agree that certain network plan designs and practices, such as excluding all or most providers that specialize in treating certain conditions, may be discriminatory under section 1557, we will not establish minimum network adequacy standards in this rulemaking. As discussed in the Proposed Rule, 87 FR 47877, covered entities employing network plan designs may be subject to network adequacy standards governed by State and Federal law. For example, CMS regulations establish network adequacy requirements for qualified health plans, Medicare Advantage plans, and Medicare Part D prescription drug plans, and require states to develop and enforce network adequacy standards for their contracted Medicaid managed care plans. *See* 87 FR 47877. Many of these regulations establish specific requirements that must be satisfied, such as inclusion of certain types of providers and time and distance standards. Recognizing that network adequacy is regulated by other Departmental regulations, as we noted in the 2016 Rule, and again note here, it is outside the scope of section 1557 to establish uniform or minimum network adequacy standards.

Comment: Commenters asserted that discriminatory network design practices lead to excessive, and often insurmountable, administrative burdens

[288] Network plans offer medical care through a defined set of providers under contract with the issuer. *See* 42 U.S.C. 300gg–91(d)(10); 45 CFR 144.103 (defining ''network plan'' as ''health insurance coverage of a health insurance issuer under which the financing and delivery of medical care (including items and services paid for as medical care) are provided, in whole or in part, through a defined set of providers under contract with the issuer'').

for enrollees. Commenters also stated that provider network appeals processes can be opaque, arbitrary, and ultimately a tool to deny access to necessary care that meet the definition of a disability under the ADA. Commenters expressed concern over the increase in ''phantom networks,'' plans that list providers as in-network when they are not actually accepting patients, particularly for mental health providers. For example, commenters cited a recent study that showed that 60 percent of the mental health providers in the Oregon Medicaid managed care network were not actually accepting patients.[289] Commenters expressed frustration in discovering that certain in-network providers are unable or unwilling to address multiple co-occurring disabilities or general medical care for people with disabilities.

Response: Plan designs that subject individuals protected by section 1557 to excessive administrative burdens to access coverage benefits that other enrollees do not have to navigate to access coverage may be discriminatory under section 1557. Section 92.207(b) prohibits covered entities from discrimination ''in providing *or administering*'' (emphasis added) health insurance coverage or other health-related coverage.

Comment: Commenters requested strict monitoring and enforcement of provider network compliance with section 1557. A commenter suggested that OCR include scrutiny of provider networks via regular compliance reviews in addition to investigating complaints. To determine whether a certain network design is discriminatory, a commenter urged OCR to consider access measures such as medication adherence, uptake of innovative therapies, and complaints and appeals regarding delayed or denied access to specialists and drugs. A commenter requested that OCR provide greater scrutiny to the impact of provider network consolidation, especially those involving religiously affiliated institutions, in creating discriminatory impacts on health care recipients.

Other commenters stated that OCR should not establish network adequacy standards, as they believe that discrimination through network adequacy is sufficiently addressed by other State and Federal agencies as well as the National Association of Insurance Commissioners, National Committee for Quality Assurance, and URAC (formerly Utilization Review Accreditation Commission). Commenters noted that as network requirements increase, providers and facilities demand increased reimbursement rates, additional contracts for other member or system facilities, and specific network tier placement. Commenters asked OCR to consider limiting provider contracting practices such as ''all-or-nothing'' contracting and anti-tiering clauses. They noted that such practices harm consumers by increasing provider leverage and driving up health care costs.

Response: While we will not establish minimum network adequacy standards in this rulemaking, we emphasize that to ensure compliance with section 1557, covered entities must develop their networks in a nondiscriminatory manner. When determining whether an entity has violated this section, OCR will conduct a fact-intensive investigation to determine whether the challenged network excludes individuals from participation in or denies them the benefits of the plan, or otherwise discriminates against them on the basis of race, color, national origin, sex, age, or disability. This analysis will include evaluating whether a covered entity utilized, in a nondiscriminatory manner, a neutral rule or principle when deciding to adopt its provider network. As noted in the Proposed Rule, OCR is cognizant that a variety of factors may affect a covered entity's provider network design.[290] If OCR determines that a network design is discriminatory, covered entities will be expected to provide a neutral, nondiscriminatory reason for the network design that is not a pretext for discrimination.

Concerns around provider consolidation are out of the scope of this regulation; however, OCR acknowledges that as providers consolidate, there may be increased or novel concerns around discriminatory provider network design and impact to access to care for protected classes.

Medical Diagnostic Equipment

In the Proposed Rule, 87 FR 47836, OCR noted that individuals with mobility disabilities experience challenges accessing preventative, primary, and specialty care due to inaccessible medical diagnostic equipment (MDE). OCR sought comment on the extent to which a lack of accessible MDE within a provider network limits or denies access to care for individuals with disabilities. OCR also requested comment on whether it should incorporate the U.S. Access Board's Medical Diagnostic Equipment Standards (MDE Standards) as enforceable standards and whether a lack of accessible MDE constitutes discriminatory benefit design or network inadequacy.

Comment: OCR received many comments urging OCR to adopt the MDE Standards, created pursuant to section 510 of the Rehabilitation Act, in the final rule. These commenters stated that inaccessible MDE leads to poor health outcomes for people with disabilities, mainly because inaccessible MDE results in individuals with disabilities receiving less preventative care, including mammograms and cervical screenings, compared to their counterparts without disabilities.[291] One commenter also noted that this lack of preventative care, and ensuing poor health outcomes, could also place people with disabilities at unnecessary risk for institutionalization. Finally, these commenters urged OCR to state that the denial of services to individuals with disabilities due to inaccessible MDE is discrimination under other Federal disability rights laws, including section 504 and the ADA.

One commenter recommended that OCR require covered entities to ensure that within 30 days of the publication of the final rule, all newly purchased or replaced MDE comply with the MDE Standards. The commenter also recommended that OCR require all covered entities that use MDE to ensure that within two (2) years of the publication of this rule, all of their MDE meets the MDE Standards. A different commenter recommended that OCR use a similar approach to that required by the 2010 ADA Standards for Accessible Design, 75 FR 56236 (Sep. 15, 2010), where accessible MDE would be purchased to replace older equipment as needed.

Response: OCR appreciates the numerous comments requesting that the final rule require covered entities to comply with the MDE Standards. OCR agrees that when individuals with disabilities are denied appropriate preventative health care due to the

[289] Jane M. Zhu et al., *Phantom Networks: Discrepancies Between Reported and Realized Mental Health Care Access in Oregon Medicaid,* 41 Health Affairs 7, 1016 (2022), *https://www.healthaffairs.org/doi/abs/10.1377/hlthaff.2022.00052.*

[290] Such factors include ''the geographic location of the service area, the number of available providers and specialists in the service area, reimbursement rates, the number of providers willing to contract with the payer, and the overall design of the plan as it relates to premiums.'' 87 FR 47877. We note that the importance of geographic limitations may be reduced due to the industry growth in virtual care and ease of medical travel, where clinically appropriate.

[291] *See* Nat'l Council on Disability, *Enforceable Accessible Medical Equipment Standards: A Necessary Means to Address the Health Care Needs of People with Mobility Disabilities* (2021), *https://www.ncd.gov/assets/uploads/reports/ncd_medical_equipment_report_508.pdf.*

inaccessibility of MDE, they are placed at increased risk of poor health outcomes and potentially institutionalization. As noted, section 504, the ADA, and section 1557 all prohibit covered entities from discriminating against people with disabilities by denying them appropriate health care services. Requiring covered entities to comply with the MDE Standards would be one method to ensure that people with certain disabilities receive appropriate health care services, while allowing for greater patient autonomy.

On September 14, 2023, OCR issued an NPRM proposing updates to the Department's section 504 regulations.[292] OCR proposed specific accessibility standards, scoping requirements, and time periods for compliance for MDE used by recipients of Federal financial assistance in that NPRM.[293] Accordingly, while OCR recognizes the importance of ensuring that all people, regardless of disability status, receive effective preventative care, we will not address the MDE Standards in the regulatory text of this rulemaking.

Comment: Many commenters noted that while the MDE Standards were published in 2017, many providers, including recipients of Federal financial assistance, have failed to abide by the standards and acquire accessible MDE. As evidence, some commenters point to the data collected by the State of California concerning the prevalence of accessible MDE among providers, which they state indicates that the majority of California providers do not have accessible MDE.[294] These commenters note that until a Federal regulation creates specific requirements, accessible MDE will not be used by the majority of providers. Finally, commenters noted that even if providers acquire accessible MDE, they still must ensure that their staff are able to use the MDE effectively in order for people with disabilities to benefit.

Response: OCR recognizes that in the absence of an enforceable standard that requires providers to acquire MDE with specific features, providers may not acquire accessible MDE. This may be due in part to the cost of accessible MDE exceeding the cost of non-accessible MDE and the durability of existing MDE. OCR also agrees that if a provider acquires accessible MDE, such as an adjustable exam table, but does not ensure that staff can effectively use the table and assist patients with transfers, patients with disabilities will not benefit. For the MDE Standards to be effective, providers must also know how to use accessible MDE. OCR will continue to enforce existing nondiscrimination obligations and, as noted above, is in the process of rulemaking to adopt enforceable standards for accessible MDE under section 504.

Comment: Numerous commenters requested that OCR consider expanding on the existing MDE Standards. Some commenters requested that OCR create new standards specific to individuals with visual impairments, sensory limitations, or cognitive disabilities. Some commenters also requested that OCR expand the MDE Standards to non-diagnostic medical equipment in addition to MDE, with others, requesting that OCR determine the scoping requirements that covered entities would have to follow under the MDE Standards.

Response: OCR appreciates commenters' suggestions. Because we are not requiring providers to abide by the MDE Standards in this rulemaking, we will not determine whether to expand the MDE Standards beyond diagnostic equipment, create new standards unique to individuals with other disabilities, or determine the scoping requirements of the MDE Standards. However, we will consider these recommendations and note that regardless of whether medical equipment is diagnostic, a covered entity must make its health programs and activities accessible to individuals with disabilities.

Comment: Numerous commenters stated that because of inaccessible MDE, many patients with disabilities have been asked to bring someone with them to appointments in order to help them transfer onto MDE. The commenters state that it is never appropriate to require this of a patient.

Response: Existing Federal civil rights laws, including section 504, title II of the ADA, and the existing section 1557 implementing regulation, forbid providers from requiring a patient with a disability to bring their own aide or support person to an appointment to assist them with transfers. Any person who has been required by a provider to bring another person to an appointment to assist with transfers is encouraged to file a complaint with OCR.

Comment: One commenter stated that the use of accessible MDE could be considered a reasonable modification for persons with disabilities as required by existing disability rights laws.

Response: Providing accessible MDE is one method that providers can use to ensure that a patient with a disability is able to access a provider's programs and activities. A provider would likely violate Federal disability discrimination laws like section 504, the ADA, and section 1557 if the health programs and activities they provide, including preventative and diagnostic care, are not accessible to people with disabilities.

Comment: One commenter stated that while requiring covered entities to obtain and use accessible MDE would be beneficial to people with disabilities, in certain circumstances it may be sufficient for a covered entity without accessible MDE to offer transportation to another covered entity with accessible MDE.

Response: While a provider acquiring and using accessible MDE so that its patients with disabilities are able to receive health care in its offices is preferrable, there may be specific situations where it is appropriate for the provider to offer transportation to another facility that has accessible MDE.

Comment: Many commenters stated that they consider accessible MDE to raise both network adequacy and benefit design implications. They believed that a lack of accessible MDE leads to a lack of in-network care and a lack of network adequacy, which they alleged to be discriminatory. They stated that benefit design could be used to embed accessible MDE requirements. They also stated that accessibility should also be considered in conjunction with time and distance standards to determine network adequacy.

Response: OCR appreciates commenters raising these important opinions concerning how the presence of accessible MDE affects network adequacy and benefit design. While OCR has decided not to explicitly address accessible MDE in this rulemaking, we refer commenters to the discussion of network adequacy and benefit design under this section.

Summary of Regulatory Changes

For the reasons set forth in the Proposed Rule and considering the comments received, OCR is finalizing the nondiscrimination in health insurance coverage and other health-related coverage provision at § 92.207 as proposed, with modification. We have revised § 92.207(b)(6) to clarify that the integration requirement extends to practices that result in the serious risk of institutionalization or segregation. We have revised § 92.207(c) to strike the text following ''legitimate,

[292] 88 FR 63392 (Sept. 14, 2023).

[293] 88 FR 63392, 63511 (Sept. 14, 2023) (proposed subpart J).

[294] Nancy R. Mudrick et al., *Presence of Accessible Equipment and Interior Elements in Primary Care Offices,* 3.1 Health Equity 275 (2019), *https://dredf.org/wp-content/uploads/2019/10/Presence-of-Accessible-Equipment-and-Interior-Elements-in-Primary-Care-Offices.pdf.*

nondiscriminatory reason for'' and now the text prohibits ''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.'' This section also provides that ''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.'' We have also made conforming edits to include ''or any combination thereof'' to the list of prohibited bases of discrimination found § 92.207(a) and (b)(1) and (2).

Prohibition on Sex Discrimination Related to Marital, Parental, or Family Status (§ 92.208)

In § 92.208, OCR proposed to prohibit covered entities from discriminating on the basis of sex in their health programs and activities with respect to an individual's marital, parental, or family status. The 2016 and 2020 final rules did not include a similar provision. This is not a new concept, however, as it is similar to the Department's title IX implementing regulations. *See* 45 CFR 86.40(a). Section 92.208 provides that, 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 into account in applying any rule concerning an individual's current, perceived, potential, or past marital, parental, or family status.[295]

The comments and our responses regarding § 92.208 are set forth below.

Comment: Many commenters supported the inclusion of § 92.208 because it provides clarity for patients and providers and brings OCR into alignment with other nondiscrimination practices set by section 1557, ensuring that all vulnerable groups receive the same level of civil rights protections. Several commenters mentioned that this change aligned with the title IX regulation, which has, since 1975, explicitly interpreted sex discrimination to encompass discrimination on the basis of current, potential, or past parental, family, or marital status that treats persons differently on the basis of sex. Commenters also raised other civil rights statutes, like the Civil Service Reform Act that is applicable to Federal employees, which explicitly includes protections based on marital status.[296]

Response: OCR agrees that including this provision brings regulations in line with other civil rights laws that recognize policies that treat people differently on the basis of sex in applying rules related to marital, parental, or family status,[297] as discrimination on the basis of sex, particularly, and as stated in the Proposed Rule's preamble, the Department's longstanding acknowledgment of this interpretation of title IX, at 45 CFR 86.40(a).

Comment: Numerous commenters supported proposed § 92.208. Some of these commenters explained that taking marital, parental, or family status into account has engendered arbitrary policies at medical facilities that create barriers to accessing health care, which can result in harmful and inequitable treatment of individuals. Many commenters stated that this provision will help alleviate the denial of care some women experience because they are single, unmarried, childless, or not in the presence of a male partner or husband when they are seeking, for instance, birth control.

Response: OCR agrees that absent the prohibition on taking sex into account in marital, parental, or family status, covered entities may adopt arbitrary policies that could create unnecessary inequities and result in harmful health outcomes. Section 92.208 prohibits discrimination that applies different policies and procedures based on sex in the context of marital, parental, or family status; it does not, however, prohibit discrimination on the basis of marital status alone (*i.e.,* single, divorced, widowed, etc.). As discussed in the 2022 NPRM, OCR encountered complaints, in the course of its enforcement work, where covered entities applied different policies for married men and married women. For example, OCR has settled cases against covered entities with policies of automatically assigning a male spouse as the guarantor when a female spouse received medical services, while not automatically assigning a female spouse as the guarantor when a male spouse received medical services. 87 FR 78878.

Comment: Many commenters supported the protections against discrimination on the basis of sex in the context of marital, parental, and family status contained in § 92.208 because of their impact on same-sex couples and the varying types of discrimination that this group experiences, including past experiences of discrimination on the basis of marital, parental, and family status alone. For example, some commenters said that these protections are critical because, although many same-sex couples live in committed relationships, they are less likely to be married, largely due to laws that until recently prohibited same-sex marriage. These protections, commenters argued, help to insulate LGBTQI+ individuals who have experienced discrimination in many health care settings, such as hospitals where they have been denied visitation rights and authority to make medical decisions impacting their loved ones' health conditions. Many commenters highlighted that these forms of discrimination were well documented during the AIDS crisis, when longtime partners were regularly denied hospital visitation rights and lacked adequate protections, even for discrimination based solely on marital status. For similar reasons, some commenters stated that this provision would protect families headed by same-sex couples, who may be denied the right to make medical decisions for their children. These commenters noted, that in the health care context, the involvement of family and external support systems can improve health outcomes, management of chronic illnesses, and continuity of care.

Response: OCR agrees that the prohibition on taking an individual's sex into account in applying any rule concerning an individual's current, perceived, potential, or past marital, parental, or family status can be critical in health care settings involving medical decision-making and visitation rights, particularly for same-sex couples. Section 92.208 prohibits a covered entity from implementing a policy related to marital, parental, or family status that treats individuals differently on the basis of sex (*e.g.,* male spouses of women can make medical decisions for their children but non-male spouses of women cannot, or allowing visitation rights for a married heterosexual couple but denying visitation rights to a married same-sex couple), but it does not prohibit covered entities from making distinctions based upon their marital status alone (*e.g.,* applying different rules to married and nonmarried individuals that do not distinguish based on an individual's sex).

Comment: Other commenters also discussed the impact that the protections contained in proposed

[295] This final rule does not preclude the application of Federal laws regarding eligibility criteria for certain Federal programs under CMS.

[296] *See* Public Law 95–454, sec. 101, 92 Stat. 1111, 1113–14 (Oct. 13, 1978), codified at 5 U.S.C. 2301(b).

[297] The term ''family status'' used in this rule is distinct from any defined terms in other rules, including ''familial status'' as defined in the Fair Housing Act, 42 U.S.C. 3601 *et seq.*

§ 92.208 have on same-sex couples seeking fertility treatments. They stated that these protections are needed because some health insurance coverage or other health-related coverage include in vitro fertilization (IVF) treatments as a covered benefit for heterosexual married couples, but not for same-sex married couples. Some commenters highlighted how, in their view, institutional policies' definition of ''infertility'' lead to such a discriminatory practice. This establishes what commenters describe as an impossible standard for same-sex couples to meet when seeking fertility treatment and coverage.

Response: OCR understands that not all covered health insurance issuers offer fertility coverage or treatments. However, those that do must offer such benefits in a nondiscriminatory manner. For example, a covered health insurance issuer that offers fertility coverage or treatments for married different-sex couples could not deny the same coverage or treatments to married same-sex couples. section 1557's prohibitions of discrimination apply across all covered health programs and activities.

Comment: Other commenters who supported the inclusion of § 92.208 stated that these protections are important because they help ensure nondiscrimination against a wide range of family structures.

Response: OCR reminds commenters that this section prohibits discrimination on the basis of sex when applying rules related to marital, parental, and family status, and is not to be conflated with prohibition against discrimination on the basis of these statuses alone. Thus, policies and procedures that include conditions or limitations tied to these statuses would not run afoul of this rule unless they applied differently based on the sex of the individuals.

Comment: Some commenters supported § 92.208 because in their view, a medical practice cannot refuse a female patient solely because she has a female spouse or partner, as this could constitute a denial on the basis of association.

Response: OCR agrees that a medical practice may not refuse to see a prospective female patient based solely on the fact that the patient has a female spouse if they otherwise accept married individuals into their practice. This is because the refusal would be based on the sex of the prospective patient and would therefore constitute sex discrimination related to marital status. And, as noted in the Proposed Rule, a denial based on a female patient having a female spouse or partner would also constitute discrimination on the basis of association, which is specifically addressed in § 92.209, as the refusal would be based on the sex of an individual with whom the patient is known to have a relationship or association. 87 FR 47880.

Comment: Many commenters opposed the inclusion of § 92.208, stating that if Congress meant to include ''marital, parental, or family status'' in section 1557 it would have done so, just as it did in part in the Equal Credit Opportunity Act (ECOA) (including ''marital status'') and the Fair Housing Act (FHA) (including ''familial status''). These commenters contended that adding these protections would make the addition of marital and familial status a mere surplusage to the text of the ECOA and FHA, and that it would include additional terms to their application despite neither statute explicitly including the additional terms. Some commenters who opposed the provision also stated that OCR needs to account for the additional costs of including these changes, especially as it may impact religious institutions that provide marital counseling services.

Response: OCR disagrees that clarifying these protections under section 1557 impacts either the ECOA or FHA.[298] While these statutes bar discrimination on the basis of an individual's marital or familial status *per se,* § 92.208 bars discrimination on the basis of sex as it relates to marital and family status. As discussed in the 2022 NPRM, 87 FR 47878, this final rule's interpretation is consistent with a parallel, longstanding prohibition included in the Department's title IX implementing regulations, 45 CFR 86.40(a). OCR has consistently interpreted the scope of section 1557's prohibition on the ground of sex consistently with the scope of title IX's prohibition of discrimination on the ground of sex, which includes discrimination within the context of marital, parental, or family status.[299] This provision will apply similar standards already enforced by OCR, and we do not anticipate additional costs for covered entities, including religious institutions beyond the costs already captured in the Regulatory Impact Analysis below for recipients to seek assurances of religious and conscience exemptions under § 92.302(b).

Discrimination on the Basis of Pregnancy-Related Conditions

In proposing § 92.208, OCR stated its view that it could be beneficial to include a provision that would specifically prohibit discrimination on the basis of pregnancy-related conditions as a form of sex-based discrimination, and sought comment on how to include such a provision in the final rule. 87 FR 47879. This proposal was specifically requesting comment on a stand-alone provision, separate from the inclusion of ''pregnancy or related conditions'' in § 92.101(a)(2)'s inclusion of the term. Including such a provision at § 92.208 would mirror its placement to those of the Department's title IX implementing regulations at 45 CFR 86.21(c), 86.40, 86.52(b), and 86.57. The 2016 Rule explicitly included ''pregnancy, false pregnancy, termination of pregnancy, or recovery therefrom, childbirth or related medical conditions'' in former § 92.4. While the 2020 Rule did not include any definition of ''sex discrimination,'' it indicated that section 1557 would be enforced consistent with title IX and its implementing regulations, which includes these terms. For the reasons explained below, we decline to add ''pregnancy or related conditions'' to § 92.208.

The comments and our responses regarding this request for comment are set forth below.

Comment: Many commenters supported the inclusion of a provision that includes pregnancy-related conditions as a prohibited form of discrimination on the basis of sex. Numerous commenters discussed that pregnancy-related conditions are inherently linked to sex because discrimination on that basis affects an individual's ability to make decisions about their reproductive health and life, and affects individuals' ability to be equal and participating members of society.

Response: OCR appreciates these comments and agrees that clarifying that discrimination on the basis of sex includes pregnancy-related conditions, as § 92.101(a)(2)(ii) (''discrimination on the basis of sex includes . . . pregnancy or related conditions'') does, is critical to ensuring that individuals are protected against this form of sex discrimination. OCR also agrees that discrimination on the basis of

[298] *Cf. Conn. Nat'l Bank* v. *Germain,* 503 U.S. 249, 253 (1992) (courts must give effect to statutes with overlapping coverage ''so long as there is no 'positive repugnancy' between the two'').

[299] As discussed in the 2022 NPRM, 87 FR 47878, OCR has resolved complaints against covered entities with policies of automatically assigning a male spouse as the guarantor when a female spouse received medical services, while not automatically assigning a female spouse as the guarantor when a male spouse received medical services. *See* U.S. Dep't of Health & Hum. Servs., Off. for Civil Rts., *Sex Case Summaries: Summary of Selected OCR Compliance Activities, https://www.hhs.gov/civil-rights/for-providers/compliance-enforcement/examples/sex-discrimination/index.html.*

pregnancy or related conditions can negatively affect an individual's ability to make decisions about their reproductive health and life, and their ability to be equal and participating members of society.

Comment: Many commenters who supported the inclusion of pregnancy-related conditions discussed the need for clarity in light of the Supreme Court's decision in *Dobbs.* Commenters contended that pregnancy-related conditions should be included in the definition of ''sex discrimination'' because it would reinforce covered entities' legal obligations under section 1557, and would allow OCR to address related discrimination more holistically and inclusively.

Commenters maintained that pregnancy protections are critical in light of total or near-total abortion bans in some States after the *Dobbs* decision. Commenters explained that this legal uncertainty warrants clarity and explicit protections for pregnancy-related conditions, including termination of pregnancy, because patients and providers have been left uncertain and fearful of their ability to provide care, are subjected to additional scrutiny, and face the possibility of criminal prosecution and civil litigation in States that have limited reproductive health care options.

Response: OCR affirms that under section 1557, covered entities may not discriminate against individuals for their pregnancy-related decisions, past, present, or future. OCR declines to add in additional protections outside of the scope of this rule. At the same time, 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).[300] HHS will comply with this provision.

Comment: Some commenters discussed privacy concerns involving HIPAA, as some providers have worried that medical privacy may be compromised when patients seek care or information, even if unrelated to abortion. Commenters argued for the need to include pregnancy-related protections under section 1557 so that patients are not discriminated against for their pregnancy-related decisions, past, present, or future.

Response: OCR appreciates the privacy concerns raised by these commenters. OCR affirms that under section 1557, covered entities may not discriminate against individuals for their pregnancy-related decisions, past, present, or future, including where the patient discloses the information or where such information is contained in medical records. Indeed, HIPAA was enacted to protect such sensitive patient health information from being disclosed without the patient's consent or knowledge. Separately, OCR is considering revisions to the HIPAA Privacy Rule to strengthen privacy protections for individuals' protected health information related to reproductive health care. *See HIPAA Privacy Rule To Support Reproductive Health Care Privacy,* notice of proposed rulemaking, 88 FR 23506 (Apr. 17, 2023).

Comment: Other commenters urged OCR to address pregnancy-related conditions but to do so elsewhere in the rule, either in the provisions on what constitutes discrimination on the basis of sex (§ 92.101(a)(2)), equal program access on the basis of sex (§ 92.206(b)), or nondiscrimination in health insurance coverage (§ 92.207(b)). These commenters explained that confining the discussion of the pregnancy-related conditions to § 92.208 (Prohibition on sex discrimination related to marital, parental, or family status) risked a narrow interpretation and application of the prohibition, and could lead providers to consider this prohibition to be limited in context and scope. Commenters emphasized that pregnancy-related protections are relevant to a wide range of conduct beyond the context of marital, parental, or familial status and should not exclude individuals who are single. Commenters also raised that pregnancy-related discrimination applies to a broad scope of protected services, such as the decision to access certain reproductive health care services (*e.g.,* contraception), as well as denials of reproductive services and insurance coverage. Many commenters suggested that OCR include pregnancy-related conditions in a standalone provision, because OCR could then further clarify the interplay between section 1557 and other Federal statutes or regulations related to termination of pregnancy that may apply to covered entities.

Response: OCR appreciates these comments. In the 2022 NPRM, OCR considered including additional details regarding discrimination on the basis of ''pregnancy or related conditions'' in § 92.208 to mirror its placement to the Department's title IX implementing regulations at 45 CFR 86.21(c), 86.40, 86.52(b), and 86.57. However, having considered the comments received, OCR concluded that the rule is better served by leaving ''pregnancy or related conditions'' in § 92.101(a)(2), which outlines the scope of discrimination on the basis of sex. The Department believes § 92.101(a)(2)—which addresses forms of sex discrimination generally—is a better location, so as to not suggest that discrimination based on pregnancy or its related conditions is limited to instances of discrimination involving only marital, parental, or family status.

Comment: Many commenters supported the inclusion of pregnancy-related conditions, but suggested additional changes to the rule, including explicit descriptions of what pregnancy or related conditions encompasses. Several commenters encouraged OCR to add language establishing that pregnancy-related conditions specifically include pregnancy termination, childbirth, false pregnancy, ectopic pregnancy, miscarriage, and recovery, including any refusal of service or procedure based on any other protected basis under the rule.

Response: OCR agrees that protections for ''pregnancy or related conditions'' are critical and affirms that covered entities may not discriminate against individuals based on pregnancy or related conditions under section 1557. However, additional language to identify what the term ''pregnancy or related conditions'' means is not necessary given that the regulatory language is not intended to be exhaustive as explained above. As noted in the NPRM, OCR understands the term as including childbirth, false pregnancy, termination of pregnancy, and recovery therefrom, which are the ''grounds'' prohibited under title IX.[301] 87 FR 47878.

Comment: Some commenters opposed the inclusion of pregnancy-related conditions. One commenter cautioned OCR to not rely on the *Dobbs* decision or its effects as a basis for prohibiting discrimination on pregnancy-related conditions, including pregnancy termination. Some commenters stated *Dobbs* held that the regulation of abortion was returned to the States, and thus, OCR cannot propose a provision that is inclusive of abortion, which would be contrary to Congressional and judicial prohibitions. Other commenters, despite acknowledging

[300] The application of this final rule to covered entities with conscience or religious freedom objections are discussed more fully below in §§ 92.3 (Relationship to other laws) and 92.302 (Notification of views regarding application of Federal religious freedom and conscience laws).

[301] 45 CFR 86.40(a).

that the title IX regulations have since 1975 included ''pregnancy and related conditions'' (which includes termination of pregnancy), argued that because the term ''termination of pregnancy'' is not defined in the title IX regulations, the term should not be adopted here. A commenter suggested that OCR either not include ''termination of pregnancy'' as a pregnancy-related condition or clarify that ''termination of pregnancy'' does not include abortion because abortion is not morally equivalent to pregnancy or childbirth and should not be treated as such. Some commenters who opposed including pregnancy-related conditions argued that if the final rule includes such a term, OCR must account for its impact.

Response: OCR appreciates comments regarding the inclusion of ''pregnancy or related conditions,'' including those concerns related to *Dobbs.* OCR is not promulgating this rule in response to *Dobbs,* which addressed the question of whether the Constitution provides a right to abortion. This rule does not purport to interpret the Constitution, nor does it address whether States may regulate or ban abortions. Indeed, we emphasize that section 1303 of the ACA specifically states that ''[n]othing in this Act shall be construed to preempt or otherwise have any effect on State laws regarding the prohibition of (or requirement of) coverage, funding, or procedural requirements on abortions, including parental notification or consent for the performance of an abortion on a minor.'' 42 U.S.C. 18023(c)(1). Pursuant to that provision, this rule should not be read to override any such State abortion laws. OCR reiterates that 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 care, based on a professional or business judgement about the scope of services it wishes to offer, or for any other nondiscriminatory reason.

This rule implements section 1557 of the ACA, which prohibits discrimination on the basis of race, color, national origin, sex, age, or disability in covered health programs or activities by incorporating the ''grounds prohibited under'' title VI, title IX, the Age Act, and section 504. Under title IX, discrimination based on pregnancy has been understood to constitute sex discrimination since 1975. Consistent with this long-standing interpretation, OCR will consider complaints of sex discrimination, including discrimination based on pregnancy or related conditions, on a case-by-case basis, and it will look to title IX and section 1557 case law to determine whether discrimination on the basis of sex has occurred. OCR is unaware of any instance in which a covered entity has been required to provide an abortion under title IX, title VI, the Age Act, or section 504.

Consistent with this understanding of the incorporated statutes, the relevant case law, and historical practice, OCR emphasizes that a covered provider's decision not to provide abortions is not itself sex 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. As noted above, a covered provider that generally offered abortion care could violate that prohibition if, for example, it generally offers or provides abortions to patients but refused to offer or provide an abortion to a particular patient because of that patient's 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.

Comment: Many commenters stated that *Dobbs* prevents OCR from protecting access for abortion care through its proposed definition of sex, because the Supreme Court held there is no constitutional right to an abortion and returned the issue to the States. Other commenters also stated that, because *Dobbs* returned the issue of abortion to the States, OCR cannot create regulations that would create conflicts with State laws banning or restricting abortion. Additionally, these commenters raised section 1303 as another basis under which the ACA prohibits OCR from issuing regulations that preempt State laws regarding abortion.

Other commenters raised the view that *Dobbs* reaffirmed *Bray* v. *Alexandria Women's Health Clinic,* 506 U.S. 263 (1993), which held that opposition to abortion does not constitute animus against women. They contend that OCR cannot therefore define sex to include pregnancy termination. Commenters also stated that *Dobbs* established that there is no compelling government interest in promoting abortion, and therefore OCR has no authority to promulgate rules in support of abortion. A few commenters expressed that under the ''major questions'' doctrine, OCR cannot set an abortion policy such as prohibiting discrimination on the basis of pregnancy termination without explicit authorization from Congress.

Response: OCR appreciates the commenters' concerns and their interpretation of *Dobbs.* The *Dobbs* opinion did not address title IX or section 1557. *Dobbs* nowhere prohibits OCR from issuing regulations or promulgating rules under its statutory authorities. Indeed, under section 1557, HHS is charged by Congress with the elimination of discriminatory barriers in the administration and provision of a diverse range of health programs and activities.

As OCR has previously stated, this rule does not establish a Federal policy requiring or promoting abortion services. Although OCR has concluded that section 1557 does not require the Department to incorporate the language of title IX's abortion neutrality provision, see § 92.208 (Prohibition on sex discrimination related to marital, parental, or family status), as we note throughout this preamble, OCR emphasizes that a covered provider's decision not to provide abortions does not itself constitute discrimination in violation section 1557. Section 1557 prohibits discrimination on the basis of race, color, national origin, sex, age, or disability in covered health programs or activities.

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).

OCR's interest is protecting individuals against prohibited forms of discrimination under section 1557 when accessing the range of health programs and activities covered under the statute. OCR also disagrees that the ''major questions'' doctrine is implicated by its promulgation of rules that protect individuals from discrimination on the basis of sex consistent with the manner in which the term has long been interpreted in the title IX context.

Comment: Many commenters stated that *Dobbs* had—and continues to have—a significant impact that warrants section 1557's protections against

discrimination on the basis of pregnancy or related conditions. Many commenters discussed that *Dobbs* limited access to abortion nationwide and created a complex web of State laws that ban or severely restrict access to care. These commenters stated that certain communities, including people of color, people with low incomes, immigrants, young people, people with disabilities, and LGBTQI+ individuals are most likely to face legal barriers to accessing abortion care, including an increased threat of arrest and prosecution in States hostile to abortion.

Many commenters also posited that States' efforts to restrict access to abortion have resulted in further challenges to accessing other reproductive health care, including contraception, fertility care and treatment, and miscarriage or early pregnancy loss management. Commenters cited examples from multiple States where women experiencing miscarriages have been denied care even as their pregnancy-related complications threaten their health and lives.

Response: OCR understands commenters' concerns regarding the negative health impacts stemming from the *Dobbs* decision, including on those with pregnancy-related conditions. We emphasize, as we have repeatedly throughout this preamble, that this rule is neither a response to *Dobbs* nor affected by that decision. This rule rests on the application of section 1557's nondiscrimination prohibition, and the longstanding interpretation of title IX's prohibition on sex discrimination to include discrimination on the basis of pregnancy and related conditions.

Comment: Many commenters raised concerns about access to prescriptions related to contraception, miscarriages or early pregnancy loss, and medication abortion. Commenters also raised concerns about access to drugs prescribed to treat conditions like chronic disease or illness that are unrelated to abortion, but may have the effect of terminating a pregnancy. Some commenters explained that pharmacists are fearful about dispensing medications that could terminate a pregnancy even when the medication is not prescribed for the purpose of abortion, and in some instances, pharmacists have refused to fill prescriptions in certain States that have banned abortion.

In States that have banned abortion, commenters noted that physicians, health care providers, and pharmacists fear they will be criminally prosecuted under State law, leading to denials or delays in lawful access to medications to treat conditions unrelated to abortion. For instance, many commenters explained that certain drugs prescribed to treat health conditions such as cancer, arthritis, ulcers, autoimmune diseases, or other chronic conditions are being denied or limited because they can result in termination of a pregnancy. Specifically, commenters relayed that some treatments for conditions such as breast cancer, brain cancer, prostate cancer, alcoholism, post-traumatic stress disorder, and depression involve drugs that are being denied because of an indirect potential relationship with pregnancy termination.

Similarly, many commenters requested clarification that section 1557's prohibitions on discrimination protect access to contraception in the retail pharmacy setting. They raised concerns and described instances where individuals are denied access to hormonal contraception at a pharmacy that provides other forms of contraceptives. Some commenters opined that a pharmacy's refusal to provide prescribed medication to enable IUD (intrauterine device) insertion, or to treat an incomplete miscarriage, should be considered a section 1557 violation.

Commenters were concerned that such discrimination is not only sex and disability discrimination, but also creates additional and unnecessary barriers to prescription drugs that people need to live and maintain their health. For example, many commenters discussed that people with disabilities are increasingly denied or subjected to barriers to obtaining methotrexate, which is a prescription drug used to treat cancer and autoimmune conditions, because of the drug's potential effects on pregnancy. Many commenters explained that a pharmacist's refusal to fill an individual's prescription or a pharmacist's decision to not stock a specific drug or class of drugs inevitably harms persons with disabilities and women, especially those experiencing miscarriages and early pregnancy loss. They stated that women are also more likely than men to have autoimmune diseases for which many of these drugs are prescribed.

Response: OCR appreciates comments relating to access to lawfully prescribed and medically necessary medications. To start, OCR notes that, on September 29, 2023, after the close of the comment period for this rule, OCR issued revised guidance to pharmacies that supersedes the guidance referred to by some commenters.[302] If a covered entity denies or delays lawful access to medications to support persons with disabilities, treat cancer, or treat an autoimmune condition, that refusal could violate section 1557 if, for example, the refusal is on the basis of a prohibited ground, such as the person's race, age, disability, or sex. But, as OCR clarified in its updated guidance to the nation's pharmacies, section 1557 does not require pharmacies to fill prescriptions for medication for the purpose of abortion, nor does the guidance suggest or imply an obligation of pharmacies to fill prescriptions for medication in violation of State laws, including those banning or restricting abortion.[303] OCR provided several examples in the guidance, in which denying lawfully prescribed medication to customers may violate civil rights laws.[304] For example, where a treating physician diagnoses a miscarriage complicated by a uterine infection and orders an antibiotic to treat a patient's chills, fever, and vaginal bleeding, a pharmacy that refuses to provide the antibiotic because of concern that subsequent care may include an abortion may be discriminating on the basis of sex. OCR will evaluate and apply all applicable statutory protections, including relevant religious freedom and conscience protections, on a case-by-case basis.

In addition, the ACA is hardly silent on the issue of abortion. It contains an elaborate set of rules for when and how a qualified health plan may refuse or be prohibited from providing or paying for certain abortions. See 42 U.S.C. 18023(a)–(b). It further specifies that State laws regarding abortion are not preempted and that ''nothing in this act shall be construed to have effect on federal laws regarding—(i) conscience protections; (ii) willingness or refusal to provide abortion; and (iii) discrimination on the basis of willingness or refusal to provide, pay

---

[302] *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.* On April 5, 2024, the court in *State of Texas* v. *Becerra et al.,* No. 7:23–cv–00022–DC, Order for S.J., ECF No. 69 (W.D. Tex.), held that the revised guidance mooted plaintiffs' legal challenge to the superseded guidance.

[303] *See* U.S. Dep't of Health & Hum. Servs., *Guidance to Nation's Retail Pharmacies: Obligations under Federal Civil Rights Laws to Ensure Nondiscriminatory Access to Health Care at Pharmacies* (September 29, 2023), *https://www.hhs.gov/civil-rights/for-individuals/special-topics/reproductive-healthcare/pharmacies-guidance/index.html* (''nor does the guidance suggest or imply an obligation of pharmacies to fill prescriptions for medication in violation of State laws, including those banning or restricting abortion'').

[304] *Id.*

for, cover, or refer for abortion or to provide or participate in training to provide abortion.'' *Id.* at 18023(c).

Comment: OCR sought comment on the title IX abortion neutrality provision's inclusion and on other possible readings of that provision. Although OCR also sought comment on whether the Department should align its title IX regulation regarding the abortion neutrality provision of title IX with the 2000 ''Common Rule'' version of that regulatory provision that more than 20 agencies have long adopted,[305] no comments addressed this specifically. Many commenters supported OCR's proposal to not import the language of title IX's abortion neutrality provision into section 1557's final rule. Doing so, they contended, would undermine and be contrary to OCR's implementation of section 1557, which is to eliminate barriers and expand access to health care and coverage. These commenters discussed how abortion is a critical form of health care and patients seek or need to terminate a pregnancy for a wide variety of reasons.

Response: OCR's determination to not incorporate title IX's abortion neutrality provision is based on our conclusion that doing so is not required and unnecessary as the ACA itself speaks to this issue. The ACA provides that nothing in the statute, 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). By contrast, the ACA does not contain specific language directing the incorporation of title IX's abortion neutrality provision. That section 1557 does not require its incorporation is therefore the better reading of the statute with regard to title IX. We reiterate, moreover, that this rule does not—and indeed, cannot—create a right to abortion; it operates only to prohibit discrimination on specific prohibited grounds.

Comment: Several commenters highlighted the differences between section 1557's coverage of health care from title IX's coverage of education because the decision to receive health care from a particular provider is often driven by factors, including geographic location, cost, insurance coverage, the type of care being sought, and the urgency of that care. Many other commenters stated that importing title IX's abortion neutrality provision would allow denials of care that can directly harm patients, including putting at risk a patient's life or health.

Response: OCR agrees with commenters that health care is fundamentally different from education. And although section 1557 incorporates ''the ground prohibited under'' title IX and the ''enforcement mechanisms provided for and available under'' that statute, 42 U.S.C. 18116(a), it does not incorporate title IX's other provisions. Title IX's abortion neutrality provision does not purport to define what constitutes prohibited sex discrimination under title IX—the ''ground prohibited'' under that statute—and it is not an enforcement mechanism; it provides only that nothing in title IX shall be construed to require or prohibit any person or entity to provide or pay for abortion or related benefit or service.

Congress made clear that the ACA, including section 1557, would have no effect on several specific Federal laws protecting individuals and entities that refuse to provide abortions. *See* 42 U.S.C. 18023(c)(2)(A). The ACA itself restates provisions of longstanding Federal law by making clear in 18023(c)(2)(A) that ''nothing in this act shall be construed to have effect on federal laws regarding—(i) conscience protections; (ii) willingness or refusal to provide abortion; and (iii) discrimination on the basis of willingness or refusal to provide, pay for, cover, or refer for abortion or to provide or participate in training to provide abortion.'' These provisions reiterate existing Federal restrictions on abortion. For example, the Weldon Amendment forbids funds appropriated to HHS from being ''made available to a Federal agency or program, or to a State or local government, if such agency, program, or government subjects any institutional or individual health care entity to discrimination on the basis that the health care entity does not provide, pay for, provide coverage of, or refer for abortions.'' [306] The Coats-Snowe Amendment forbids discriminating against an entity that refuses to undergo training in performance of or referrals for abortions.[307] The Church Amendment forbids requiring any individual ''to perform or assist in the performance of any part of a health service program . . . if his performance or assistance in the performance of such part of such program . . . would be contrary to his religious beliefs or moral convictions.'' [308] It also provides that an entity's receipt of any grant, contract, loan, or loan guarantee under the Public Health Service Act, the Community Mental Health Centers Act, or the Developmental Disabilities Services and Facilities Construction Act ''does not authorize any court or any public official or other public authority to require . . . such entity to . . . make its facilities available for the performance of any sterilization procedure or abortion if the performance of such procedure or abortion in such facilities is prohibited by the entity on the basis of religious beliefs or moral convictions.'' [309] The Church Amendments also prohibit discrimination against health care personnel related to their employment or staff privileges because they ''performed or assisted in the performance of a lawful sterilization procedure or abortion.'' [310] The same nondiscrimination protections also apply to health care personnel who refuse to perform or assist in the performance of sterilization procedures or abortion.[311] In addition, some of HHS's programs and services are specifically governed by abortion restrictions in the underlying statutory authority or program authorization.[312] The ACA also contains a variety of ''special rules'' that apply specifically to

[305] *See* 65 FR 52869 (Aug. 30, 2000); *see also, e.g.,* 28 CFR 54.235(d)(1) (DOJ regulation). The agencies that have adopted the Common Rule include: Agency for International Development, 22 CFR part 229; Corporation for National and Community Service, 45 CFR part 2555; Department of Agriculture, 7 CFR part 15d.; Department of Commerce, 15 CFR part 8a; Department of Defense, 32 CFR part 196; Department of Energy, 10 CFR part 1040; Department of Homeland Security, 6 CFR part 17; Department of Housing and Urban Development, 24 CFR part 3; Department of the Interior, 43 CFR part 41; Department of Justice, 28 CFR part 54; Department of Labor, 29 CFR part 36; Department of State, 22 CFR part 146; Department of Transportation, 49 CFR part 25; Department of the Treasury, 31 CFR part 28; Department of Veterans Affairs, 38 CFR part 23; Environmental Protection Agency, 40 CFR part 5; Federal Emergency Management Agency, 44 CFR part 19; General Services Administration, 41 CFR part 101–4; National Aeronautics and Space Administration, 14 CFR part 1253; National Archives and Records Administration, 36 CFR part 1211; National Science Foundation, 45 CFR part 618; Nuclear Regulatory Commission, 10 CFR part 5; Small Business Administration, 13 CFR part 113; and Tennessee Valley Authority, 18 CFR part 1317.

[306] Consol. Appropriations Act, 2024, Public Law 118–47, div. H, tit. V, section 507(d)(1), 138 Stat. 460, 703 (Mar. 23, 2024). *See also, e.g., id.* sections 506–07, 138 Stat. 460, 703 (Hyde Amendment provisions).

[307] 42 U.S.C. 238n(a).

[308] 42 U.S.C. 300a–7(d).

[309] 42 U.S.C. 300a–7(b)(2)(A).

[310] 42 U.S.C. 300a–7(c)(1); *see also* U.S. Dep't of Health & Hum. Servs., *Guidance on Nondiscrimination Protections under the Church Amendments, https://www.hhs.gov/conscience/conscience-protections/guidance-church-amendments-protections/index.html.*

[311] 42 U.S.C. 300a–7(c)(1).

[312] *See, e.g.,* title X of the PHS Act, 24 U.S.C. 300a–6; section 1303(b)(4) of the ACA, 42 U.S.C. 18023.

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

providers may rely on the protections in Federal law for religious freedom and conscience or seek assurance of such protections from OCR, if they wish.

Comment: Many commenters who objected to OCR's proposal not to import title IX's abortion neutrality provision in this rule expressed concern regarding the Proposed Rule's discussion of EMTALA and emergency medical conditions that may necessitate abortion. Some commenters opined that the Proposed Rule's preamble was a potential regulatory change by HHS to designate an ''abortion mandate'' in EMTALA. Some commenters also noted that such an ''abortion mandate'' meant that HHS could preempt State laws that prohibit abortion or alter State licensing and health and safety laws. Other commenters raised the ''major questions'' legal doctrine to conclude that Congress would not have granted HHS the authority to promulgate such rules that would rewrite the text of EMTALA on any grounds, including on the issue of abortion.

Response: These comments fall outside the scope of the final rule. To be clear, EMTALA does not alter any of section 1557's requirements, and this rule does not alter existing obligations under EMTALA, or any of the Department's previous guidance regarding EMTALA. Thus, nothing about the final rule imposes any change to EMTALA's statutory scheme, let alone a ''radical or fundamental change'' such that the major questions doctrine is implicated.[314] Further, commenters' view that the ''major questions'' legal doctrine applies is also misplaced. The ''major questions'' doctrine applies in certain ''extraordinary cases'' in which courts will refuse to defer to agency action it considers having ''vast economic and political significance'' absent express authorization from Congress.[315] As described, the final rule does not alter any existing obligations or guidance as to EMTALA. The ''major questions'' doctrine is not relevant here.

Additionally, there is no basis for commenters' concerns about a potential regulatory change or preemption of State laws, including those involving licensing and health and safety. Per the ACA itself, this rule does not override State laws regarding ''the prohibition of (or requirement of) coverage, funding, or procedural requirements on abortions'' or alter preexisting obligations under Federal law. *See* 42 U.S.C. 18023(c)(1), (d).

Comment: Other commenters stated that the *Franciscan Alliance* opinion vacating provisions similarly related to pregnancy-related conditions in the 2016 Rule precludes OCR from issuing this final rule with similar provisions that do not import title IX's abortion neutrality provision. Some commenters maintained that if OCR promulgates this rule with similar provisions, OCR risks being held in contempt of court. Other commenters stated that to adequately issue this final rule, OCR must explain why the holdings of the *Franciscan Alliance* court are incorrect or inapplicable to this rulemaking.

Response: OCR appreciates commenters' concerns, but notes that they mischaracterize the impact of the relief ordered in *Franciscan Alliance* on this rulemaking. The *Franciscan Alliance* court vacated a portion of the 2016 Rule—namely its interpretation of sex discrimination to include gender identity and termination of pregnancy.[316] The court also enjoined the Federal Government from interpreting or enforcing section 1557 or any related implementing regulations against the plaintiffs in that particular case in a manner that would require those plaintiffs to perform or provide insurance coverage for gender-transition procedures or abortions.[317] The court's orders have no effect on, and do not apply to, OCR's authority to promulgate new regulations, including this final rule, and to enforce those regulations against covered entities that were not plaintiffs in *Franciscan Alliance.* The instant rulemaking is new and includes significant changes that address concerns raised against the 2016 Rule in *Franciscan Alliance.* Also notable is the fact that § 92.302 outlines new procedures whereby persons may rely on the protections of Federal conscience or religious freedom laws or choose to seek assurance of such protections, if they wish. And OCR has issued a separate final rule codifying safeguards for Federal conscience protections. *See* 89 FR 2078 (Jan. 11, 2024). In addition, OCR has considered the legal and factual developments since the issuance of the 2016 Rule, which help to inform its decisions in this final rule. Therefore, OCR's promulgation of its new regulation in no way contravenes the *Franciscan Alliance* court's orders, and OCR will comply with that court's orders, and all other applicable orders, in enforcing this final rule. OCR thus disagrees that issuing this rule puts the agency at risk of being held in contempt, merely for acting within the authority that has been lawfully delegated to HHS under section 1557.

Comment: Some commenters requested that OCR provide clarification, either in a final rule or via sub-regulatory guidance, as to how the proposed pregnancy discrimination protections relate to and may be different from those guaranteed by the Pregnancy Discrimination Act of 1978.

Response: OCR appreciates these commenters' request and is intent on providing clear guidance on the scope of the final rule and its application through educational outreach efforts, trainings, and individualized assistance. OCR clarifies that it does not enforce the Pregnancy Discrimination Act of 1978, Public Law 95–555, which amended title VII, and applies to discrimination on the basis of pregnancy, childbirth, or related medical conditions in employment settings, while section 1557 applies to health programs or activities that receive Federal financial assistance. We also note that section 1557, title IX, and title VII are read consistently to apply similar protections in the different contexts in which they apply.

Comment: Other commenters expressed concern that *Dobbs* created tension between health care providers and patients, increasing distrust in providers. Commenters also stated that *Dobbs* has created chaos in the health care system, increasing the risk that patients will experience discriminatory care and suffer delays in lifesaving treatment as a direct result of legal and medical uncertainty. These commenters said that discrimination in care propagates more distrust, which is a significant barrier for individuals seeking care and is precisely what section 1557 was designed to protect against.

Response: OCR appreciates the commenters' concerns. OCR understands that the provider-patient relationship is critical to the provision of quality, competent health care and critical for achieving optimal health. For example, in proposing the policies and procedures required under § 92.8, OCR confirmed that patients value the ability to have their concerns directly heard by

[314] *West Virginia* v. *EPA,* 597 U.S. 697, 723 (2022).

[315] *West Virginia* v. *EPA,* 597 U.S. at 716 (Invalidating the Environmental Protection Agency's plan to require power plants to shift from coal to renewables, reducing gross domestic product by at least a trillion dollars within two decades); *Nat'l Fed. of Indep. Business* v. *OSHA,* 142 S. Ct. 661, 665 (2022) (per curiam) (Invalidating the Occupational Safety and Health Administration order requiring ''84 million Americans to either obtain a COVID–19 vaccine or undergo weekly medical testing'').

[316] *Franciscan All., Inc.* v. *Azar,* 414 F. Supp. 3d 928, 945–47 (N.D. Tex. 2019).

[317] *Franciscan All., Inc.* v. *Becerra,* 553 F. Supp. 3d 361, 378 (N.D. Tex. 2021).

their provider,[318] and understands that not all communities in the United States feel the same level of trust in their health care provider, particularly among racially and ethnically diverse communities.[319] OCR further recognizes that in light of *Dobbs,* in certain States, a patient may fear sharing critical information relevant to their health status. OCR is separately considering revisions to the HIPAA Privacy Rule to strengthen privacy protections for individuals' protected health information related to reproductive health care, which will assist in generating more trusting patient-provider relationships. *See* HIPAA Privacy Rule To Support Reproductive Health Care Privacy, notice of proposed rulemaking, 88 FR 23506 (Apr. 17, 2023).

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 § 92.208, with modification. For clarity, we are finalizing by adding a cross-reference to § 92.101(a)(2)'s description of sex discrimination.

Nondiscrimination on the Basis of Association (§ 92.209)

In § 92.209, we proposed prohibiting discrimination against an individual on the basis of the race, color, national origin, sex, age, or disability of an individual with whom the individual is known to have a relationship or association.

The comments and our responses regarding proposed § 92.209 are set forth below.

Comment: Commenters on this provision overwhelmingly expressed support for the inclusion of an explicit prohibition on associational discrimination, which many stated will protect individuals, including children and elders, who associate with LGBTQI+ individuals. Other commenters said that a prohibition of associational discrimination will also protect individuals and families who associate with an individual who has a history of drug use or substance use disorder (SUD). Some commenters noted that the 2020 Rule repealed the 2016 Rule's associational discrimination protections at former 45 CFR 92.209, despite comments urging OCR to maintain the provision. Many commenters noted that courts have recognized an individual's right to be free from discrimination based on their association with another an individual protected on one or more bases under section 1557.[320]

Response: OCR agrees that it is important to include an explicit provision addressing associational discrimination, as both consistent with courts' interpretation of what constitutes discrimination as well as to protect those experiencing such forms of discrimination.[321] As commenters noted, this particularly impacts LGBTQI+ people because significant numbers of children and elders live with or are cared for by LGBTQI+ people,[322] and some providers have refused to provide health care to children, for example, because their parents are gay or lesbian.[323] This is

[318] Leslie Read et al., The Deloitte Ctr. for Health Solutions, *Rebuilding Trust in Health Care: What Do Consumers Want—and Need—Organizations to Do?,* p. 3 (2021) (''62% [of surveyed people of color] want their local hospitals to ensure patients have a voice to relay their experiences and take action to address their problems.''), *https://www2.deloitte.com/us/en/insights/industry/health-care/trust-in-health-care-system.html.*

[319] Leslie Read et al., The Deloitte Ctr. for Health Solutions, *Rebuilding Trust in Health Care: What Do Consumers Want—and Need—Organizations to Do?* (2021); *https://www2.deloitte.com/us/en/insights/industry/health-care/trust-in-health-care-system.html.*

[320] *Falls* v. *Prince George's Hosp. Ctr.,* No. Civ. A 97–1545, 1999 WL 33485550 at *11 (D. Md. Mar. 16, 1999) (holding that parent had an associational discrimination claim under section 504 when hospital required hearing parent to act as interpreter for child who was deaf); *Holcomb* v. *Iona Coll.,* 521 F.3d 130 (2nd Cir. 2008) (an employee has a cognizable title VII claim against an employer who takes an adverse action against the employee because of the employee's association with a person of another race); *Larimer* v. *Int'l Bus. Machines Corp.,* 370 F.3d 698, 702 (7th Cir. 2004) (the court affirmed lower court's summary judgment in favor of defendant employer, in part, because plaintiff employee's employment claim did not fit into any one of three recognized categories of associational discrimination under the ADA); *Loeffler* v. *Staten Island Univ. Hosp.,* 582 F.3d 268, 279 (2d. Cir. 2009) (court permitted associational discrimination claim brought by deaf father's children who were forced to interpret for him in the hospital); *Mx Grp., Inc.* v. *City of Covington,* 293 F.3d 326, 335 (6th Cir. 2002) (holding a drug and alcohol treatment center that was wrongfully denied a zoning permit because it provided services to individuals with disabilities was subjected to discrimination under title II of the ADA); *Barrett* v. *Whirlpool Corp.,* 556 F.3d 502, 512 (6th Cir. 2009) (title VII and sec. 1981 forbid employment discrimination on the basis of association with or advocacy for a protected party); *Tetro* v. *Elliot Popham Pontiac, Oldsmobile, Buick, & GMC Trucks, Inc.,* 173 F.3d 988, 994–95 (6th Cir. 1999) (court reversed lower court's dismissal of plaintiff's associational discrimination claim because title VII prohibits such discrimination); *Deffenbaugh-Williams* v. *Wal-Mart Stores, Inc.,* 156 F.3d 581, 589 (5th Cir. 1998) (court upheld jury's determination that employer wrongfully terminated employee based on employee's association with a Black person) vacated in part on other grounds by *Williams* v. *Wal-Mart Stores, Inc.,* 182 F.3d 333 (5th Cir. 1999) (en banc); *Parr* v. *Woodmen of the World Life Ins. Co.,* 791 F.2d 888, 892 (11th Cir. 1986) (trial court erred in dismissing plaintiff's associational discrimination claim because § 1981 prohibits associational discrimination); *Hively* v. *Ivy Tech Cmty. Coll. of Ind.,* 853 F.3d 339, 345 (7th Cir. 2017) (finding plaintiff had a case for sex discrimination in part based on the gender and orientation of her partner); *Zarda* v. *Altitude Express,* 883 F.3d 100, 124 (2d Cir. 2018), (court held that prohibition of associational discrimination applies with equal force to all the classes protected by title VII); *Videckis* v. *Pepperdine Univ.,* 150 F. Supp. 3d 1151, 1161 (C.D. Cal. 2015) (sexual orientation discrimination is sex discrimination in part because it involves treatment that was based on the sex of the person(s) with whom the individual associates); *Baldwin* v. *Foxx,* 2015 WL 4397641 (EEOC July 15, 2015) (''Sexual orientation discrimination is also sex discrimination because it is associational discrimination on the basis of sex.''); *Kauffman* v. *Maxim Healthcare Servs., Inc.,* No. 04–CV–2869, 2006 WL 1983196, at *3 (E.D.N.Y. July 13, 2006) (''Although Defendant correctly points out that the Second Circuit has not recognized as valid causes of action third-party claims of association discrimination or retaliation like those presented in the instant case, there is nevertheless a wealth of support in the prior decisions of the courts in this Circuit and our highest Court for recognizing these types of claims.'').

[321] *See Kengerski* v. *Harper,* 6 F.4th 531, 537–539 (3d Cir. 2021) (a white plaintiff employee's claim is justiciable under an associational discrimination legal theory under title VII of the Civil Rights Act of 1964, where his employer retaliated against him for complaining about a supervisor's racist remarks directed at the employee's biracial family member and other minority coworkers); *Kelleher* v. *Fred A. Cook, Inc.,* 939 F.3d 465, 469–470 (2d Cir. 2019) (an employer's reaction to a non-disabled employee's reasonable accommodation request to care for disabled dependent can support an inference of associational discrimination); *McGinest* v. *GTE Serv. Corp.,* 360 F.3d 1103, 1118 (9th Cir. 2004) (case involving indirect comments in the workplace that crossed racial lines, noting that ''Title VII has . . . been held to protect against adverse employment actions taken because of the employee's close association with black friends or coworkers'') (internal citations omitted); *Johnson* v. *Univ. of Cincinnati,* 215 F.3d 561, 574 (6th Cir. 2001) (a plaintiff who is not a member of a recognized protected class nevertheless alleges a cognizable discrimination claim under title VII and 42 U.S.C. 1981 if he alleges that he was discriminated against based on his association with a member of a recognized protected class); *Tetro* v. *Elliot Popham Pontiac, Oldsmobile, Buick & GMC Trucks Inc.,* 173 F.3d 988, 994–95 (6th Cir. 1999) (holding that white plaintiff with biracial child stated a claim under title VII based on his own race ''even though the root animus for the discrimination is a prejudice against the biracial child''); *Parr* v. *Woodmen of the World Life Ins.,* 791 F.2d 888, 892 (11th Cir. 1986) (''Where a plaintiff claims discrimination based upon an interracial marriage or association, he alleges by definition that he has been discriminated against because of his race.''). *Cf. Loving* v. *Va.,* 388 U.S. 1 (1967).

[322] Family Equality Council, *LGBTQ Family Fact Sheet, https://www2.census.gov/cac/nac/meetings/2017-11/LGBTQ-families-factsheet.pdf,* (as of 2017, between 2 and 3.7 million children in the US have LGBTQ+ parents); Family Equality Council, *LGBTQ Family Building Survey* (2019), *https://www.familyequality.org/wp-content/uploads/2019/02/LGBTQ-Family-Building-Study_Jan2019-1.pdf* (77 percent of LGBTQ+ millennials either are already parents or are considering expanding their families in the years ahead); SAGE, *Caregiving in the LGBT Community* (2017), *https://www.lgbtagingcenter.org/resources/pdfs/SAGE%20Caregiver%20Guide%20Final%20Interactive.pdf* (approximately 3 million LGBTQ+ people are the primary caregiver for someone over the age of 50).

[323] Tresa Baldas, *Pediatrician Won't Treat Baby With 2 Moms,* USA Today (Feb. 18, 2015), *https://www.usatoday.com/story/news/nation/2015/02/18/doctor-discrimination-baby/23642091/.*

likely also to be particularly important for people, especially children, who cannot access health care without the support of a caregiver. Such conduct by a covered entity may violate this provision and other provisions of this part, including §§ 92.101 (Discrimination prohibited), 92.206 (Equal program access on the basis of sex), 92.207 (Nondiscrimination in health insurance coverage and other health-related coverage), and 92.208 (Prohibition on sex discrimination related to marital, parental, or family status). Additionally, associational or caregiver discrimination also frequently arises in the context of disability discrimination, as addressed above in the preamble discussion of § 92.202 (Effective communication for individuals with disabilities). Another potential example of discrimination based on association relates to individuals with a substance use disorder (SUD) [324] and related stigma.[325] The ADA, section 504, and section 1557 prohibit discrimination on the basis of disability, and individuals with an SUD or a history of having an SUD typically are protected under these authorities, unless they are engaged in the current illegal use of drugs.[326] Section 92.209 makes clear that discrimination against individuals (including friends, nonfamilial caregivers, and family members) based on their association with individuals in recovery from SUD or with a history of drug use is prohibited under section 1557.

Comment: One commenter accurately observed that, unlike the Proposed Rule, the 2016 Rule's associational nondiscrimination provision referenced protections for both individuals and *entities* that associate with others. Emphasizing that an entity can also be discriminated against by other covered entities based on the original entity's association with an individual due to the individual's race, color, national origin, sex, disability or age, this commenter described a scenario where a health plan might discriminate against an entity that largely serves patients with LEP, LGBTQI+ populations, or an entity that provides Medications for Opioid Use Disorder (MOUD) to individuals with opioid use disorder.

Response: OCR recognizes that there may be instances where covered entities may discriminate against other entities based on these other entities' associations with populations they serve (including LGBTQI+ individuals, individuals with disabilities, etc.). For example, § 92.209 prohibits a covered entity from discriminating against another entity because that entity serves individuals protected under this rule, *e.g.,* individuals with SUD,[327] people with intellectual and developmental disabilities, people of a particular race or national origin, or people of a particular age. In this case, § 92.209 is violated based on the discriminated-against entity's association with an individual or individuals based on their race, color, national origin, sex, age, or disability. OCR did not intend to suggest in the Proposed Rule that this was no longer considered a prohibited form of discrimination and therefore is including ''entity'' in the final rule text.

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 § 92.209, with modification. We have revised the provision to clarify that covered entities are prohibited from discriminating against individuals and entities under this provision by adding ''or entity'' in the following locations: ''. . . against an individual *or entity* . . .,'' and ''. . . with whom the individual *or entity* . . . .''

Nondiscrimination in the Use of Patient Care Decision Support Tools (§ 92.210)

Proposed § 92.210, entitled ''Use of clinical algorithms in decision-making,'' provided that a covered entity must not discriminate against any individual on the basis of race, color, national origin, sex, age, or disability through the use of clinical algorithms in its decision-making. We invited extensive public comment on this proposed provision, including on whether to limit the provision to clinical algorithms or to include additional forms of automated or augmented decision-making tools or models, such as artificial intelligence (AI) and machine learning, and whether the provision should include more specificity, such as explaining actions covered entities must take to identify and mitigate potential discrimination from these tools. 87 FR 47884. The Proposed Rule preamble described clinical algorithms as ''tools used to guide health care decision-making that could range in form from flowcharts and clinical guidelines to complex computer algorithms, decision support interventions, and models.'' 87 FR 47880. The preamble also described clinical algorithms as tools used by ''hospitals, providers, and payers (*e.g.,* health insurance issuers) . . . to assist with health care decision-making for various purposes,'' including ''screening, risk prediction, diagnosis, prognosis, clinical decision-making, treatment planning, health care operations, and allocation of resources, all of which affect the care that individuals receive.'' 87 FR 47880. The comments and our responses regarding § 92.210 are set forth below.

Comment: Many commenters requested that OCR codify a definition for the term ''clinical algorithm.'' Some commenters requested a definition for ''clinical algorithm'' to include any form of automated decision systems and AI used in health programs or activities. Many commenters also recommended that § 92.210 apply to tools used in a covered entity's health programs and activities in addition to those used in a clinical setting. These commenters suggested that § 92.210 should apply to a covered entity's administrative health care operations because the use of these tools can impact individuals' access to a covered entity's health programs and activities and the quality of services provided.

Arguing that the term ''clinical algorithm'' is insufficient, some commenters cited examples of tools that covered entities use in their health programs and activities, such as those used for budgeting and billing processes, utilization management, benefit design, program eligibility and enrollment, provider contracting, and pricing by providers and insurers which are susceptible to discriminatory bias. Commenters also identified tools used in skilled nursing facilities, tools used to allocate home and community-based services, and Medicaid eligibility systems.

Response: In the Proposed Rule's preamble, we indicated that ''clinical algorithms'' include tools beyond actual algorithms, 87 FR 47880, and we solicited comment about whether ''clinical algorithms'' should ''include additional forms of automated or augmented decision-making tools or models such as artificial intelligence or

[324] *Substance Use Disorder Demographics,* American Addiction Centers, (Dec. 9, 2022), *https://sunrisehouse.com/addiction-demographics* (more than 40 million Americans aged 12 or older suffered from a substance use disorder in 2020).

[325] Janet Zwick et al., *Stigma: How It Effects the Substance Use Disorder Patient,* 15 Substance Abuse Treatment, Prevention, & Pol., (2020), *https://link.springer.com/article/10.1186/s13011-020-00288-0* (Stigma serves as a barrier to individuals with SUD seeking help, entering treatment, and accepting medications.).

[326] *See, e.g.,* U.S. Dep't of Justice, *The ADA and Opioid Use Disorder: Combatting Discrimination Against People in Treatment and Recovery* (Apr. 5, 2022), *https://www.ada.gov/resources/opioid-use-disorder/.*

[327] *See MX Grp., Inc.* v. *City of Covington,* 293 F.3d 326, 335 (6th Cir. 2002) (a public entity violated title II of the ADA when it discriminated against a drug and alcohol treatment center by denying it a zoning permit because the center provided services to individuals with disabilities).

machine learning,'' 87 FR 47884. The Proposed Rule described ''clinical algorithms'' as ''*tools* used to guide health care decision-making that can range in form from flowcharts and clinical guidelines to complex computer algorithms, decision support interventions, and models,'' which hospitals, providers and health insurance issuers use to ''assist with decision-making for various purposes,'' including ''screening, risk prediction, diagnosis, prognosis, clinical decision-making, treatment planning, *health care operations,* and *allocation of resources,* all of which affect the care that individuals receive.'' 87 FR 47880 (emphases added). Thus, the Proposed Rule described clinical algorithms broadly to include a variety of health care decision-making tools in a covered entity's health programs and activities related to patient care. We further solicited comment about ''what types of clinical algorithms are being used in covered health programs and activities; how such algorithms are being used by covered entities; [and] whether they are more prevalent in certain health settings . . . .'' 87 FR 47884.

As discussed in the preamble under § 92.4, we are adopting the more precise term ''patient care decision support tool'' to replace the term ''clinical algorithm.'' This new term more closely aligns with what we described as ''clinical algorithms'' in the preamble to the Proposed Rule, such as various tools used to guide health care decision-making that affect the care that patients receive. *See* 87 FR 47880. In § 92.4, we define ''patient care decision support tool'' to mean ''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.'' The definition applies to tools that are used by a covered entity in its clinical decision-making that affect the patient care that individuals receive. Given covered entities' widespread use of automated decision systems and AI, and the scale by which AI can influence covered entities' clinical decision-making,[328] we are confirming that the types of patient care decision support tools subject to § 92.210 include automated decision systems and AI used to support clinical decision-making.

Covered entities may use patient care decision support tools in their health care decision-making in a variety of ways. Covered entities typically use patient care decision support tools at the individual patient level, such as a provider using clinical guidance from an algorithm to assess a patient's risk of a severe cardiac event.[329] Other patient care decision support tools pertain to health care administration decisions, typically used with regard to a group of patients (or a population) based on shared characteristics. For example, there is evidence that hospital system treatment protocol varies by geographic area due to variations produced by risk adjustment modeling.[330] In addition to these examples, patient care decision support tools would also include tools used for prior authorization and medical necessity analysis,[331] which directly impacts clinical decision-making and affects the care received by patients as directed by their providers. For example, a medical necessity review tool used by Medicare Advantage plans has been shown to deny enrollees' medical claims for rehabilitative care without considering enrollees' individual circumstances.[332]

One subset of patient care decision support tools to which § 92.210 applies includes ''predictive decision support interventions'' as defined in the Office of the National Coordinator for Health Information Technology's (ONC) recently published final rule for ''Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing.'' [333] In its rule, ONC defines the term ''predictive decision support intervention'' (Predictive DSI) to mean ''technology that supports decision-making based on algorithms or models that derive relationships from training data and then produce an output that results in prediction, classification, recommendation, evaluation, or analysis.'' 89 FR 1192 (codified at 45 CFR 170.102). As ONC discussed in the Proposed Rule, Predictive DSI are used to predict unknown values based on relationships learned in training data, and they pertain to automated tools used for clinical, financial, or administrative purposes. ''Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing.'' 88 FR 23746, 23785 (April 18, 2023).

It is important to note that § 92.210 is not duplicative of ONC's rule regarding Predictive DSIs because ONC's rule applies to and includes requirements for health information technology (IT) *developers,* whereas § 92.210 applies to and includes requirements for section 1557 covered entity *users* of patient care decision support tools (including Predictive DSIs). A section 1557 covered entity may, of course, develop its own Predictive DSI, in which case that entity may be subject to ONC's Predictive DSI requirements as well as section 1557's nondiscrimination requirements under § 92.210. Refer to section V of ONC's January 2024 Final Rule, 89 FR 1242–54, for more detailed information regarding Predictive DSIs. OCR worked closely with ONC during the development of this final rule and ONC's rule to advance a coordinated Departmental response in regulating

[328] Nat'l Acad. of Med., *Artificial Intelligence in Health Care: The Hope, the Hype, the Promise, the Peril,* pp. 2, 3 (2019), *https://doi.org/10.17226/27111*; Nat'l Inst. of Standards & Tech., *Artificial Intelligence Risk Management Framework* (AI RMF 1.0), NIST AI 100–1, pp. 1, 17, 40 (2023), *https://doi.org/10.6028/NIST.AI.100-1*.

[329] *See, e.g.,* Darshali A. Vyas et al., *Hidden in Plain Sight—Reconsidering the Use of Race Correction in Clinical Algorithms,* 383 N. Engl. J. Med. 874, 876–78 (Aug. 27, 2020).

[330] Elliott Fisher et al., *Health Care Spending, Quality, and Outcomes—More Isn't Always Better,* The Dartmouth Inst. for Health Pol. & Clinical Practice (2009), *https://www.ncbi.nlm.nih.gov/books/n/darthhcspending/pdf/*; Ziad Obermeyer et al., *Dissecting Racial Bias in an Algorithm Used to Manage the Health of Populations,* 366 Science 447 (2019), *https://www.science.org/doi/10.1126/science.aax2342*.

[331] *See, e.g.,* Casey Ross & Bob Herman, *UnitedHealth Pushed Employees to Follow an Algorithm to Cut Off Medicare Patients' Rehab Care,* STAT News (Nov. 14, 2023), *https://www.statnews.com/2023/11/14/unitedhealth-algorithm-medicare-advantage-investigation/*; Patrick Rucker et al., *How Cigna Saves Millions by Having Its Doctors Reject Claims Without Reading Them,* ProPublica (March 25, 2023), *https://www.propublica.org/article/cigna-pxdx-medical-health-insurance-rejection-claims*; Casey Ross & Bob Herman, *Denied by AI: How Medicare Advantage Plans Use Algorithms to Cut Off Care for Seniors in Need,* STAT News, (Mar. 13, 2023) *https://www.statnews.com/2023/03/13/medicare-advantage-plans-denial-artificial-intelligence/*; Shahed Al-Haque et al., *AI Ushers in Next-Gen Prior Authorization in Healthcare,* McKinsey & Co. (Apr. 19, 2022), *https://www.mckinsey.com/industries/healthcare/our-insights/ai-ushers-in-next-gen-prior-authorization-in-healthcare#/*.

[332] *See, e.g.,* Casey Ross & Bob Herman, *Denied by AI: How Medicare Advantage Plans Use Algorithms to Cut Off Care for Seniors in Need,* STAT News, *https://www.statnews.com/2023/03/13/medicare-advantage-plans-denial-artificial-intelligence/* (Mar. 13, 2023).

[333] 45 CFR 170.102; U.S. Dep't of Health & Hum. Servs., Off. of the Nat'l Coordinator for Health Info. Tech., Health Data, *Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing,* Final Rule, 89 FR 1192 (January 9, 2024). Regarding the term ''intervention,'' ONC notes that the term ''intervention'' in ''prediction decision support intervention'' was not intended to mean an intervention (medicine, medical procedure, or medical treatment) as the term is used in the practice of medicine, but rather, an intervention occurring within a workstream, including but not limited to alerts, order sets, flowsheets, dashboards, patient lists, documentation forms, relevant data presentations, protocol or pathway support, reference information or guidance, and reminder messages. Their use of the term intervention was consistent with how the Program used the term in § 170.315(a)(9).

tools used to support health care decision-making.

Section 92.210's definition for ''patient care decision support tool'' also includes non-automated and evidence-based tools that rely on rules, assumptions, constraints, or thresholds, as these also have the potential to result in discrimination. This includes ''evidence-based decision support interventions'' identified in ONC regulations at 45 CFR 170.315(b)(11)(iii). An example of a non-automated patient care decision support tool is a Crisis Standards of Care [334] flowchart for triage guidance. Such a flowchart may result in discrimination if, for example, it screens out individuals with disabilities, prohibiting them from equally accessing a health care service, program, or activity that a covered entity offers by assessing an individual's potential response to life-saving care without making an individualized assessment of the individual's health and without providing modifications for how an individual's disability or age could affect the assessment factors used in the algorithm or the time needed for the individual to respond to treatment. Another example is the race-adjusted estimated glomerular filtration rate (eGFR) equation that relies not only on training data, but also discriminatory assumptions and thresholds such as by applying a race-adjusted coefficient to the eGFR equation to reflect that Black people have been associated with higher levels of blood creatinine as compared with that of non-Black people, which results in a higher significance threshold for Black patients, thereby requiring more advanced kidney failure for Black patients than non-Black patients before they can receive the same level of care. Other examples of patient care decision support tools include, but are not limited to: flowcharts; formulas; equations; calculators; algorithms; utilization management applications; software as medical devices (SaMDs); software in medical devices (SiMDs); screening, risk assessment, and eligibility tools; and diagnostic and treatment guidance tools.

Comment: Some commenters urged OCR to narrow the definition for ''clinical algorithm'' and to clarify that the scope of § 92.210 does not extend beyond flowcharts and clinical algorithms to any forms of automated decision systems or AI. These commenters contended that a narrow definition is necessary to limit covered entities' liability and burden, disruption to covered entities' decision-making, and patients' exposure to greater health risks.

Response: Section 92.210 does not apply to tools used to support decision-making unrelated to clinical decision-making affecting patient care or that are outside of a covered entity's health programs or activities. For example, § 92.210 does not apply to the following activities when such activities are unrelated to clinical decision-making affecting patient care: automated or non-automated tools that covered entities use for administrative and billing-related activities; automated medical coding; fraud, waste and abuse; patient scheduling; facilities management; inventory and materials management; supply chain management; financial market investment management; or employment and staffing-related activities.

The purpose of § 92.210 is to prohibit discrimination that occurs through covered entities' use of patient care decision support tools in their health programs or activities. The rule does not seek to disrupt covered entities' clinical decision-making, expose patients to greater health risks, or to prevent the use of these tools entirely. We encourage covered entities to continue procuring, developing, and using patient care decision support tools that will improve patient care and access to quality care. Section 92.210 will help covered entities use these tools in a nondiscriminatory manner. Under § 92.210, evidence-based researchers, whose findings inform many inputs to patient care decision support tools, will be incentivized to recalibrate data, assumptions, and methods used in earlier studies.

Comment: Many commenters expressed support for proposed § 92.210 and discussed the extent of discrimination in health care resulting from the use of algorithms. Commenters were particularly concerned about the prevalence of ethnic and racial bias in clinical algorithms that results in fewer health care services provided to Black, Hispanic/Latino, Asian, and American Indian/Alaska Native patients. Others discussed Crisis Standards of Care, stating they are too often biased against people with disabilities, people of color (who disproportionately have at least one disability), and older individuals because these tools assess an individual's potential response to life-saving care without making an individualized assessment of the individual's health and without providing modifications for how an individual's disability or age could affect the assessment factors used in the algorithm or the time needed for the individual to respond to treatment.

Response: OCR appreciates commenters' feedback regarding proposed § 92.210. We share commenters' concerns about the potential for discrimination caused by the use of algorithms in health care, which are receiving considerable attention from the Department and Administration,[335] other executive agencies, Congress, stakeholders, professional associations, medical journals, and the media. As OCR implements section 1557 and other civil rights laws, it will continue to consider additional actions to support covered entities in implementation and compliance consistent with Federal law, including guidance or provision of technical assistance.

We particularly note that, since publication of proposed § 92.210, the Administration has issued: (1) a *Blueprint for an AI Bill of Rights,* which includes a principle for protecting the public from algorithmic discrimination; [336] (2) E.O. 14091, *Further Advancing Racial Equity and Support for Underserved Communities Through the Federal Government,* which includes a section requiring agencies to consider opportunities to ''prevent and remedy discrimination, including by protecting the public from algorithmic discrimination;'' [337] and (3) E.O. 14110, *Safe, Secure, and Trustworthy Development and Use of Artificial Intelligence,* which sets forth

[334] Crisis Standards of Care inform decision-making designed to accomplish the best outcome for a group of patients rather than focusing on an individual patient.

[335] *See, e.g.,* U.S. Dep't of Health & Hum. Servs., *HHS Finalizes Rule to Advance Health IT Interoperability and Algorithm Transparency* (2023), *https://www.hhs.gov/about/news/2023/12/13/hhs-finalizes-rule-to-advance-health-it-interoperability-and-algorithm-transparency.html*; U.S. Dep't of Health & Hum. Servs., *Guiding Principles Help Healthcare Community Address Potential Bias Resulting from Algorithms* (2023), *https://www.hhs.gov/about/news/2023/12/15/guiding-principles-help-healthcare-community-address-potential-bias-resulting-from-algorithms.html*; U.S. Dep't of Health & Hum. Servs., *Delivering on the Promise of AI to Improve Health Outcomes* (2023), *https://www.whitehouse.gov/briefing-room/blog/2023/12/14/delivering-on-the-promise-of-ai-to-improve-health-outcomes/*; U.S. Dep't of Health & Hum. Servs., *FACT SHEET: Biden-Harris Administration Announces Voluntary Commitments from Leading Healthcare Companies to Harness the Potential and Manage the Risks Posed by AI* (2023), *https://www.hhs.gov/about/news/2023/12/14/fact-sheet-biden-harris-administration-announces-voluntary-commitments-leading-healthcare-companies-harness-potential-manage-risks-posed-ai.html.*

[336] The White House, *Blueprint for an AI Bill of Rights* (Oct. 4, 2022), *https://www.whitehouse.gov/ostp/ai-bill-of-rights/.*

[337] E.O. 14091, sec. 8(f), 88 FR 10825, 10831 (Feb. 22, 2023), *https://www.federalregister.gov/documents/2023/02/22/2023-03779/further-advancing-racial-equity-and-support-for-underserved-communities-through-the-federal.*

numerous executive actions designed to ensure the equitable, safe, and secure use of AI.[338] E.O. 14110 addresses civil rights violations and discrimination related to AI and seeks to protect individuals' civil rights by preventing discrimination, including algorithmic discrimination, through the use of automated systems and AI.[339]

Executive Order 14110 directs the Department to take actions, ''possibly including regulatory action,'' to ''ensure the safe, responsible deployment and use of AI in the healthcare, public-health, and human-services sectors.'' [340] It also directs the Department to ''consider appropriate actions to advance the prompt understanding of, and compliance with, Federal nondiscrimination laws by health and human services providers that receive Federal financial assistance, as well as how those laws relate to AI.'' [341]

We also acknowledge the recent surge in academic research highlighting potential harms caused by use of patient care decision support tools that may create or contribute to discrimination prohibited by section 1557, as discussed in the Proposed Rule at 87 FR 47880–82.

We appreciate the comments addressing the potential bias in Crisis Standards of Care, which, as discussed at length in the Proposed Rule, 87 FR 47881–82, were the focus of OCR's enforcement efforts during the COVID–19 Public Health Emergency and resulted in six States revising their Crisis Standards of Care to prevent discriminatory prioritization of hospital resources.[342]

Comment: Some commenters opposed proposed § 92.210, in part, because existing laws and regulations already prohibit discrimination in algorithmic tools. Other commenters opposed to finalizing § 92.210 urged OCR to use the feedback we received during the public comment period to inform engagement with stakeholders, including the Food and Drug Administration (FDA), device manufacturers, algorithm developers, clinicians, patients, and others, through which OCR could develop a regulatory framework involving risk-based approaches.

Response: While several Federal departments and agencies are taking action to regulate AI and other decision-making tools,[343] OCR, consistent with its underlying authority, is in a unique position to provide additional specificity regarding the application of long-standing nondiscrimination requirements to the use of such tools to ensure that discrimination does not result from covered entities' use of patient care decision support tools in their health programs or activities. The Department has authority to enforce section 1557, which prohibits covered entities from discriminating in their health programs and activities, including through the use of AI and other tools. Section 92.210 provides additional clarity to covered entities regarding their obligations. We are finalizing § 92.210 with a delayed applicability date of no later than 300 days after the final rule's effective date to give covered entities a reasonable period of time to come into compliance with § 92.210(b) and (c).

We received significant input on this issue from stakeholders during the public comment period, and the breadth of stakeholders' input and available research has informed the revisions in the final version of § 92.210. As OCR implements section 1557 and other civil rights laws, it will continue to consider additional actions to support covered entities in implementation and compliance consistent with Federal law, including guidance or engaging in future rulemaking. As AI, clinical algorithms, and predictive analytics are more widely used, OCR will continue to engage with the FDA, ONC, and other Federal partners to ensure consistency and a coordinated governmental effort to regulate such tools in health care. We will also continue to solicit stakeholders' input and to assist covered entities with compliance.

Comment: Some commenters expressed concern that proposed § 92.210 would not apply to health care-related AI products that are autonomous or that augment a covered entity's decision-making in its health programs and activities.

Response: This final rule clarifies that § 92.210 applies to all patient care decision support tools used in a covered entity's health programs or activities to support clinical decision-making, including patient care decision support tools that are autonomous and those that assist or augment a covered entity's clinical decision-making.

Comment: Some commenters recommended that § 92.210 exclude tools designed to improve health equity because these tools serve to protect members of historically marginalized communities. Relatedly, one commenter asked how proposed § 92.210 would affect algorithms that are currently in use and specifically designed to identify certain groups of patients susceptible to a particular condition or that may benefit from a particular therapy.

Response: Section 92.210 does not prohibit covered entities from using patient care decision support tools that identify, evaluate, and address health disparities so long as their use does not constitute prohibited discrimination on

[338] E.O. 14110, 88 FR 75191 (Nov. 1, 2023).

[339] E.O. 14110, sec. 7, 88 FR 75191, 75211 (Nov. 1, 2023).

[340] E.O. 14110, sec. 8(b)(i), 88 FR 75191, 75214 (Nov. 1, 2023).

[341] E.O. 14110, sec. 8(b)(iii), 88 FR 75191, 75214 (Nov. 1, 2023).

[342] For more information on OCR's work related to discrimination in Crisis Standards of Care, *see Civil Rights and COVID–19, Non-Discrimination in Crisis Standards of Care,* U.S. Dep't of Health & Hum. Servs., Off. for Civil Rts., *https://www.hhs.gov/civil-rights/for-providers/civil-rights-covid19/index.html.*

[343] *See, e.g.,* Proposed Rule at 87 FR 47882–84, n.569, 571, 578; U.S. Dep't of Health & Hum. Servs., Ctrs. for Medicare & Medicaid Servs., *Medicare Program; Contract Year 2024 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly,* Final Rule, 88 FR 22120, 22195 (Apr. 12, 2023), *https://www.govinfo.gov/content/pkg/FR-2023-04-12/pdf/2023-07115.pdf* (''MA organizations must ensure that they are making medical necessity determinations based on the circumstances of the specific individual, as outlined at § 422.101(c), as opposed to using an algorithm or software that doesn't account for an individual's circumstances.''); U.S. Dep't of Health & Hum. Servs., Ctrs. for Medicare & Medicaid Servs., *Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Organ Acquisition; Rural Emergency Hospitals: Payment Policies, Conditions of Participation, Provider Enrollment, Physician Self-Referral; New Service Category for Hospital Outpatient Department Prior Authorization Process; Overall Hospital Quality Star Rating; COVID–19,* Final Rule, 87 FR 71748, 72036 (Nov. 23, 2022), *https://www.federalregister.gov/documents/2022/11/23/2022-23918/medicare-program-hospital-outpatient-prospective-payment-and-ambulatory-surgical-center-payment* (responding to comment solicitation on how to prevent and mitigate bias in algorithms and predictive modeling); U.S. Dep't of Health & Hum. Servs., Food & Drug Admin., *Artificial Intelligence/Machine Learning (AI/ML)-Based Software as a Medical Device (SaMD) Action Plan* (2021), *https://www.fda.gov/medical-devices/software-medical-device-samd/artificial-intelligence-and-machine-learning-software-medical-device*; U.S. Dep't of Health & Hum. Servs., Off. of the Nat'l Coordinator for Health Info. Tech., *Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing,* Final Rule, 89 FR 1192 (January 9, 2024); Consumer Fin. Protection Bureau, U.S. Dep't of Justice, U.S. Equal Employment Opportunity Comm'n, & Fed. Trade Comm'n, *Joint Statement on Enforcement Efforts Against Discrimination and Bias in Automated Systems* (Apr. 2023), *https://files.consumerfinance.gov/f/documents/cfpb_joint-statement-enforcement-against-discrimination-bias-automated-systems_2023-04.pdf;* Fed. Deposit Ins. Corp., *Request for Information and Comment on Financial Institutions' Use of Artificial Intelligence, Including Machine Learning,* 86 FR 16837–38 (May 24, 2021), *https://www.govinfo.gov/content/pkg/FR-2021-05-24/pdf/2021-10861.pdf;* Nat'l Inst. of Standards & Tech., *Artificial Intelligence Risk Management Framework* (AI RMF 1.0), NIST AI 100–1 (2023), *https://doi.org/10.6028/NIST.AI.100-1.*

the basis of race, color, national origin, sex, age, or disability.

Comment: Many commenters requested that OCR revise § 92.210 to include transparency requirements for covered entities regarding their use of clinical algorithms in their health programs and activities, including a requirement that covered entities notify individuals about the training data, assumptions, constraints, thresholds, and other inputs used to design each clinical algorithm in use. Commenters noted that otherwise, individuals would not know whether there has been a violation of § 92.210.

Response: A covered entity may routinely change the patient care decision support tools it uses. While there may be benefits to providing such information to patients, we decline to revise § 92.210 to require covered entities to notify patients about the patient care decision support tools used in their health programs and activities given the possible frequent changes and the costs associated with notifying patients.

We similarly decline to revise § 92.210 to require covered entities to notify patients about the training data and other inputs used to design and develop the patient care decision support tools used by a covered entity because, in addition to the costs discussed above, currently, patient care decision support tool developers may not ordinarily share this information with covered entities. We note, however, that ONC's final rule requires decision support interventions, supplied by a developer of certified health IT as part of its Health IT Module certified to 45 CFR 170.315(b)(11) criterion, to support making this information (source attributes) available to users of the Health IT Module. In addition, developers of certified health IT certified to 45 CFR 170.315(b)(11)(iii)(B) are required to make summary information of intervention risk management practices publicly available for Predictive DSIs the developer supplies as part of its Health IT Module provided through 45 CFR 170.523(f)(1)(xxi). 89 FR 1192 (January 9, 2024). Covered entities using decision support interventions supplied by a developer of certified health IT should have this type of information available to them.

In addition, to the extent that covered entities subject to HIPAA document their use of a patient care decision support tool in an individual's medical record, individuals may obtain that information when they exercise their HIPAA right of access to their protected health information contained in their respective designated record sets. *See* 45 CFR 164.524. Other Departmental agencies may also issue transparency-related guidance and requirements for AI developers. OCR seeks to partner with other agencies and covered entities to address best practices and may release guidance in the future.

While we decline to impose transparency requirements under § 92.210 for the reasons stated above, we note that it would be a best practice for covered entities to disclose information to patients about the patient care decision support tools used in their health programs and activities.[344] We further note, however, that such voluntary disclosure does not ensure compliance with § 92.210.

Comment: Many commenters recommended that OCR revise § 92.210 to clarify the steps that a covered entity must take to comply with § 92.210 and to ensure nondiscriminatory use of clinical algorithms. Commenters explained that when providers use a patient care support tool, they often rely on a developer's intended uses for the tool. Commenters discussed that covered entities do not design or develop many of the clinical algorithms that they use and are therefore unlikely to be aware of how the tool operates. They also stated that it is infeasible to require a covered entity to audit all algorithms in its health programs or activities and that proposed § 92.210 would force covered entities to police their own supply chains for clinical algorithms, which they state is also impracticable. Commenters expressed concern that covered entities may incur liability when they are unaware that an algorithmic output may result in discrimination and opined that covered entities should not be liable in such cases. Another commenter specified that physician liability should be limited to when a reasonable physician knows or should have known that the algorithm in question utilizes inputs and logic that are likely to result in discrimination. Further, commenters asserted that the additional steps that covered entities would need to take to comply with proposed § 92.210 are very likely to contribute to providers' already strained workload and further contribute to burnout.

Response: We appreciate commenters' concerns and have revised § 92.210 to provide additional clarity. We have added additional clarification on covered entities' obligations under § 92.210. Section 92.210 sets forth the general prohibition on discrimination on the basis of race, color, national origin, sex, age, or disability by a covered entity in its health programs or activities through the use of patient care decision support tools. Section 92.210(b) requires a covered entity to make reasonable efforts to identify patient care decision support tools used in its health programs and activities that employ input variables or factors that measure race, color, national origin, sex, age, or disability. Section 92.210(c) requires that for each patient care decision support tool identified in paragraph (b), 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.

We appreciate comments regarding how a covered entity may learn that a patient care decision support tool used in its health programs or activities creates a risk of discrimination on a protected basis. In the Proposed Rule, we noted that use of clinical algorithms may result in discriminatory outcomes when variables are used as a proxy for a protected basis, and that discrimination may result from correlations between a variable and a protected basis. 87 FR 47881. As a threshold matter, we note that section 1557 prohibits proxy discrimination as a general civil rights principle that applies to the entire final rule.[345] However, given the many possible indirect measures of race, color, national origin, sex, age, and disability, covered entities are not required to identify all patient care decision support tools with input variables or factors that indirectly measure these protected bases. However, covered entities should exercise caution when using patient care decision support tools that are known to use indirect measures for race, color, national origin, sex, age, or disability, which could result in prohibited discrimination.

We understand that covered entities in some circumstances may be largely unaware of the datasets developers use to train the patient care decision support tools that covered entities use. Section 92.210 does not require covered entities to obtain datasets or other attribute information from developers when purchasing or using patient care decision support tools. However, if a covered entity does not know whether a developer's patient care decision support tool uses variables or factors that measure race, color, national origin,

[344] *See, e.g.,* Am. Med. Ass'n, *American Medical Association Principles for Augmented Intelligence Development, Deployment, and Use,* pp. 2–4 (2023), *https://www.ama-assn.org/system/files/ama-ai-principles.pdf.*

[345] *See* discussion of proxy discrimination at § 92.207.

sex, age, or disability but has reason to believe such variables or factors are being used, or the covered entity otherwise knows or should know that the tool could result in discrimination, the covered entity should consult publicly available sources or request this information from the developer.

Further, ONC's recently published final rule discussed above revises existing certification criteria for developers of certified health IT by requiring developers with Health IT Modules certified to § 170.315(b)(11) to disclose information about a decision support intervention's source attributes relevant to health equity with the decision support intervention users. 89 FR 1192. This disclosure requirement will work in tandem with § 92.210 by enabling a covered entity that uses Health IT Modules certified to § 170.315(b)(11) to learn from a developer whether a specific decision support intervention relies on attributes that measure race, color, national origin, sex, age, or disability.

We are aware that covered entities use patient care decision support tools based on their respective needs and in accordance with developers' intended uses. But covered entities must exercise due diligence when acquiring and using such tools to ensure compliance with § 92.210.

Covered entities may learn that use of patient care decision support tools risk resulting in discrimination when OCR included that information in the Proposed Rule. In the Proposed Rule, in addition to the use of the race-adjusted eGFR equation discussed above, we identified uses of other categories of tools that may result in discrimination based on race, including tools used in ''cardiology (to assess the risk of heart failure), cardiac surgery (to assess the risk of complications and death), obstetrics (to determine risks associated with vaginal birth after cesarean), urology (to assess the risk of kidney stones and urinary tract infections), oncology (to predict rectal cancer survival and breast cancer risk), endocrinology (to assess osteoporosis and fracture risks), and pulmonology (to measure lung function).'' 87 FR 47881. The Proposed Rule also identified that use of Crisis Standards of Care to allocate health care resources may also discriminate on the basis of disability and/or age. 87 FR 47880–82. OCR aims to continue providing additional guidance to the public and covered entities as such information on potential discrimination in the use of such tools becomes available.

The Department itself regularly publishes information and advisories to the public. For example, the Agency for Healthcare Research and Quality (AHRQ) recently issued a report on the ''Impact of Healthcare Algorithms on Racial and Ethnic Disparities in Health and Healthcare.'' [346] Additionally, addressing published medical journals' research studies and the subsequent media attention about racial bias resulting from the use of pulse oximeters, the FDA published a safety communication to announce that the FDA was reassessing the content of its pulse oximetry guidance document and would share additional updates with the public.[347]

Published articles of research studies in peer-reviewed medical journals are also a reliable source of information about evidence-based adverse outcomes based on patient care decision support tools that may result in discrimination. Such articles are increasing in prevalence given the growing use of AI and other patient care decision support tools in health care decision-making.[348] For example, peer-reviewed medical journals have recently published several articles related to racial discrepancies resulting from the use of pulse oximeters.[349] One such study found that pulse oximeters more commonly overestimated arterial oxygen saturation levels in patients from minority racial and ethnic groups and led to delayed recognition of need for COVID–19 therapy among Black patients compared with white patients.[350]

Covered entities also may gain knowledge that use of a patient care decision support tool creates a risk of discrimination based on a prohibited basis through media outlets that may report on reliable studies.[351]

Health care professional and hospital associations are also often dependable sources of information that notify health care providers about developments in the practice of various specialties and in the administration of medical care, which can include potential discrimination that may result from the use of certain patient care decision support tools.[352] Health insurance-related associations also provide information to their members and the public.[353] Relevant information is also

[346] Kelley Tipton et al., U.S. Dep't of Health & Hum. Servs., Agency for Healthcare Rsch. & Quality, *Impact of Healthcare Algorithms on Racial and Ethnic Disparities in Health and Healthcare,* Comparative Effectiveness Review No. 268, AHRQ Publication No. 24–EHC004 (2023), *https://effectivehealthcare.ahrq.gov/sites/default/files/related_files/cer-268-racial-disparities-health-healthcare.pdf.*

[347] U.S. Dep't of Health & Hum. Servs., Food & Drug Admin., *Pulse Oximeter Accuracy and Limitations: FDA Safety Communication, https://public4.pagefreezer.com/content/FDA/20-02-2024T15:13/https://www.fda.gov/medical-devices/safety-communications/pulse-oximeter-accuracy-and-limitations-fda-safety-communication.*

[348] *See, e.g.,* Armando D. Bedoya et al., *A Framework for the Oversight and Local Deployment of Safe and High-Quality Prediction Models,* 29 J. of Am. Med. Informatics Ass'n. 9, 1631–1636 (2022), *https://doi.org/10.1093/jamia/ocac078* (describing a governance framework that combines current regulatory best practices and lifecycle management of predictive models being used for clinical care and maintaining a governance portfolio where models are actively added); Shyam Visweswaran et al., *Clinical Algorithms with Race: An Online Database,* medRxiv [Preprint], doi: 10.1101/2023.07.04.23292231 (2023), *https://pubmed.ncbi.nlm.nih.gov/37461462/#:~:text=These%20clinical%20algorithms%20based%20on,the%20inappropriate%20use%20of%20race* (conducting a comprehensive search of online resources, the scientific literature, and the FDA Drug Label Information to identify clinical algorithms that incorporate race or ethnicity as an input variable or predictor in determining diagnoses, prognoses, treatment plans, or risk assessments; finding 39 race-based risk calculators, 6 laboratory test results with race-based reference ranges, 1 race-based therapy recommendation, and 15 medications with race-based recommendations; and creating a current and open-access database to track race-based clinical algorithms).

[349] *See, e.g.,* Ashraf Fawzy et al., *Racial and Ethnic Discrepancy in Pulse Oximetry and Delayed Identification of Treatment Eligibility Among Patients with COVID–19,* 182 JAMA Internal Med. 730 (2022), *https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2792653*; Valeria S.Valbuena et al., *Racial and Ethnic Bias in Pulse Oximetry and Clinical Outcomes,* 182 JAMA Internal Med. 699 (2022), *https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2792654*; Michael W. Sjoding et al., *Racial Bias in Pulse Oximetry Measurement,* 383 New Eng. J. Med. 2477 (2020) *https://www.nejm.org/doi/full/10.1056/nejmc2029240.*

[350] Ashraf Fawzy et al., *Racial and Ethnic Discrepancy in Pulse Oximetry and Delayed Identification of Treatment Eligibility Among Patients with COVID–19,* 182 JAMA Internal Med. 730 (2022), *https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2792653.*

[351] Following medical journals' publication of research articles related to racial bias through the use of pulse oximeters, several media outlets amplified those findings further to the public. *See, e.g.,* Anil Onza et al., *COVID–19 Made Pulse Oximeters Ubiquitous. Engineers are Fixing Their Racial Bias,* (Feb. 13, 2023), *https://www.npr.org/2023/02/10/1156166554/covid-19-pulse-oximeters-racial-bias*; *Pulse Oximeters Should Not Be Used to Diagnose COVID–19, U.S. FDA Says,* Reuters (Feb. 19, 2021), *https://www.reuters.com/article/us-health-coronavirus-pulse-oximeter/pulse-oximeters-should-not-be-used-to-diagnose-covid-19-u-s-fda-says-idUSKBN2AJ2G7.*

[352] *See, e.g., Augmented Intelligence in Medicine,* Am. Med. Ass'n, *https://www.ama-assn.org/practice-management/digital/augmented-intelligence-medicine* (updated Mar. 1, 2024); *Clinical Applications of Artificial Intelligence* (webinar), Am. Coll. of Physicians, *https://www.acponline.org/meetings-courses/webinars/clinical-applications-of-artificial-intelligence* (June 8, 2023). *See generally, Medical & Professional Associations,* Meditech, *https://www.meditec.com/resourcestools/professional-associations-list.*

[353] *See, e.g., Artificial Intelligence,* Nat'l Ass'n of Ins. Comm'rs, *https://content.naic.org/cipr-topics/artificial-intelligence*; *Creating Better Health Outcomes with Digital Tools and Artificial*

Continued

provided through various nonprofit organizations in the field of AI.

ONC's rule also provides an opportunity for covered entities to learn about the data used in decision support interventions. Developers of decision support interventions that develop certified health IT as part of its Health IT Module are required to support making specific information disclosures under ONC's rule regarding discriminatory bias in their tools, including disclosure of source attributes, and risk management and governance practices.[354]

OCR will assess each allegation that a covered entity is violating § 92.210 on a case-by-case basis. For example, when OCR investigated complaints related to State Crisis Standards of Care guidelines during the COVID–19 pandemic, the investigations involved a fact-specific analysis of each of the guidelines in question. They also included extensive technical assistance with States to revise their Crisis Standards of Care guidelines to remove the alleged discriminatory.[355]

In our analysis of whether a covered entity is in compliance with § 92.210(b)'s ''reasonable efforts to identify'' requirement, OCR may consider, among other factors: (1) the covered entity's size and resources (*e.g.,* a large hospital with an IT department and a health equity officer would likely be expected to make greater efforts to identify tools than a smaller provider without such resources); (2) whether the covered entity used the tool in the manner or under the conditions intended by the developer and approved by regulators, if applicable, or whether the covered entity has adapted or customized the tool; (3) whether the covered entity received product information from the developer of the tool regarding the potential for discrimination or identified that the tool's input variables include race, color, national origin, sex, age, or disability; and (4) whether the covered entity has a methodology or process in place for evaluating the patient care decision support tools it adopts or uses, which may include seeking information from the developer, reviewing relevant medical journals and literature, obtaining information from membership in relevant medical associations, or analyzing comments or complaints received about patient care decision support tools.

In summary, OCR recognizes the challenges in identifying the discriminatory potential of every use of each patient care decision support tool, and therefore § 92.210(b) requires covered entities to make reasonable efforts to identify tools that employ input variables based on a protected basis.

Comment: Many commenters referred to potential devastating consequences from the use of specific clinical algorithms [356] and recommended that § 92.210 be revised to include a requirement for covered entities to mitigate the risk of discrimination that results from the use of clinical algorithms. Some commenters suggested that OCR require specific mitigation efforts, such as requiring covered entities to: develop and implement policies specific to covered entities' use of clinical algorithms; require staff training; use clinical algorithms in accordance with FDA clearance and developer's intended uses; use peer-reviewed research to inform adjustments to clinical algorithms; notify patients of suspect clinical algorithms; request an assessment of discriminatory inputs from developers; neutralize any discriminatory inputs by using the predominant cohort in the tool's training data; and submit annual reports to OCR regarding their use of clinical algorithms and mitigation efforts.

Response: OCR agrees with commenters' concerns about the potential for harm resulting from discriminatory algorithms and the need to mitigate the risks of discrimination when possible. However, we acknowledge that it is not always possible to completely eliminate the risk of discriminatory bias in patient care decision support tools,[357] and these tools also serve important health care functions. Section 92.210(c) requires covered entities to make reasonable efforts to mitigate the risk of discrimination resulting from the covered entity's use of a patient care decision support tool identified in § 92.210(b). This standard allows a covered entity to adopt more robust safeguards to prevent discrimination, should it choose to do so.

For example, in order to comply with § 92.210(c)'s mitigation requirement, a covered entity that uses the race-adjusted eGFR equation could discontinue using that equation and instead use the revised eGFR equation that does not adjust for race.[358] The covered entity may also implement measures to ensure that staff members follow proper protocols when using the race-adjusted eGFR equation.[359] OCR will evaluate mitigation measures covered entities take on a case-by-case basis to determine compliance with § 92.210(c).

A covered entity's obligation to mitigate risk of discrimination under § 92.210(c) is consistent with the National Institutes of Standards and Technology's (NIST) Artificial Intelligence Risk Management Framework, which explains that AI bias mitigation helps minimize potential negative impacts of AI systems while providing opportunities to maximize positive impacts, without articulating express mitigation measures.[360] The same is true for patient care decision support tools that a covered entity uses

Intelligence (webinar), Am.'s Health Ins. Plans, *https://www.ahip.org/webinars/creating-better-health-outcomes-with-digital-tools-and-artificial-intelligence* (Dec. 8, 2023).

[354] U.S. Dep't of Health & Hum. Servs., Off. of the Nat'l Coordinator for Health Info. Tech., *Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing,* Final Rule, 89 FR 1192 (January 9, 2024).

[355] *See, e.g.,* U.S. Dep't of Health & Hum. Servs., Off. for Civil Rts., *Civil Rights and COVID–19, Non-Discrimination in Crisis Standards of Care, https://www.hhs.gov/civil-rights/for-providers/civil-rights-covid19/index.html*; Press release, U.S. Dep't of Health & Hum. Servs., Off. for Civil Rts., *OCR Resolves Complaint with Utah After It Revised Crisis Standards of Care to Protect Against Age and Disability Discrimination* (Aug. 20, 2020), *https://public3.pagefreezer.com/content/HHS.gov/31-12-2020T08:51/https://www.hhs.gov/about/news/2020/08/20/ocr-resolves-complaint-with-utah-after-revised-crisis-standards-of-care-to-protect-against-age-disability-discrimination.html.*

[356] Examples included race-adjusted correction factors used in spirometry, nephrology, and cardiology; State Medicaid eligibility systems that reduce benefits impacting historically marginalized individuals disproportionately to the overall population; health care utilization algorithms that use prior health care spending data to predict future health care needs that results in under-representing Black patients as compared to white patients; and other examples discussed throughout this preamble.

[357] *See, e.g.,* Nat'l Inst. of Standards & Tech., *Artificial Intelligence Risk Management Framework* (AI RMF 1.0), NIST AI 100–1, (2023), *https://doi.org/10.6028/NIST.AI.100-1.*

[358] *See, e.g.,* Cynthia Delgado et al., *Special Report: A Unifying Approach for GFR Estimation: Recommendations of the NKF–ASN Task Force on Reassessing the Inclusion of Race in Diagnosing Kidney Disease,* 79 a.m. J. of Kidney Diseases, 268–288 (Sept. 23, 2021), *https://www.ajkd.org/article/S0272-63862100828-3/fulltext.*

[359] *See, e.g.,* Press Release, U.S. Dep't of Health & Hum. Servs., Health Servs. & Rsch. Admin., Organ Procurement & Transplantation Network, *OPTN Board Approves Waiting Time Adjustment for Kidney Transplant Candidates Affected by Race-Based Calculation* (Jan. 5, 2023), *https://optn.transplant.hrsa.gov/news/optn-board-approves-waiting-time-adjustment-for-kidney-transplant-candidates-affected-by-race-based-calculation/.*

[360] Nat'l Inst. of Standards & Tech., *Artificial Intelligence Risk Management Framework* (AI RMF 1.0), NIST AI 100–1, p. 4 (2023), *https://doi.org/10.6028/NIST.AI.100-1,* (The NIST AI Framework provides: ''Where tradeoffs among the trustworthy characteristics arise, measurement provides a traceable basis to inform management decisions. Options may include recalibration, impact mitigation, or removal of the system from design, development, production, or use, as well as a range of compensating, detective, deterrent, directive, and recovery controls.'').

in its health programs and activities for clinical decision-making.

While we appreciate the breadth of mitigation techniques suggested by commenters—and agree that many of those efforts would be best practices to prevent algorithmic discrimination—we decline to require covered entities to take any specific mitigation efforts under § 92.210(c). We have determined that a reasonable efforts mitigation requirement strikes the right balance between the need for covered entities to mitigate the risk of discrimination resulting from their use of patient care decision support tools and the burden placed on covered entities. In the Proposed Rule, 87 FR 47883, we noted that covered entities may choose to mitigate discrimination by establishing written policies and procedures governing how clinical algorithms will be used in decision-making, including adopting governance measures; monitoring any potential impacts and developing ways to address complaints; and training staff on the proper use of such systems in decision-making. We encourage covered entities to take these and other additional mitigating efforts to comply with § 92.210.[361] We further note that this rule does not excuse a covered entity from complying with any other applicable Federal or State law that may apply, including but not limited to requirements for FDA approval where appropriate, such as the Food Drug and Cosmetic Act [362] and the Medical Device Amendments.[363]

In addition, once a covered entity identifies a particular use of patient care decision support tool under § 92.210(b), a covered entity's mitigation efforts under § 92.210(c) may vary based on the input variable or factor, as well as the purpose of the tool in question. OCR acknowledges that some input variables may generate greater scrutiny, such as race, which is highly suspect,[364] as compared to other variables, such as age, which is more likely to have a clinically and evidence-based purpose. Some bases protected by section 1557, such as age, are likely prevalent in patient care decision support tools and may not require extensive mitigation efforts under § 92.210(c) if use of the variable in the tool does not result in discrimination. For instance, where a tool employs an input variable for age, the covered entity's mitigation efforts under § 92.210(c) regarding that tool may include justifying the tool's use of age as an input variable by showing that age is clinically indicated as a measure in the particular tool and/or aligns with evidence-based clinical best practices that do not result in discrimination. We further note that the Age Act itself allows age distinctions under certain circumstances, including when related to age distinctions that reasonably take into account age as a factor necessary to the normal operation or the achievement of any statutory objective of a program or activity. 42 U.S.C. 6103(b)(1); 45 CFR 91.13 (adopting statutorily permissive age distinctions found at 42 U.S.C. 6103(b)(1)).

Comment: Some commenters indicated that clinicians trust the FDA's process for reviewing and approving clinical use of patient care decision support tools as well as published data illustrating a tool's efficacy in their use of these tools.

Response: The FDA regulates the sale of medical devices (including diagnostic tests) and monitors the ongoing safety and effectiveness of regulated marketed devices.[365] The FDA has released draft guidance on Predetermined Change Control Protocol (PCCP AI/ML) [366] and will be publishing draft guidance for Artificial Intelligence/Machine Learning (AI/ML)-enabled Device Software Functions: Lifecycle Management Considerations and Premarket Submission Recommendations. In addition, FDA is actively working through public-private partnerships to set uniform guidelines on addressing bias in AI across its lifecycle.

Section 92.210 is concerned with ensuring that covered entities' use of a patient care decision support tool does not result in prohibited discrimination, which includes medical devices as ''automated or non-automated tool[s] . . . used by a covered entity to support clinical decision-making.'' While FDA's premarket review processes strive to minimize discriminatory biases in patient care decision support tools before they are authorized to market, real world post-market deployment of FDA-approved devices can introduce discriminatory bias. Therefore, it is important to identify different points of bias and provide an action plan for remediation.[367]

Comment: Many commenters suggested that covered entities should share liability with algorithm creators for the consequences related to covered entities' use of these tools because clinicians may lack sufficient information to detect that an algorithm can result in discrimination. Another commenter suggested that § 92.210 should impose strict liability on manufacturers of algorithms, not the end users. Yet another commenter suggested that OCR create a safe harbor for covered entities that use clinical algorithms consistent with and within the scope of their intended purpose.

Response: Each covered entity is independently required to comply with all provisions in section 1557, including § 92.210. A covered provider's liability under section 1557 is not contingent on or related to a developer's potential liability under this rule or this provision. As discussed above, § 92.210(b) requires a covered entity to identify use of patient care decision support tools in its health programs and activities that employ input variables or factors that measure race, color, national origin, sex, age, or disability, and § 92.210(c) requires covered entities to make reasonable efforts to mitigate the risk of discrimination that results from the covered entity's use of a tool identified in § 92.210(b) in clinical decision-making.

If a developer is subject to section 1557, § 92.210 applies to it in the same manner it applies to all covered entities. Under § 92.210, covered entities must take requisite actions to ensure their use of a patient care decision support tool does not result in discrimination. We decline to impose strict liability on covered entities in their use of these tools, including covered developers.

---

[361] *See, e.g.,* Marshall H. Chin et al., *Guiding Principles to Address the Impact of Algorithm Bias on Racial and Ethnic Disparities in Health and Health Care,* 6 JAMA Network Open 12 (2023), *https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2812958*; Coalition for Health AI, *Blueprint for Trustworthy AI Implementation Guidance and Assurance for Healthcare* (2023), *https://www.coalitionforhealthai.org/papers/blueprint-for-trustworthy-ai_V1.0.pdf.*

[362] 21 U.S.C. 301 *et seq.*

[363] Pub. L. 94–925.

[364] *See, e.g.,* Michelle Tong & Samantha Artiga, *Use of Race in Clinical Diagnosis and Decision Making: Overview and Implications,* KFF (2021), *https://www.kff.org/report-section/use-of-race-in-clinical-diagnosis-and-decision-making-overview-and-implications-issue-brief/.*

[365] *See* U.S. Dep't of Health & Hum. Servs., Food & Drug Admin., *FDA's Role in Regulating Medical Devices, https://www.fda.gov/medical-devices/home-use-devices/fdas-role-regulating-medical-devices#:~:text=FDA%20regulates%20the%20sale%20of,of%20all%20regulated%20medical%20products.*

[366] 88 FR 19648 (Apr. 3, 2023); *see also* U.S. Dep't of Health & Hum. Servs., Food & Drug Admin., *CDRH Issues Draft Guidance on Predetermined Change Control Plans for Artificial Intelligence/Machine Learning-Enabled Medical Devices, https://www.fda.gov/medical-devices/medical-devices-news-and-events/cdrh-issues-draft-guidance-predetermined-change-control-plans-artificial-intelligencemachine.*

[367] *See* U.S. Dep't of Health & Hum. Servs., Food & Drug Admin., *About FDA: Patient Q&A, https://www.fda.gov/media/151975/download#:~:text=The%20FDA%20does%20not%20regulate,by%20health%20insurance%20or%20Medicare*; Alessandro Hammond et al., *An Extension to the FDA Approval Process Is Needed to Achieve AI Equity,* 5 Nature Machine Intelligence 96 (2023), *https://www.nature.com/articles/s42256-023-00614-8.*

Comment: Some commenters opined that proposed § 92.210 lacked sufficient specificity and that our reference in the Proposed Rule to covered entities' overreliance on clinical algorithms was confusing because there is no definition or criteria about what it means to ''rely'' on a clinical algorithm.

Response: We appreciate commenters' concerns. We note that § 92.210 relates to covered entities' *use* of patient care decision support tools rather than their reliance on them. In the Proposed Rule, we cautioned that a covered entity's overreliance on clinical algorithms in its decision-making can result in discrimination, and that covered entities should refrain from *over-relying* on patient care decision support tools by using them beyond their reasonably expected scope as a replacement or substitute for providers' clinical judgment. 87 FR 47880–82.

Comment: Some commenters characterized § 92.210 as a novel provision and argued that, in consequence, OCR investigative staff need to conduct fact-specific analyses of allegations of discrimination. Other commenters supported OCR's proposed approach to conduct a case-by-case factual inquiry into compliance with § 92.210. Many commenters pointed out that proactive oversight by OCR is also needed due to the non-transparent, systemic nature of this form of discrimination, which may limit complaints.

Response: OCR will investigate each complaint under § 92.210 on a case-by-case basis. OCR will review all applicable evidence to determine whether the covered entity took reasonable steps to identify whether the patient care decision support tool it is using is a tool that employs input variables that measure race, color, national origin, sex, age, or disability under § 92.210(b). When an investigation reveals that a covered entity has appropriately identified its use of a patient care decision support tool under § 92.210(b), OCR will determine whether the covered entity took reasonable efforts to mitigate the risk of discrimination resulting from the use of the patient care decision support tool at issue in accordance with § 92.210(c), as described above. As we have affirmed elsewhere with respect to other provisions of this final rule, OCR will employ all available means to investigate alleged violations of § 92.210, including through complaint investigations and compliance reviews based upon potential complaints in order to provide proactive oversight over the use of these tools.

Comment: A professional association commenter recommended that OCR's enforcement actions should consider whether covered entities have set up incentives to pressure health care professionals to follow the recommendations of clinical algorithms even if they conflict with the professional's clinical judgment.

Response: We appreciate this comment, and OCR will take such situations into account on a case-by-case basis when determining whether a covered entity violates this provision as OCR evaluates the facts in complaints brought under § 92.210.

Comment: Commenters recommended that OCR work with covered entities to achieve compliance by providing covered entities, specifically physician practices, with technical assistance and guidance, to help them integrate both clinical algorithms and improvements for these algorithms into existing clinical workflows to increase efficiency and minimize administrative burden.

Response: OCR seeks to provide covered entities with technical assistance regarding compliance with all civil rights requirements, including compliance with § 92.210. OCR is committed to partnering with covered entities to eliminate discrimination resulting from the use of patient care decision support tools in covered entities' health programs and activities.

Comment: Some commenters were concerned that complying with § 92.210 would be difficult for smaller covered entities with fewer resources.

Response: Section 92.210 applies to all covered entities regardless of size, including smaller entities. All covered entities must make reasonable efforts to mitigate the risk of discrimination resulting from their use of a patient care decision support tool identified in § 92.210(b), but the size and resources of the covered entity will factor into the reasonableness of their mitigation efforts and their compliance with § 92.210.

Comment: Some commenters encouraged OCR to require covered entities to comply with § 92.210 as quickly as possible, while one commenter suggested that covered entities should be required to evaluate their algorithms and mitigate bias within 12 months.

Response: We acknowledge that covered entities may need additional time to comply with the new requirements in § 92.210(b) and (c). Therefore, OCR is revising § 92.1 to reflect a delayed applicability date that specifies covered entities must comply with § 92.210(b) and (c) within 300 days following the effective date of the rule.

Request for Additional Comment

OCR seeks comment on whether we should engage in additional rulemaking to expand the scope of § 92.210, and if so, in what ways. Specifically, OCR seeks comment on other decision support tools that are being used in covered entities' health programs and activities that do not directly impact patient care and clinical decision-making, but may nevertheless result in unlawful discrimination in violation of section 1557, and whether § 92.210 should apply to such decision support tools. For example, we are aware of decision support tools that are used by health insurance issuers to determine amounts owed to them or by providers for services rendered. Other examples include tools used for automated coding for billing,[368] and fraud, waste, and abuse.[369] Additionally, covered entities may use decision support tools for administrative and operational activities, such as patient scheduling, and we are aware that there is research suggesting that these tools can result in rushed and inadequate care for lower socioeconomic patients.[370] Decision support tools may also be used to allocate resources, such as allocating spending geographically on diagnostic imaging that favors regions with historically more expensive, high-tech equipment and a lower presence of historically marginalized and underserved persons.[371] OCR seeks comment on these uses and others that may result in unlawful discrimination in violation of section 1557, and whether § 92.210 should be expanded to cover these tools as well.

Summary of Regulatory Changes

For the reasons set forth in the Proposed Rule and considering the comments received, we are finalizing § 92.210 with modifications. First, we are adding a § 92.210(a), which reads

[368] *See, e.g.,* Jessica Miller, *How Is AI Quickly Taking Medical Coding to the Next Level?,* Medicodio (June 6, 2023) *https://medicodio.com/how-is-ai-quickly-taking-medical-coding-to-the-next-level/#:~:text=AI%20has%20transformed%20medical%20coding,codes%2C%20and%20assign%20them%20automatically.*

[369] *See, e.g.,* Bill Siwicki, *At UMich, AI-Based Fraud, Waste, and Abuse System Aims to Cut Costs and Protect Patients,* HealthcareITNews (Aug. 1, 2023), *https://www.healthcareitnews.com/news/umich-ai-based-fraud-waste-and-abuse-system-aims-cut-costs-and-protect-patients.*

[370] *See, e.g.,* Howard Fine et al., *Health Care Embraces AI,* Los Angeles Business Journal (June 12, 2023), *https://labusinessjournal.com/special-reports/health-care-embraces-ai/.*

[371] *See, e.g.,* Brent Nelson et al., *Computerized Decision Support for Concurrent Utilization Review Using the HELP System,* 1 J. Am. Med. Informatics Ass'n. 339 (1994), *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC116216/pdf/0010339.pdf.*

the same as proposed § 92.210 except that we added ''General prohibition'' to the beginning of the provision and replaced the term ''clinical algorithm'' with the term ''patient care decision support tool.'' Second, we added § 92.210(b), which states, ''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.'' Third, we have added § 92.210(c), which states, ''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 the covered entity's health programs or activities.''

Nondiscrimination in the Delivery of Health Programs and Activities Through Telehealth Services (§ 92.211)

In § 92.211, we proposed that 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.

OCR sought comment on this approach and whether covered entities and others would benefit from a specific provision addressing accessibility in telehealth services for individuals with disabilities and individuals with LEP. We invited comment on what such a provision should include, and why the provisions at proposed §§ 92.201 (Meaningful access for individuals with LEP), 92.202 Effective communication for individuals with disabilities), and 92.204 (Accessibility of ICT for individuals with disabilities), would be insufficient. Further, we requested comment on challenges with accessibility specific to telehealth and recommendations for telehealth accessibility standards that would supplement the effective communication and ICT provisions of this part. We encouraged commenters to consider the range of technology available for accessing telehealth, including user-friendly design, as well as security and privacy requirements (for example, when using public Wi-Fi access).

The comments and our responses regarding § 92.211 are set forth below.

Comment: Most commenters on this issue were supportive, stating that a specific provision requiring nondiscrimination in delivery of health programs and activities through telehealth services is important for addressing health equity for underserved groups and areas, social determinants of health, and improving access to a wide range of health care. Some commenters added that the expansion of telehealth has been particularly important for access to care for those who are immunocompromised or otherwise at risk for COVID–19 and potential future pandemics, those who live in rural communities, and those in need of gender-affirming care. Many commenters called for increased investment and training to promote technological literacy as a vital complement to this effort.

Response: We agree that a standalone provision requiring nondiscrimination in delivery of health programs and activities through telehealth services is warranted and we appreciate the thoughtful comments. We welcome the opportunity to promote health literacy and provide technical assistance within our scope of authority.

Comment: A few commenters indicated that covered entities will require additional time, technical assistance, and/or safe harbors to come into compliance with this provision, particularly if specific language access and accessibility requirements regarding telehealth platforms are incorporated. Furthermore, one commenter contended that regulation is premature since telehealth technology and platforms are too new.

Response: While we appreciate the concerns expressed by covered entities, we respectfully disagree with the proposition that it is premature to regulate nondiscrimination in health programs and activities delivered via telehealth. As stated in the Proposed Rule and the Department's joint guidance with DOJ on nondiscrimination in telehealth (Telehealth Guidance),[372] covered entities that use telehealth are already prohibited from doing so in a discriminatory manner. The Telehealth Guidance explains covered entities' responsibilities to ensure effective communication and the provision of auxiliary aids and services (section 504 and § 92.202) and the provision of language assistance services for individuals with LEP (title VI and § 92.201). Telehealth platforms, in particular, are also covered by the ICT provision (§ 92.204). Given the dramatic expansion in the use of telehealth and continuing barriers in access to care experienced by individuals due to inaccessibility of telehealth services, we believe it is necessary and appropriate to regulate this medium of health care provision. OCR will provide further technical assistance and clarifying guidance as appropriate to help covered entities further understand their responsibilities.

Comment: Some commenters requested that OCR apply a broad definition of ''telehealth'' requesting inclusion of medical devices, tests, and equipment used as part of telehealth services. Other commenters requested OCR define telehealth as ''the use of digital technology to deliver health care, health information, and other health services, including diagnosis, treatment, assessment, monitoring, communications, and education.''

Some commenters also requested that audio-only and remote patient monitoring be required to comply with §§ 92.201 (Meaningful access for individuals with LEP), 92.202 (Effective communication for individuals with disabilities), and 92.204 (accessibility of ICT for individuals with disabilities).

Response: OCR has determined it is appropriate to codify the definition of the term ''telehealth'' as provided by the Health Resources and Services Administration [373] and the Office of the National Coordinator for Health Information Technology [374] referenced in the Proposed Rule at 87 FR 47884. As such, we are adding a definition for telehealth to the final rule under § 92.4. which will read ''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.'' Audio-only and remote patient monitoring services are included in this definition. Additionally, medical devices, tests, and equipment that are used as part of a health program or activity delivered through telehealth services must also be accessible.

Comment: Some commenters requested OCR amplify and make clear

[372] U.S. Dep't of Health & Hum. Servs., Off. for Civil Rts., U.S. Dep't of Justice, Civil Rts. Div., *Guidance on Nondiscrimination in Telehealth: Federal Protections to Ensure Accessibility to People with Disabilities and Limited English Proficient Persons* (July 29, 2022), *https://www.hhs.gov/civil-rights/for-individuals/disability/guidance-on-nondiscrimination-in-telehealth/index.html.*

[373] U.S. Dep't of Health Hum. Servs., Health Rsch. Servs. Admin., *What Is Telehealth?, https://www.hrsa.gov/rural-health/telehealth/what-is-telehealth.*

[374] HealthIT.gov, *What Is Telehealth? How Is It Different from Telemedicine?, https://www.healthit.gov/faq/*what-telehealth-how-telehealth-different-telemedicine.

that the privacy provisions under HIPAA are a part of this section. Many commenters detailed privacy concerns specific to individuals with disabilities and individuals with LEP. For individuals with disabilities, concerns were expressed for those who lack privacy in the home and might need additional functionality to be able to use telehealth privately.[375] Other commenters described concerns individuals with LEP may have about their data being shared with immigration or law enforcement.[376]

Response: Comments related to HIPAA are outside of the scope of this rulemaking. However, we direct commenters to HIPAA guidance we have released related to HIPAA and reproductive health care,[377] protecting the security of health information,[378] and audio-only telehealth.[379] Given our responsibility for HIPAA, OCR is very sensitive to privacy concerns among both people with disabilities and individuals with LEP and we remain committed to protecting their privacy and confidentiality.[380]

Comment: One commenter requested that OCR clarify that proposed § 92.211 on nondiscrimination through telehealth services does not apply to prescribing medication abortion or referring for abortion.

Response: The specific content of the health services provided via telehealth is beyond the scope of this rulemaking. In the same way in which we have generally declined to revise the final rule to address how a particular provision applies in the context of the provision of a particular type of care, we decline to do so here as well.

Comment: Many commenters wrote that ensuring equitable payment for and access to telehealth across a range of modalities (including audio-only telehealth, audio-video telehealth, real-time text, and in-person services), as well as making payment rules for telehealth implemented during the COVID–19 Public Health Emergency permanent, is needed to ensure nondiscrimination in the administration of telehealth. Other commenters said that audio-only telehealth should be reimbursed for individuals without smartphones or reliable broadband service. One State commenter requested CMS provide additional guidance on how this rule would impact service delivery in rural areas in light of CMS' audio-only service delivery in Medicare.

Response: Although OCR is cognizant of and sensitive to health equity concerns involving coverage and payment policies for health care services delivered via telehealth, such policies are outside the scope of OCR authorities and the section 1557 rulemaking. However, in general, OCR does not expect the rule to affect audio-only delivery of Medicare services in rural areas.

Comment: Several commenters wrote that inadequate reimbursement of telehealth and disparate medical management requirements limiting access to telehealth are discriminatory and that such practices ought to be prohibited.

Response: OCR will consider complaints raising the issues of whether inadequate reimbursement of telehealth or disparate medical management requirements limiting access to telehealth is discriminatory under section 1557 on a case-by-case basis. To the extent a covered entity's telehealth policies or practices delay or deny an individual's access to a health program or activity delivered via telehealth, OCR will consider whether the delay or denial is based on prohibited grounds under section 1557 as set forth in this rule, including as a discriminatory benefit design prohibited under § 92.207(b)(2). Covered entities have flexibility in determining the reimbursement rates and medical management requirements in their plans, and this rule does not establish specific reimbursement requirements or medical management requirements. However, as noted elsewhere in this preamble, such practices must be implemented in a nondiscriminatory manner.

Comment: Some commenters requested the rule prohibit covered entities from requiring individuals to use telehealth for programs, services, and assessments for which telehealth is inappropriate or risks substandard services or findings. Some commenters also asked OCR to require covered entities to offer in-person alternatives to telehealth services.

Response: OCR recognizes that not all health programs and activities are appropriately delivered via telehealth, and OCR will review complaints related to payers or providers that require individuals to receive programs, services, or assessments via telehealth for potential discrimination concerns. However, we decline to issue a blanket prohibition on the use of telehealth in specific circumstances as requested by commenters, as the use in those situations may not be per se discriminatory or there may be a legitimate, non-discriminatory reason for the practice.

A covered entity may need to offer in-person alternatives to telehealth, as a reasonable modification for individuals with disabilities who cannot be properly provided with effective communication or as a reasonable step to provide meaningful access for individuals with LEP through telehealth services. However, we decline to implement a general requirement that covered entities providing telehealth offer an in-person alternative.

Comment: Many commenters urged that individuals with a disability be afforded the opportunity to choose between telehealth and in-person care based on the service delivery model that works better for their health and communications needs and urged the inclusion of an opt-out provision.

Response: Any individual with a disability who needs to opt-out from receiving care via telehealth should request a reasonable modification of policies and procedures from the covered entity. Unless the reasonable modification fundamentally alters the health program or activity, the covered entity should approve an in-person visit.

Comment: A number of commenters called on OCR to codify WCAG 2.0 (AA), WCAG 2.1 (AA),[381] section 508, or related standards for telehealth platforms. Some recommended requiring certifications of compliance

[375] Rupa S. Valdez et al., *Ensuring Full Participation of People with Disabilities in an Era of Telehealth,* 28 J. Am. Med. Inform. Ass'n 389 (Feb. 2021), *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7717308/.*

[376] Aswita Tan-McGrory et al., *Addressing Virtual Care Disparities for Patients With Limited English Proficiency,* The Am. J. of Managed Care (2022) *https://www.ajmc.com/view/addressing-virtual-care-disparities-for-patients-with-limited-english-proficiency.*

[377] U.S. Dep't of Health & Hum. Servs., Off. for Civil Rts., *HIPAA Privacy Rule and Disclosures of Information Relating to Reproductive Health Care* (June 29, 2022), *https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/phi-reproductive-health/index.html.*

[378] U.S. Dep't of Health & Hum. Servs., Off. for Civil Rts., *Protecting the Privacy and Security of Your Health Information When Using Your Personal Cell Phone or Tablet* (June 29, 2022), *https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/cell-phone-hipaa/index.html.*

[379] U.S. Dep't of Health & Hum. Servs., Off. for Civil Rts., *Guidance on How the HIPAA Rules Permit Covered Health Care Providers and Health Plans to Use Remote Communication Technologies for Audio-Only Telehealth* (Jun. 13, 2022), *https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/hipaa-audio-telehealth/index.html.*

[380] U.S. Dep't of Health & Hum. Servs., Off. for Civil Rts., *A Health Care Provider's Guide to the HIPAA Privacy Rule: Communicating with a Patient's Family, Friends, or Others Involved in the Patient's Care* (Sept. 16, 2008), *https://www.hhs.gov/sites/default/files/provider_ffg.pdf.*

[381] Web Content Accessibility Guidelines 2.1 (AA), W3C World Wide Web Consortium Recommendation, *https://www.w3.org/TR/WCAG21/.*

from covered entities. One commenter recommended that covered entities be required to attest to making their best effort to accommodate patient needs. Another commenter suggested an elaborate alternative regulatory scheme that would treat telehealth platforms like public accommodations. Other commenters suggested that standards should be adopted in such a manner as to grant covered entities time to come into compliance, and others suggested safe harbors for compliance if a covered entity meets WCAG standards.

Response: OCR recognizes that this is a complex and evolving area, and given the rapid evolution of platforms and technologies, we have decided not to adopt specific accessibility standards at this time for telehealth platforms, particularly given other ongoing rulemakings in this field. Both OCR and DOJ recently issued NPRMs addressing the accessibility of web content and mobile apps used by recipients of Federal financial assistance and public entities, respectively.[382] Those rulemakings provide greater clarity on obligations to ensure that web content and mobile applications are accessible. This rulemaking requires covered entities to ensure telehealth platforms are accessible to individuals with disabilities, unless doing so would impose undue financial and administrative burdens or would result in a fundamental alteration in the nature of a covered entity's health programs or activities. Specifically, OCR notes that communications before, during, and after telehealth appointments must be accessible to individuals with disabilities and individuals with LEP, consistent with pre-existing section 504, title VI, and section 1557 requirements.

Comment: A number of commenters recommended expanding the nondiscrimination requirement of § 92.211 to designated companions or caregivers of people with disabilities, since shared involvement is often necessary to set and facilitate telehealth appointments.

Response: Yes, companions with disabilities are covered under the effective communications requirements of this rule at § 92.202, and therefore we do not believe this language needs to be added. Companions with LEP are similarly covered under the meaningful access requirements of this rule at § 92.201.

Comment: Many commenters stated that providers should assess individuals with disabilities seeking to use telehealth platforms for visual, cognitive, intellectual, mobility, and functional needs, and that platforms should be adapted to address the needs of a wide variety of people with diverse functional limitations who have difficulties communicating through traditional telehealth, including, but not limited to, people with visual, hearing, and speech disabilities.

Response: OCR agrees that such an assessment would be informative and is recommended as a best practice and as a means of connecting individuals with the most appropriate auxiliary aids and services to meet their needs. However, OCR has concluded it is important to allow covered entities flexibility in determining whether to assess individuals with disabilities seeking to use telehealth platforms. We therefore decline to adopt an assessment requirement at this time. However, OCR will continue to monitor developments in methodology for assessing individuals with disabilities.

Comment: Many commenters recommended that covered entities be required to provide individuals with a Notice of Availability (§ 92.11) when covered entities electronically communicate to individuals that they may make telehealth appointments with the covered entity.

Response: Such a scheduling communication is already covered by § 92.11(c)(5)(v), because it relates to services that ''require or request a response from a participant, beneficiary, enrollee, or applicant.''

Comment: A significant number of commenters recommended adopting detailed specifications and performance standards for accessibility features on telehealth platforms for individuals with specific disabilities. Several commenters also said OCR needed to provide specific requirements related to qualified interpreters on telehealth platforms with ''specific provisions addressing accessibility in telehealth services and particularly related to access for individuals with disabilities and LEP individuals.''

Response: While OCR appreciates commenters' request for detailed performance standards, we decline to adopt such provisions at this time given the rapid evolution of platforms and technologies. Requirements addressed elsewhere in the rule, including at §§ 92.201 (Meaningful access for individuals with LEP) and 92.202 (Effective communication for individuals with disabilities), provide a baseline from which covered entities can tailor their compliance. OCR will continue to consider issuing additional guidance on this topic.

Comment: One commenter wrote that audio-only visits are inherently inferior to audio-visual telehealth visits as they exclude information and meaning conveyed through visual cues, increasing chances for poor communications, misdiagnoses, flawed evaluations, and other subpar outcomes. This commenter advised requiring in-person care be available on the same terms as telehealth.

Response: Although OCR appreciates the comment and recognizes that audio-only telehealth communication may not be appropriate for all circumstances, we decline to disallow audio-only as an option for telehealth delivery. We believe this would erect an unnecessary and unjustified barrier to telehealth for individuals who lack the quality or consistent internet access necessary for audio-visual telehealth. As stated previously, a covered entity may need to offer in-person alternatives to telehealth to ensure effective communication for individuals with disabilities (section 504, the ADA, and section 1557), or meaningful access for individuals with LEP (title VI and section 1557), but we decline to implement a general requirement that in-person care be available on the same terms as telehealth. For further information, we once again direct commenters to the Telehealth Guidance.[383]

Comment: One commenter wrote that, given that telehealth is incorporated in ''information and communication technology for individuals with disabilities'' (§ 92.204), it would be helpful to explain the interaction between these two sections.

Response: This commenter is correct that telehealth is closely related to the ICT section. ICT is generally a means by which to facilitate access to information in a health program or activity, whereas telehealth is a medium through which a health program or activity is delivered and for which access is needed. Health programs and activities provided through ICT include telehealth, which we define as 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. In contrast, ICT relates to the technology and other equipment,

[382] *See* 88 FR 63392 (Sept. 14, 2023) (HHS) and 88 FR 51948 (Aug. 4, 2023) (DOJ).

[383] U.S. Dep't of Health & Hum. Servs., Off. for Civil Rts., U.S. Dep't of Justice, Civil Rts. Div., *Guidance on Nondiscrimination in Telehealth: Federal Protections to Ensure Accessibility to People with Disabilities and Limited English Proficient Persons* (July 29, 2022), *https://www.hhs.gov/civil-rights/for-individuals/disability/guidance-on-nondiscrimination-in-telehealth/index.html.*

such as 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. Thus, while telehealth interfaces and applications are a form of ICT, the rapid expansion of its use by providers and broad impact on the health care landscape necessitate careful consideration independent of a broader ICT section. The telehealth section is designed to ensure that health programs and activities delivered via telehealth technologies are done so in a manner that does not discriminate.

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 § 92.211 without modification.

Subpart D—Procedures

Enforcement Mechanisms (§ 92.301)

Proposed § 92.301 provides that 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 the part.

The comments and our responses regarding § 92.301 are set forth below.

Comment: Many commenters strongly supported OCR's clarification that section 1557 provides an independent basis for regulation of discrimination in covered health programs and activities. Supporters indicated that the rule as proposed would provide for robust enforcement of section 1557, consistent with existing law and the clear intent of Congress. One commenter expressed support for the different mechanisms of enforcement and emphasized the importance of enforcement that is level, targeted, and constant to ensure long-term adherence to section 1557's nondiscrimination provisions.

Response: OCR appreciates and acknowledges the need for strong enforcement mechanisms in order to adequately address discrimination in health programs and activities.

Comment: One commenter noted that making a clear procedure for claims of discrimination on multiple bases is important, not only for the complainant to fully understand their rights and remedies, but also for the covered entity to know how best to respond to a grievance. Commenters also suggested that OCR provide guidance on how covered entities should proceed with complaints that involve multiple bases of discrimination.

Response: OCR agrees that it is important to provide clarity to both complainants and covered entities regarding the procedures for raising a claim under section 1557. We currently offer resources on our website to provide the public and covered entities with information about the complaint process and how covered entities implement and maintain compliance. As discussed in § 92.303, in an effort to simplify the complaint process, OCR is revising the regulatory text to apply a single administrative enforcement procedure for discrimination complaints filed under section 1557, regardless of the alleged basis of discrimination. This will eliminate confusion for both covered entities and the public with regard to how OCR will evaluate and investigate allegations of discrimination brought under this part, including allegations involving multiple bases of discrimination. Covered entities should handle section 1557 grievances involving multiple bases of discrimination under one process. OCR will continue to provide guidance to covered entities on an ongoing basis to ensure compliance with the rule.

Comment: Several commenters stated that section 1557 creates a health-specific, nondiscrimination private cause of action. They opine that, because Congress expressly adopted one provision to prohibit discrimination on multiple grounds, the enforcement mechanisms available under each of the referenced statutes are not intended to be limited to the particular ground of alleged discrimination but rather would be available regardless of the ground of discrimination at issue.

Many commenters strongly recommended that OCR expressly state, as it did in the 2016 Rule preamble, that it will interpret section 1557 as authorizing a private right of action for claims of disparate impact for all grounds of prohibited discrimination. They stated that making the private right of action language explicit in the rule will provide for transparency and patient protection and enable more consistent enforcement of section 1557. Commenters stated that without a disparate-impact theory of liability, a private right of action will ring hollow for people of color and other systemically marginalized groups. Additionally, commenters noted that in an era where artificial intelligence and automated decision-making are increasingly responsible for resource allocation, recognition of disparate-impact liability is critical. Other commenters noted that a private right of action is essential to ensuring that individuals who experience discrimination on the basis of sex in health care are not solely reliant on OCR to enforce the law and may be entitled to seek compensation through a private right of action for the harm they experience.

Commenters further stated that the Supreme Court has affirmed the right of all private individuals to sue in Federal court to challenge violations of the protections of section 1557. Other commenters noted that a private right of action is essential to ensuring that individuals who experience discrimination on the basis of sex in health care are not solely reliant on OCR to enforce the law. Commenters also stated that by expressly including enforcement mechanisms ''available under'' the statutes, Congress authorized disparate-impact claims to be brought under section 1557.

Finally, commenters raised specific concerns regarding the Age Act's administrative exhaustion requirement, 42 U.S.C. 6104(f), and many commenters recommended that OCR include regulatory language in the final rule clarifying that administrative exhaustion is not required before a court action involving multiple bases of discrimination that includes age can be filed by the complainant. These commenters stated that because section 1557 is its own statute—enforceable by private right of action in the courts—an older adult who is discriminated against based on age and another basis should not be disadvantaged due to the Age Act's administrative-exhaustion requirement.

Response: Courts have long recognized that section 1557 authorizes a private right of action under any of the bases for discrimination. OCR declines 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.

Comment: One commenter requested that OCR clarify whether providers caring for individuals with disabilities and relatives of such individuals have the ability to bring a civil rights action in appropriate cases, such as where the provider or relative are themselves harmed by the plan's discriminatory conduct.

Response: OCR cannot provide legal advice as to whether an individual can appropriately bring a private claim under section 1557. If an individual—

including providers and relatives of a plan holder—believes they have experienced discrimination prohibited by section 1557, they are able to file a complaint with OCR. OCR will conduct a case-by-case analysis to determine its jurisdiction over the complaint allegations.

Comment: Some commenters urged OCR to increase enforcement capacity through coordination among agencies within the Department, and that the final rule should authorize OCR to empower other Department components, such as CMS, to investigate and enforce section 1557 claims.

Response: As a law enforcement agency with specialized knowledge and delegated authority over section 1557 enforcement, OCR is the agency within the Department that investigates and enforces section 1557 complaints. However, OCR continues to work with other agencies on many different initiatives and issues, including to promote compliance with Federal civil rights laws such as section 1557.

Comment: Some commenters suggested that OCR should pair enforcement with robust outreach and education. Several commenters requested that OCR postpone any enforcement action until after OCR provides education resources and technical assistance, to allow time for different practices to come into compliance without penalty.

Several commenters requested that OCR use enforcement discretion for particular groups of providers. For example, one commenter asked OCR to provide assurances that pharmacists can use reasonable clinical judgment to treat patients within their scope of practice, and not be subject to additional administrative burden and legal liability. Another commenter requested that OCR use enforcement discretion and not penalize physicians for failing to provide interpreter services as long as they make reasonable efforts to satisfy the final rule's requirements. This commenter also requested that OCR provide guidance and support for physicians in rural and other hard to reach areas for procuring and using the necessary technology to connect with remote interpreters. Specifically, this commenter pointed to concerns with physician practices in remote areas where interpreter availability is inconsistent and remote connectivity to interpreter services is either substandard or non-existent due to the lack of necessary broadband.

Response: We appreciate the commenters' concern, but section 1557 has been in effect since 2010 and OCR declines to postpone enforcement past the effective date of 60 days after publication of the final rule. We note, however, that we have provided delayed implementation dates for a number of provisions. Further, prior to taking an enforcement action (*i.e.,* terminating Federal financial assistance or referring a matter to DOJ for enforcement), OCR must attempt to achieve a covered entity's voluntary compliance with the law, such as through providing technical assistance and reviewing policies and procedures.[384]

Comment: Some commenters recommended adding a new provision requiring OCR to publish general information about the number and types of complaints received and resolved on a yearly basis and to publicly post information regarding resolution agreements within 14 days of resolving a complaint.

Response: Much of the information requested is already provided to Congress annually through OCR's Congressional Justifications and these annual justifications are also available on OCR's website.[385] In addition, OCR posts its resolution agreements to its website, available to anyone to review. We intend to continue with this practice as more cases are resolved.

Comment: Some commenters were also concerned with mandatory arbitration agreements and recommended that OCR include a specific provision prohibiting insurers from requiring binding arbitration as the exclusive means to resolve a complaint arising under section 1557. These commenters were concerned that binding arbitration greatly favors defendants, particularly large corporations.

Response: OCR appreciates concerns with regards to arbitration but notes that agreements between private parties is beyond the scope of this rulemaking.

Summary of Regulatory Changes

For the reasons set forth above and in the Proposed Rule and considering the comments received we are finalizing the provisions as proposed in § 92.301, without modification.

[384] *See, e.g.,* U.S. Dep't of Health & Hum. Servs., Off. for Civil Rts., *HHS Office for Civil Rights Resolves Complaints with CVS and Walgreens to Ensure Timely Access to Medications for Women and Support Persons with Disabilities* (June 16, 2023), *https://www.hhs.gov/civil-rights/for-providers/compliance-enforcement/agreements/cvs-walgreens/index.html.*

[385] Current and past OCR Congressional Justifications can be found at *https://www.hhs.gov/ocr/about-us/budget/index.html.*

Notification of Views Regarding Application of Federal Religious Freedom and Conscience Laws (§ 92.302)

In proposed § 92.302, OCR proposed an administrative process under which recipients can notify OCR of their views that they are exempt from certain provisions of section 1557 due to an applicable Federal conscience or religious freedom law. This proposed provision was not in either the 2016 or 2020 Rule.

Proposed § 92.302(a) provided that a recipient may notify OCR of its view that it is exempt from certain provisions of this part due to the application of a Federal conscience or religious freedom law. Proposed § 92.302(b) provided that once OCR receives such notification from a particular recipient, OCR shall promptly consider those views in responding to any complaints or otherwise determining whether to proceed with any investigation or enforcement activity regarding that recipient's compliance with the relevant provisions of this part. We further explained that any relevant ongoing investigation or enforcement activity regarding the recipient shall be held in abeyance until a determination has been made under § 92.302(c).

Proposed § 92.302(c) provided that based on the information provided in the notification under Proposed § 92.302(a), OCR may determine at any time whether a recipient is exempt from the application of certain provisions of this part, or whether modified application of the provision is required with respect to specific contexts, procedures, or health care services, based on an applicable Federal conscience or religious freedom law. In doing so, we further explained that OCR will assess whether there is a sufficiently concrete factual basis for making a determination and will apply the applicable legal standard of the relevant law. Proposed § 92.302(c) also provided that OCR will communicate its determination to the recipient. Proposed § 92.302(d) provided that if OCR determines that a recipient is exempt from the application of certain provisions of this part or modified application of the provision is required as to specific contexts, procedures, or health care services, based on a Federal conscience or religious freedom law, that determination does not otherwise limit the application of any other provision of this part to the recipient or to other contexts, procedures, or health care services.

The comments and our responses regarding § 92.302 are set forth below.

Comment: Many commenters expressed support for the proposed provision primarily because, in their view, § 92.302 would balance the need to protect both the religious and conscience views of recipients and the civil rights protections for patients, providers, and consumers. In commenting on the purpose of section 1557, one religious, organizational commenter stated that it ''strongly supports the principle of nondiscrimination in health programs and activities established by the ACA and the promulgation of regulations to ensure that principle is implemented robustly'' because ''[a]ccess to health care is essential to promote and protect the inherent and inalienable worth and dignity of every individual.'' Another religious, organizational commenter stated that ''[e]nsuring access to health coverage and health care, and removing barriers to these, is without question a laudable goal.''

Response: OCR appreciates these commenters' views and agrees that § 92.302 allows OCR to fully consider and uphold religious freedom and conscience laws as well as civil rights laws for patients, providers, and consumers, to ensure broad access to health care for all individuals.

Comment: Many other commenters opposed the addition of § 92.302. Commenters maintained that the process for notifying OCR of their exemption requests would burden religious entities and favor the interests of third parties. Some commenters raised concerns that claims of third-party harms can be used by opponents of religious liberty as a basis for denying any religious exemption. Additionally, a few commenters asserted that any investigation by OCR that excludes consultation with the Conscience and Religious Freedom Division will lead to religious and conscience objectors losing to claims of third-party harms. Commenters thus requested that OCR explain the types of harm that may overcome religious objections.

Response: OCR appreciates commenters' objections to § 92.302 and recognizes the request for guidance and clarification. In response to commenters who stated that the notification process itself burdens religious entities, OCR has added clarifications to the regulatory text stating that recipients may rely on the protections in religious freedom and conscience laws or seek further assurance of these protections from OCR, if they wish. OCR notes that under revised § 92.302, recipients are not required to seek assurance of an exemption in advance but may raise a claim under an applicable Federal religious freedom and conscience protection in the context of an OCR investigation or enforcement action. Also, we have revised § 92.302(a) to make clear that, 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. This language is consistent with language added to § 92.3(c) and has been interpreted by courts to support the Department's position that it ''will abide by RFRA in any enforcement of Section 1557'' and that the Department ''has never enforced section 1557 to require a provider with a religious objection to perform gender transition services.'' *Am. Coll. of Pediatricians* v. *Becerra,* 2022 WL 17084365 (E.D. Tenn. 2022) (citing to this language from the 2016 Rule as support).

In making determinations under § 92.302, OCR will faithfully apply the legal standards set forth in the Federal religious freedom or conscience law at issue. For example, RFRA provides that the Federal Government may not substantially burden a person's exercise of religion unless ''it demonstrates that application of the burden to the person—(1) is in furtherance of a compelling governmental interest; and (2) is the least restrictive means of furthering that compelling governmental interest.'' 42 U.S.C. 2000bb–1(b). Further, while case law interpreting RFRA requires consideration of any potential third-party harms, such harms, where relevant, are one of several factors that will be considered. Other Federal religious freedom and conscience laws set forth different tests. For example, a provision of the Church Amendments, 42 U.S.C. 300a–7, states that the receipt of Federal financial assistance (under certain statutes implemented by HHS) ''by any individual or entity does not authorize any court or any public official or other public authority to require . . . such individual to perform or assist in the performance of any sterilization procedure or abortion if his performance or assistance in the performance of such procedure or abortion would be contrary to his religious beliefs or moral convictions,'' *id.* 300a–7(b)(1). When administering its exemption process, OCR will carefully apply the text of these statutes and judicial precedents interpreting them, including by being mindful of the ways in which the texts of these statutes differ from one another.

We continue to believe that this approach is most consistent with the Federal religious freedom and conscience protections. In addition, OCR has consulted with the appropriate Department staff regarding the application of religious freedom and conscience protections during this rulemaking and will continue to engage staff during OCR's enforcement of the final rule.

Comment: Many commenters said that by not allowing a categorical pre-enforcement exemption and instead making the exemption process case-by-case, OCR will increase doubt among providers, inviting constant reliance upon administrative adjudication and litigation that will cost unnecessary time and money. Some commenters asserted that OCR's consideration of claims on a case-by-case basis is problematic for large health care systems with multiple sites of care. These commenters raised concerns that hospital systems would be deprived of the clarity and certainty needed to adhere to their religious principles and to establish compliance with policies covering all member hospitals, such that the health system would ensure that claimed exemptions were being appropriately and narrowly applied. These commenters claimed that because a recipient would be left with significant uncertainty until OCR considered any enforcement action, the process of claiming a pre-enforcement exemption with OCR affords few assurances of future enforcement protections.

Still, many other commenters supported the § 92.302 process because, in their view, such a case-by-case inquiry allows OCR an opportunity to consider objections in the context-specific manner that Federal religious freedom laws like RFRA require. Many commenters emphasized that in the context of health care under section 1557, the government has a compelling interest in not only preventing discrimination but ensuring taxpayer dollars are not used to further discrimination. Other commenters, however, asserted that RFRA imposes an affirmative obligation on the government to respect and protect religious liberty and is not a defensive argument for individuals to raise on a case-by-case basis.

Response: OCR understands some commenters' concerns and opposition to the proposed provision requiring case-by-case determinations. OCR maintains an important civil rights interest in the proper application of Federal conscience or religious freedom protections, which requires taking a case-by-case approach to such determinations. Among other things, this allows OCR to determine whether the government has a compelling

interest in denying an exemption to a particular party; [386] to consider, when relevant under the applicable legal standard, any harm an exemption could have on third parties, including other recipients, providers, patients, and the public; and to evaluate whether imposing burdens on a covered entity is the least restrictive means of furthering a compelling government's interest.[387]

However, to address commenters' concerns, OCR has revised § 92.302(a) to state that a recipient may ''rely on applicable Federal protections for religious freedom and conscience, and consistent with § 92.3(c), application of a particular provision(s) of this part to specific contexts, procedures, or health care services, shall not be required where such protections apply.'' When a recipient acts based upon its good faith reliance that it is exempt from providing a particular medical service due to the application of relevant religious freedom and conscience protections (*e.g.,* RFRA), OCR will not seek backward-looking relief against that recipient even if the recipient had not affirmatively sought assurance of an exemption under § 92.302(b). But if OCR determines, after an investigation, that the recipient does not satisfy the legal requirements for an exception, it will seek forward-looking relief as appropriate under the facts.

If the recipient wishes to receive an assurance from OCR regarding an exemption under any applicable religious freedom and conscience laws, it may do so under § 92.302(b) either prior to, or during the course of, an investigation. We understand that there was some confusion regarding the ''case-by-case approach'' discussed in how OCR proposed to evaluate exemption requests under § 92.302(b). We clarify here that a recipient may seek assurance of an exemption applying to specific contexts, procedures, or health care services generally. When OCR makes a case-by-case determination, this refers to the evaluation of the exemption assurance request as a whole—which may be requesting assurance of an exemption from a category of procedures or health care services. Thus, when we indicate that exemption requests will be evaluated on a case-by-case basis, this does not mean that a recipient must seek assurance of an exemption each time such procedure or health care is sought if an exemption already applies. Rather, a recipient may demonstrate that it is entitled to an exemption due to a religious or conscience objection to a particular provision in this part, as applied to specific contexts, procedures, or health care services.

A recipient may obtain assurance of its exemption in multiple ways under § 92.302(b). For example, if a recipient is seeking assurance of an exemption while there is no investigation pending, the notification to the OCR Director under § 92.302(b) would include: (1) identification of the provision of care to which the covered entity objects, specifying whether the objection is to the service overall or to the provision of care in a specific circumstance (per item (1)); (2) an explanation of the legal basis supporting the claim (per item (2)); and (3) the factual basis supporting the claim (per item (3)). Thus, for example, if a Catholic hospital is seeking an assurance of an exemption from having to perform sterilization procedures that would conflict with the religious tenets of their institution, their notification under § 92.302(b) would potentially include: (1) the provision to which there is an objection and that the objection is to provision of a procedure overall, *i.e.,* sterilization procedures that are prohibited by their religious tenets; (2) that they should be exempt under a specified religious freedom or conscience law; and (3) evidence that it, for example, never provides sterilization in violation of a particular religious or conscience belief for any patient, no matter their sex.

Alternatively, if a covered entity is seeking assurance of an exemption during an OCR investigation, it may similarly submit a notification under § 92.302(b). This notification would include the same information, but the factual basis for the claim would also discuss the specific context of the investigation in question. Though raised in response to a specific complaint allegation, the recipient may use this same notification to seek assurance of an exemption for the same circumstances going forward.

To take an example drawn from enforcement experience, OCR investigated allegations that a Catholic hospital discriminated against the complainant when it refused to allow his physician to perform a hysterectomy as a form of gender affirming care at their facility. The hospital confirmed during the investigation: (1) it did not perform the particular type of care or procedure (hysterectomy) on any patient under the circumstances (as it performs ''direct sterilization'' only for ''the cure or alleviation of a present and serious pathology and a simpler treatment is not available''); (2) that it was raising a defense under RFRA, citing the relevant legal standard; and (3) the factual basis for not providing such medical care and how the hysterectomy request conflicted with the exercise of its religious beliefs. OCR evaluated the complaint and the hospital's response in light of its obligations under RFRA, and determined that to require the hospital to allow the procedure in question to take place at their facility would result in a substantial burden on their religious exercise. OCR further found that section 1557's prohibition on sex discrimination as applied to the facts of this case was not the least restrictive means of achieving the government's compelling interest in preventing discrimination and therefore closed the matter.

Comment: Some commenters who supported the provision expressed appreciation that the process outlined in § 92.302 would allow OCR to consider an exemption's potential harms to third parties, such as patients or the public. Many commenters believed that this type of exemption process is structured to promote equity and transparency, while ensuring compliance with relevant legal requirements. Multiple commenters shared stories about denials of care, including in medical situations in which patients were seeking emergency services. One commenter reported an instance in which a woman was forced to deal with serious health complications when her treatment was delayed after emergency room staff learned of her sexual orientation. In another example, a commenter recalled that a pediatrician's office refused to make an appointment for an infant because the patient's parents were lesbians. Other commenters said a hospital refused to allow doctors with admitting privileges to provide their patients with, for instance, medically necessary gender-affirming care inside their facilities. Many commenters stated that even where patients are able to obtain the services from another provider, the delay in receiving care may cause irreparable harm. Multiple commenters described that the stress of being denied medical care and the fear of facing similar denials in the future can have serious negative health outcomes.

Some commenters who supported proposed § 92.302 compared the provision to the title IX religious exception, explaining that they preferred an administrative process that

[386] *Fulton* v. *City of Phila.,* 593 U.S. 522, 541–42 U.S. (2021).

[387] *See Burwell* v. *Hobby Lobby Stores, Inc.,* 573 U.S. 682, 739 (2014) (Kennedy, J., concurring) (''Among the reasons the United States is so open, so tolerant, and so free is that no person may be restricted or demeaned by government in exercising his or her religion. Yet neither may that same exercise unduly restrict other persons, such as employees, in protecting their own interests, interests the law deems compelling.'').

protects religious liberty, such as that proposed in § 92.302, over an exception that might be too broad.

Response: OCR appreciates these comments and agrees that the § 92.302 exemption process is the better approach.

Although commenters compared the proposed § 92.302 process with the title IX religious exception when expressing their support, OCR makes clear that the process provided under § 92.302 is separate and apart from title IX and this new provision does not rely upon or effectuate title IX's religious exception. Rather, as explained above, this provision clarifies the applicability of religious freedom and conscience protections and provides a process for OCR to respect applicable Federal religious freedom and conscience laws for specific recipients, whether or not they are religious organizations, in its enforcement of section 1557.

Comment: Several commenters who opposed this provision requested that OCR provide recipients with a categorical exemption, similar to what, in their view, was captured by the 2020 Rule through the importation of the title IX religious exception. In these commenters' view, such importation would provide a categorical exemption from providing procedures that would violate their religious beliefs. Many commenters also argued for incorporation of the title IX religious exception to address their concerns over what they viewed as the complexities, inconsistencies, and unpredictable nature of the § 92.302 process.

Many other commenters also stated that the process at § 92.302 is too burdensome and unclear, and in their view, it would effectively prohibit a provider from abstaining from procedures that violate their religious convictions. Additionally, some commenters stated that these burdens were unfair to religious employers, especially small employers, who the commenters said will refrain from applying for Federal funding, further harming patients due to limited providers.

A few commenters stated that, as proposed, § 92.302 forces religious entities to expose themselves to potential sanctions by requesting an exemption. Requesting any exemption, commenters argued, makes the recipient a target for an agency that, in their view, is a ''bully'' to religious organizations. Several commenters expressed concerns that in requesting an exemption, the recipient will lose, in their views, its ''privacy and anonymity,'' which could have a chilling effect on its provision of health care services.

Response: OCR appreciates and respects commenters' concerns relating to their religious convictions. The § 92.302 process demonstrates OCR's concerted effort to enforce Federal antidiscrimination laws and apply Federal religious freedom and conscience laws. Section 92.302 provides an administrative process, not implemented in either the 2016 or 2020 Rule, which responds to the shortcomings of both rules. Through the § 92.302 process, OCR is committed to implementing a rule that clarifies legal obligations and maintains transparency about its enforcement mechanisms.

Moreover, as previously addressed, *supra,* at § 92.208, OCR complies with the protections in the ACA itself; the Church, Coats-Snowe, and Weldon Amendments; the generally applicable requirements of RFRA; and other applicable Federal laws that provide religious freedom and conscience protections—§ 92.302 provides an administrative process through which providers may rely upon and assert these protections.[388] This provision helps ensure that recipients have an opportunity to seek assurance from OCR about the application of religious freedom and conscience protections. OCR does not seek to deprive a recipient of their ''privacy or anonymity,'' and the information requested is only that which is necessary to provide assurance of the exemption or modification that the recipient is seeking.

To clarify further, recipients may seek an assurance of an exemption under these Federal religious freedom and conscience laws at various points in time, including prior to an investigation or during an ongoing OCR proceeding. To begin, as explained above, a recipient may avail itself of the general application of § 92.302(a) and ''rely on applicable Federal protections for religious freedom and conscience, and application of a particular provision(s) of this part to specific contexts, procedures, or health care services, shall not be required.'' Should the recipient seek an assurance, it may—prior to any administrative investigation and enforcement—do so by filing a notification with OCR under § 92.302(b). OCR will then acknowledge receipt of the notification within 30 days, and the recipient may rely on a temporary exemption, per § 92.302(c)(1), while OCR adjudicates the assurance of exemption request. In instances where OCR has already initiated an investigation, the recipient 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). The notification will serve as a defense to the relevant investigation or enforcement activity, and a temporary exemption will then be in place per § 92.302(c)(2), pending OCR's determination regarding the request for assurance of the exemption or the conclusion of the investigation.

Finally, OCR disagrees with and respectfully objects to the characterization that it seeks to ''bully'' religiously affiliated recipients or expose them to potential sanctions. Religiously affiliated hospitals and health care facilities play a large role in the health care system, and OCR recognizes the critical patient care needs they provide, particularly in reaching underserved communities. As previously stated, the 2022 NPRM provided factual findings with respect to health care accessibility in the United States based upon health care capacity by providers, population demands, and geographic limitations. 87 FR 47840. A detailed discussion about these considerations can be found in the Regulatory Impact Analysis. In addition, OCR seeks to ensure Federal civil rights protections are fulfilled and has consulted with the appropriate staff regarding the application of religious freedom and conscience protections during this rulemaking and will continue to engage such staff during OCR's enforcement of the final rule.

Comment: Many commenters inquired about OCR's timeline for reaching a determination on a recipient's request. Specifically, commenters objected to the language in proposed § 92.302(c) that provides that, ''OCR may determine at any time whether a recipient is exempt from the application of certain provisions of this part'' because, in their view, this leaves open-ended the start and end points of the process. Some commenters opined that this uncertainty could result in disruptions or inappropriate denials of care while a recipient awaits a determination. Other commenters suggested that OCR amend § 92.302(c) to clarify what is intended by the clause ''may determine at any time'' because it may conflict with the provision in § 92.302(b) that such determinations will be made ''promptly.''

Many commenters recommended that OCR publish the anticipated timeframe for OCR's review of exemption requests, notify the requesting individuals/organizations about when OCR anticipates their review will be

[388] *See also* U.S. Dep't of Health & Hum. Servs., *Safeguarding the Rights of Conscience as Protected by Federal Statutes,* Final Rule, 89 FR 2078 (Jan. 11, 2024).

complete, and instruct the requesting individual/organization to notify patients if they will not be offering the service or treatment under review during that period. Commenters expressed the need to set a reasonable timetable to ensure that requests for exemptions are processed quickly to not impede or delay patient care. Some commenters also proposed that OCR publicize de-identified data on conscience claims and their respective review timelines to ensure public and private entities can monitor any access issues, should they occur.

Many commenters who opposed the process described in § 92.302 explained that the provision lacks the guidance or clarity necessary for recipients to comply. For example, several commenters noted that in proposed § 92.302(a), OCR merely invites health care entities to express their views on whether their Federal religious freedom and conscience rights would be violated but provides no information about when a response should be expected. Some commenters explained that proposed § 92.302(b) appears to contemplate that recipients would wait until they are investigated or subject to an enforcement action before notifying OCR of their view that Federal religious freedom and conscience laws protect them. According to commenters, as proposed, § 92.302 provides no incentive for recipients to notify OCR any earlier than that, since the subsection appears to impose no obligation on OCR to weigh the notification or request until such an investigation or enforcement action is live.

Other commenters pointed to the purported lack of guidance regarding the types of records and facts that would assist OCR in reaching a determination on the exemption request. Some commenters asserted that § 92.302(c) also does not explain how OCR will make final determinations and omits discussion of a recipient's potential recourse for appeal in the event of an adverse decision from OCR.

Response: OCR appreciates commenters' suggestions and concerns and understands the desire for additional clarity and an established timeline under which OCR will process requests for assurances of exemptions and notify recipients of any determination. We agree that there is value in providing more detail regarding what obligations OCR and recipients have during this process, and so have revised § 92.302. These revisions provide, among other things: (1) a general application provision stating that a recipient may rely on applicable Federal protections for religious freedom and conscience; (2) clarity on what a notification for an assurance of a conscience or religious freedom exemption must contain; (3) a temporary exemption that will take effect upon the recipient's submission of the notification, regardless of whether the recipient is being investigated, and that will remain valid during the pendency of OCR's review of the request and any administrative appeal; (4) a general timetable under which OCR will acknowledge and begin to evaluate requests for assurances of exemptions; (5) additional clarity with regard to the scope of an exemption that has been assured under § 92.302(d); and (6) an administrative appeal process for recipients receiving adverse determinations.

First, § 92.302(a) now provides that a recipient may rely on applicable Federal protections for religious freedom and conscience, and application of a particular provision(s) of this part to specific contexts, procedures, or health care services, shall not be required, and does not violate section 1557 if it so relies.

Second, § 92.302(b) now provides that a recipient may notify OCR of its view that it is exempt from certain provisions of this part due to the application of Federal protections for religious freedom and conscience and seek assurance of that exemption. This notification must be in writing directed to the OCR Director and the notification must include (1) the particular provision(s) of this part to which the recipient objects; (2) the legal basis supporting the assurance of exemption request, including the standards governing the applicable conscience or religious freedom law; and (3) the factual basis supporting the recipient's view that it is exempt, including identification of the conflict between the recipient's conscience or religious beliefs and the application of a provision in this part, which may include the specific contexts, procedures, or health care services that the recipient asserts will violate their conscience or religious beliefs overall.

Third, § 92.302(c) now provides that a recipient's notification and request for an assurance of an exemption to OCR will trigger the extension of a temporary exemption to the recipient. This exemption will cover the period of time it takes OCR to reach a determination on the request. The temporary exemption shall apply only to the provision(s) as applied to specific contexts, procedures, or health care services identified in the recipient's notification to OCR and will exempt conduct that occurs during the pendency of OCR's review and determination regarding the assurance of exemption request. In the event that there is an investigation or enforcement activity regarding the recipient related to the specific provisions for which an assurance of exemption has been requested, the temporary exemption will serve as a defense through the investigation or until OCR has made a determination on the assurance of exemption request, or through the administrative process if the recipient seeks an appeal under § 92.302(e). During this time, a recipient's temporary exemption shall remain effective. OCR will work promptly to reach a determination regarding the request.

Fourth, with respect to OCR's expected timetable for review, § 92.302(c) now provides that for pre-enforcement requests for an assurance of an exemption, OCR shall provide the recipient with email confirmation within 30 days of a recipient's notification acknowledging receipt of their request and stating that OCR will work expeditiously to reach a determination. If the request for an assurance of religious freedom and conscience exemption is received during the pendency of an investigation, it shall serve as a defense to the relevant investigation or enforcement activity until the final determination of the recipient's request, the conclusion of the investigation, and any relevant appeal. The temporary exemption shall exempt the recipient from the provision of care at issue in the investigation until a final determination is made on recipient's notification request or investigation, or during the pendency of any appeal.

Fifth, OCR has revised § 92.302(d) to clarify the effect of an exemption. The assurance of an exemption would exempt the recipient from OCR's administrative investigation and enforcement with regard to the application of a particular provision, which may include the specific contexts, procedures, or health care services that the recipient asserts will violate their conscience or religious beliefs. The exemption assurance will not apply to all contexts, procedures, or health care services. A recipient must otherwise have a legitimate, nondiscriminatory reason for denying or limiting service outside the scope of the granted exemption assurance, and any such decision must not be based on unlawful animus or bias, or constitute a pretext for discrimination. For example, a hospital with a religious exemption to not provide sterilizations outside of those permitted under their religious tenets may not rely on the exemption to broadly decline all health care services,

e.g., cancer treatments, to any individual if the hospital otherwise provides that care.

Sixth, § 92.302(e) now clarifies that a recipient may appeal an OCR determination under this section. The relevant revisions provide that recipients subject to an adverse determination of their request for assurance of an exemption may appeal OCR's determination of that request. Recipients who have been denied an exemption assurance under § 92.302 may raise their request before an administrative hearing examiner from the Department with the same procedural protections outlined for such administrative hearings under 45 CFR part 81. The temporary exemption granted under § 92.302(c) would remain in effect until completion of the administrative appeal process.

Comment: Many commenters supportive of the outlined process also urged OCR to revise proposed § 92.302 to require OCR to make publicly available, or publish on its website, all determinations for any exemptions claimed or granted under § 92.302. A few commenters made specific suggestions for what the public postings should contain. These commenters proposed that postings should include the name(s) of the recipient requesting the exemption, the factual basis asserted by that recipient demonstrating its eligibility under Federal law, OCR's analysis of those facts, and the specific provision(s) of the rule to which an exemption is recognized. A handful of other commenters raised the possibility of requiring exemption determinations to be published, within 10 days of issuance, in the **Federal Register** and on the Department's website. Commenters also suggested that the notice should be accompanied by an electronic link to documents that specifically state the nature, scope, and duration of the exemption granted.

Many commenters discussed that, in addition to promoting transparency, providing notice to the public of religious and conscience exemptions granted would provide guidance both to providers and patients regarding their rights and responsibilities under section 1557, reducing confusion that can impede equitable access to care, particularly for the vulnerable populations the rule is designed to protect. Many commenters stated that it is important that individuals seeking care or coverage know whether the health providers or issuers they are considering do, in fact, provide the services they need—including whether they will be presented with all available care options—and whether they will feel accepted and welcomed by the provider they see.

Response: OCR appreciates commenters' suggestions for revisions to the rule to provide notice to the public regarding assurances of exemptions granted under this provision, including through having OCR post information regarding such assurances. Consistent with our title IX regulations and those of other agencies,[389] OCR declines to revise § 92.302 to require affirmative notice of exemptions sought by or granted to recipients under this provision. OCR notes that nothing in this final rule prevents a recipient from providing public notice of any such exemption assurances it has sought or received and we encourage recipients to do so. We recognize that individuals are not always aware that the health care entities from which they seek care may be limited in the care they provide, and remain committed to working with recipients and the public to improve transparency, clarity, and access to health care through implementation of this rule. As noted above, OCR is also subject to FOIA, and information may be released to a requestor or made available for public inspection consistent with the agency's obligations under that statute and its implementing regulations.

Comment: Some commenters also criticized the process laid out in § 92.302 for failing to identify who will evaluate the exemption requests. One commenter stated that most recipients will likely wait to raise their religious defenses in litigation, as they see courts as the only neutral decisionmakers. A handful of commenters also raised concerns that the 2022 NPRM did not mention OCR's 2019 final rule, *Safeguarding the Rights of Conscience as Protected by Federal Statutes,* 84 FR 23170 (May 21, 2019), or its applicability to numerous Federal statutes protecting religious freedom and conscience in health care. As a result of this omission, these commenters expressed skepticism about OCR's ability to apply the regulatory provisions contained in that rule.

Several commenters also questioned the interaction between the proposed exemption process and private rights of action. They stated that while the § 92.302 process would apply to OCR investigations and enforcement, the provision did not address situations where a lawsuit has been filed, as there is no across-the-board requirement that the administrative process be exhausted before going to court. Commenters assumed that faith-based hospitals likely will be forced to litigate claims in the courts without the ability to stay proceedings pending OCR's consideration of their exemption claim—another factor, they argued, which undermined the usefulness of the proposal.

Response: OCR appreciates commenters' concerns regarding the process for review. OCR refers commenters to the six specific steps outlined above detailing what obligations OCR has, and what options are available to recipients. And as stated previously, OCR is committed to enforcing all Federal civil rights laws under its purview. While OCR appreciates comments regarding the 2019 *Safeguarding the Rights of Conscience as Protected by Federal Statutes* final rule, as a result of challenges to its legality, that rule has been vacated.[390] OCR has published its final rule on enforcement of religious freedom and conscience laws. *See Safeguarding the Rights of Conscience as Protected by Federal Statutes,* 89 FR 2078 (Jan. 11, 2024). Finally, OCR would not open or continue an investigation under section 1557 against the recipient regarding compliance with a provision for which they have requested an exemption assurance while a temporary exemption under § 92.302(a) is in effect, or after a final determination is made that the recipient is entitled to an exemption. While such commenters are correct that a temporary or final assurance of an administrative exemption from OCR would not itself preclude any private lawsuit under section 1557, OCR notes that the recipient could still raise the relevant Federal conscience or religious freedom law as a possible defense in judicial proceedings in such private litigation. And in cases where OCR has assured the recipient an exemption under § 92.302, the recipient could argue that that assurance is evidence that a Federal religious freedom or conscience law likely applies to the recipient in any private litigation under this final rule.

Summary of Regulatory Changes

For the reasons set forth in the Proposed Rule and considering the

[389] *See, e.g.,* 45 CFR 86.12 (no notice requirement); *see, e.g.,* 34 CFR 106.12 (Department of Education, same).

[390] *New York* v. *HHS,* 414 F. Supp. 3d 475, 580 (S.D.N.Y. 2019) (''Accordingly, as a remedy, the Court vacates the 2019 Rule in its entirety, pursuant to [the Administrative Procedure Act] § 706(2).''), *appeal dismissed without prejudice to reinstatement,* Nos. 19–4254 et al. (2d Cir.); *see also Washington* v. *Azar,* 426 F. Supp. 3d 704 (E.D. Wash. 2019), *appeal pending,* No. 20–35044 (9th Cir.); *City & Cnty. of San Francisco* v. *Azar,* 411 F. Supp. 3d 1001 (N.D. Cal. 2019), *appeal pending,* Nos. 20–15398 et al. (9th Cir.).

comments received, we are finalizing the provision as proposed in § 92.302, with modifications. First, we are adding a § 92.302(a), which provide that a recipient may rely on applicable Federal protections for religious freedom and conscience, and consistent with § 92.3, application of a particular provision(s) of the part to specific contexts, procedures, or health care services shall not be required where such protections apply.

Second, we are revising the process laid out in proposed § 92.302(b) through (d) as follows. We are revising § 92.302(b) to provide that a recipient that seeks assurance consistent with § 92.302(a) regarding the application of particular provision(s) of the part to specific contexts, procedures, or health care services may do so by submitting a notification in writing to the Director of OCR. Notification may be provided by the recipient at any time, including before an investigation is initiated or during the pendency of an investigation, and provides details on what must be submitted in writing to the OCR Director. We are revising § 92.302(c) to provide that a temporary exemption from administrative investigation and enforcement will take effect upon the recipient's submission of the notification—regardless of whether the notification is sought before or during an investigation, and then delineates the scope and application of the temporary exemption. We are revising § 92.302(d) to provide that if OCR makes a determination to provide assurance of the recipient's exemption from the application of certain provision(s) of the part or that modified application of certain provision(s) is required, the recipient will be considered exempt from OCR's administrative investigation and enforcement with regard to the application of that provision as applied to the specific contexts, procedures, or health care services provided in the written determination. The determination does not otherwise limit the application of any other provision of the part to the recipient or to other contexts, procedures, or health care services.

Third, we are adding § 92.302(e) to provide an administrative appeal process for recipients subject to an adverse determination of its request for an assurance of religious freedom and conscience exemption. Fourth, we are adding § 92.302(f) to provide that a determination under this section is not final for purposes of judicial review until after a final decision under 45 CFR part 81.

Procedures for Health Programs and Activities Conducted by Recipients and State Exchanges (§ 92.303)

Section 92.303 proposed the enforcement procedures related to health programs and activities conducted by recipients and State Exchanges.

In § 92.303(a), OCR proposed applying the procedural provisions in the title VI regulation with respect to administrative enforcement actions concerning discrimination on the basis of race, color, national origin, sex, and disability under section 1557.

Proposed § 92.303(b) applied Age Act procedures to enforce section 1557 with respect to age discrimination complaints against recipients and State Exchanges.

Proposed § 92.303(c) stated that when a recipient fails to provide OCR with requested information in a timely, complete, and accurate manner, OCR may, after attempting to reach a voluntary resolution, find noncompliance with section 1557 and initiate the appropriate enforcement procedure, found at 45 CFR 80.8.

The comments and our responses regarding § 92.303 are set forth below.

Comment: Many commenters recommended that § 92.303(a) explicitly recognize claims of discrimination involving multiple grounds, and suggested adding the language ''or a combination thereof.''

Response: As discussed in § 92.101, OCR agrees with this recommendation and we have added ''or any combination thereof'' throughout the regulatory text.

Comment: Commenters generally supported adoption of title VI procedural provisions with respect to administrative enforcement actions; however, they noted that OCR proposed to process complaints alleging discrimination on the basis of age differently given the adoption of Age Act regulation requirements under § 92.303(b). These commenters recommended that OCR clarify that for administrative enforcement, it will treat claims involving multiple bases, such as age and other protected identities, under the same procedural provisions as title VI.

Response: The Proposed Rule followed the 2016 Rule's approach to administrative enforcement procedures for complaints on the basis of race, color, national origin, sex, and disability, applying the procedures found in the title VI regulation. The Proposed Rule proposed to apply the Age Act regulatory procedures to age-based complaints. The Age Act procedures uniquely contain a requirement that the Department refer all sufficient complaints to mediation upon receipt; unresolved complaints will be returned to the Department. 45 CFR 91.43. The timeline for mediation is generally 60 days, unless a resolution is reached sooner, or the mediator has extended the time period for no more than 30 days. *Id.* at § 91.43(e). The 60-day period counts as part of the 180 days the Department has to resolve a complaint before a court action can be filed by the complainant. 47 FR 57850, 57856 (Dec. 28, 1982). The mediation requirement derives entirely from the HHS Age Act regulations. The Age Act statute does not itself mandate referral for mediation. It merely directs agencies to publish regulations that ''provide appropriate investigative, conciliation, and enforcement procedures.'' 42 U.S.C. 6104(a)(4).

In adopting the mediation requirement, the Department stated that the Age Act regulations offered ''a unique opportunity to try [the] innovative approach'' to resolution of complaints and committed to monitoring the effectiveness of the mediation process. 47 FR 57850, 57856 (Dec. 28, 1982). According to the Department's 2021 Age Act Report, the Department referred 32 complaints for mediation, and two were successfully mediated (6 percent).[391] Eight of 21 (38 percent) cases were successfully mediated in 2020, and eight of 48 (17 percent) were successfully mediated in 2019.[392] Thus, the average success rate of mediation for complaints alleging age discrimination is roughly 18 percent. When a complaint is returned to the Department, it follows the title VI procedural provisions for investigations and enforcement. 45 CFR 91.47.

We agree that individuals filing complaints with OCR under any of the bases for discrimination, including on the basis of age, should not be subject to unnecessary administrative hurdles. Given that the Age Act mediation requirement is not required by statute, but rather was an ''innovative'' approach adopted by the Department under its administrative authority to implement the Age Act, we have determined that OCR has the authority to not import such a requirement into the section 1557 procedures. While

[391] *Annual Report to Congress on Implementation of the Age Discrimination Act of 1975—Fiscal Year 2021,* p. 32, *https://www.hhs.gov/sites/default/files/age-act-2021-report.pdf.*

[392] *Annual Report to Congress on Implementation of the Age Discrimination Act of 1975—Fiscal Year 2019,* p. 30, *https://www.hhs.gov/sites/default/files/age-act-2019-report.pdf*; *Annual Report to Congress on Implementation of the Age Discrimination Act of 1975—Fiscal Year 2020,* p. 32, *https://www.hhs.gov/sites/default/files/age-act-2020-report.pdf.*

mediation may prove beneficial under certain circumstances, as reflected through the Department's reporting on Age Act enforcement, it is not successful in all cases.

Given concerns raised by commenters, the value OCR places on the efficient and timely resolution of complaints, and the potentially sensitive nature of complaints raised under section 1557, we revisited the proposal to require complainants to engage in mandatory mediation. After review, and in light of these considerations and a desire for consistency across section 1557 administrative enforcement, we are revising the regulatory text to strike proposed § 92.303(b), which would have applied the Age Act procedural provisions to administrative enforcement actions concerning age discrimination. We are also revising § 92.303(a) to apply the title VI procedures to all administrative enforcement actions brought under section 1557.

This means that a complaint filed under section 1557 alleging age discrimination would not require the complainant to engage in mediation before OCR can open an investigation and claims alleging multiple bases of discrimination would be subject to the same enforcement procedures under the final rule. We note that complainants that wish to engage in mediation to address a complaint against a recipient or State Exchange will be provided with the option to do so, as these complaints may also be addressed under the Age Act, consistent with 45 CFR 91.43.

Comment: Commenters suggested making the OCR complaint process more straightforward and accessible, especially since individual complaints remain the primary trigger for investigations and individuals often file without legal representation. Commenters suggested that the final rule offer clear, fully accessible complaint mechanisms, including directions written in plain language, for filing discrimination complaints. These commenters suggested that complainants should not be required to parse out how a covered entity perceived them or responded to differing aspects of their lives. Further, these commenters recommended that any complaint procedures include resource materials such as Frequently Asked Questions, process diagrams, and materials presented in alternative formats, including videos with instructions in ASL embedded into the website as well as a clear and simple complaint process for individuals with LEP. One commenter further suggested that OCR clarify in the final rule that citizenship status is not relevant to an enforcement process or complaint filing.

One commenter also recommended that the time allowed for filing a complaint without needing to show good cause be extended from 180 days to 6 years to account for the postpartum timeline. Another commenter urged OCR to consider putting the longest deadline on the complaint filing that it can, consistent with its statutory obligations. This commenter noted that it often takes people months to realize they have been discriminated against, decide to do something about that discrimination, and find out that there are laws against the discrimination and agencies like OCR where they can file complaints.

Response: OCR appreciates the comments regarding the complaint process. We understand the complaint filing process may be both perceived and experienced as challenging, and OCR welcomes suggestions on making the process more accessible. We currently offer resources on our website to provide the public with information about the process for submitting a complaint and what to expect once they have submitted a complaint to OCR.[393] In addition, OCR revises its own processes, as needed. The most recent updates to OCR's Civil Rights Discrimination Complaint Form and Portal, for example, include providing the form and portal in fifteen languages other than English, and inclusion of additional clarity regarding forms of discrimination to report, including sexual orientation, gender identity, pregnancy, and discrimination against individuals with LEP.[394] We consider changes to the OCR complaint process on an ongoing basis as we strive to simplify the process and make it more accessible to all.

OCR notes that the requirement that a complaint be filed no later than 180 days from the alleged discrimination is consistent with the enforcement mechanisms under title VI, which we adopt herein and have also been adopted under title IX, section 504, and the Age Act. OCR will continue to extend the 180-day filing deadline for good cause, as outlined in the title VI regulation at 45 CFR 80.7(b). Further, to make this information more widely available, we are reinstating a required Notice of Nondiscrimination (§ 92.10), which includes information on how to file a complaint with OCR should an individual believe they were discriminated against.

In response to the comments received, OCR also notes that citizenship status is not relevant to an enforcement process or complaint filing; an individual's citizenship or immigration status does not prevent or alter their ability to file a complaint or OCR's ability to enforce potential violations.

Comment: Some commenters indicated that OCR should initiate compliance reviews rather than wait on individual complaints and some noted that while a simple, accessible complaint system is helpful, it should not, and cannot be, the only means of enforcement. Commenters stated that robust enforcement must include agency-initiated oversight, monitoring, and investigations; and that OCR should proactively review medical providers' treatment of patients of color for patterns to help detect bias.

A few commenters stated that incorporating the title VI procedures in proposed § 92.303(a) means including requirements that covered entities submit compliance reports and data to OCR and authorizing OCR to conduct periodic compliance reviews of covered entities. These commenters argued that OCR is effectively declaring that its enforcement of these provisions will be based on the presumption that any business decision made by a covered entity is either intentionally discriminatory or has an impermissibly discriminatory effect, unless and until that entity can demonstrate otherwise to OCR's satisfaction. According to the commenters, this would have the effect of imposing an expansive, arbitrary, and capricious new regulatory regime.

Response: OCR appreciates the importance of compliance reviews and robust enforcement. While most OCR investigations are conducted based on complaints received, OCR also conducts compliance reviews, which may be based on, for example, news reports or other information received by OCR.[395]

[393] U.S. Dep't Health & Hum. Servs., Off. for Civil Rts., *Filing a Civil Rights Complaint, https://www.hhs.gov/civil-rights/filing-a-complaint/index.html.*

[394] U.S. Dep't of Health & Hum. Servs., Off. for Civil Rts., *Complaint Portal, https://ocrportal.hhs.gov/ocr/cp/complaint_frontpage.jsf*; U.S. Dep't of Health & Hum. Servs., Off. for Civil Rts., *Get Help in Other Languages, https://www.hhs.gov/ocr/get-help-in-other-languages/index.html*; U.S. Dep't of Health & Hum. Servs., Off. for Civil Rts., *Office for Civil Rights, Civil Rights and Conscience Complaint form* (Expiration Date: Dec. 31, 2025), *https://www.hhs.gov/sites/default/files/ocr-cr-complaint-form-package.pdf.*

[395] For example, on March 7, 2023, OCR announced that it had reached a Voluntary Resolution Agreement with Hillsborough County Fire and Rescue in Florida to improve access to care for communities of color. OCR initiated a compliance review of Hillsborough County Right and Rescue in response to public press reports indicating that its paramedics refused to transport

OCR disagrees with commenters' position that adopting the longstanding enforcement procedures of title VI creates a presumption that a covered entity is discriminating. Nor does the adoption of these procedures represent a new ''regulatory regime,'' as these procedures appear in the Department's title VI regulations, which were originally published in 1964[396] and have since been adopted in the Department's title IX and section 504 regulations. Section 92.303, adopting 45 CFR 80.6 (Compliance information), includes standard requirements related to civil rights enforcement, including seeking cooperation from recipients and State Exchanges in obtaining compliance; providing assistance and guidance to assist recipients and State Exchanges reach voluntary compliance; requiring records maintenance by recipients and State Exchanges so that they may demonstrate compliance with the conditions of their receipt of Federal funds; requiring access to pertinent records as needed to determine compliance; and sharing information with the public regarding protections against discrimination. As with all of its investigations, including compliance reviews, OCR acts as a neutral factfinder and does not presume discrimination by the covered entity.

Comment: Some commenters recommended that OCR consider creating a searchable database of complaints and provide status updates that clearly indicate where in the process a complaint stands. Commenters also noted that OCR should shorten the time between filing a complaint and resolution. They noted that lengthy timelines for resolution have been detrimental, as advocates are reluctant to file knowing the duration of an investigation, and covered entities feel less urgency to comply. Some commenters noted that an ongoing deterrent to filing administrative complaints with OCR is the lack of a mandatory response deadline from OCR in title VI procedures. These commenters recommended implementing a 90-day deadline for OCR to resolve most section 1557 complaints, and a 120-day deadline for ''more involved'' section 1557 complaints.

Response: OCR appreciates commenters' recommendation to create a searchable database of complaints, and will take that under advisement, though we cannot commit to doing so at this time. OCR works with finite resources to address complaints as quickly and efficiently as possible and will continue to do so. Title VI procedures require a prompt investigation whenever information indicates possible noncompliance. OCR intends to follow these enforcement procedures and promptly address and resolve outstanding compliance failures. Because each potentially discriminatory action involves unique facts and circumstances that must be independently investigated on a case-by-case basis before OCR can determine whether a challenged action is considered discriminatory, we decline to add a mandatory response deadline as requested by commenters.

Comment: One commenter recommended that OCR create a separate portal for complaints related to obstetric violence and obstetric racism.

Response: OCR currently uses one portal for all civil rights complaints. The portal allows complainants to select the ground(s) under which they believe they were discriminated against to help ensure their complaints are fully reviewed and considered by OCR.

Comment: Some commenters suggested merging proposed §§ 92.303 and 92.304 to help reduce confusion among complainants.

Response: While we appreciate the need to have clarity when filing complaints, maintaining two separate sections is necessary given that there are different procedures for OCR to follow depending on whether the complaint is against the Department itself, or a recipient or State Exchange. However, for the sake of additional clarity, OCR will revise § 92.303(a) to parallel § 92.304,

Comment: Some commenters recommended OCR include a provision in § 92.303 expressly stating that if OCR does not have jurisdiction over a complaint, it will refer it to the appropriate office or agency.

Response: Section 92.304 adopts the compliance procedures found in OCR's federally conducted section 504 implementing regulation, which includes a provision requiring OCR to make reasonable efforts to refer a complaint over which it does not have jurisdiction to the appropriate Federal Government agency. 45 CFR 85.61(e). There is no corresponding provision in the title VI procedures, which are adopted at § 92.303 and are applicable to recipients and State Exchanges. However, OCR's practice is to refer such complaints, and we believe this is important to reflect this in regulatory text. We have included a new provision, replacing the former age-discrimination related provision at proposed § 92.303(b), that reads: ''If OCR receives a complaint over which it does not have jurisdiction, it shall promptly notify the complainant and shall make reasonable efforts to refer the complaint to the appropriate Federal Government entity.''

A *Comment:* Some commenters recommended that any enforcement mechanism include monitoring, reporting, and ''actual penalties'' or fines.

Response: We appreciate the need for strong enforcement mechanisms to ensure compliance with section 1557. The enforcement mechanisms incorporated into the rule allow for investigations based on both complaints and OCR-initiated compliance reviews. Voluntary Resolution Agreements and Settlement Agreements resulting from investigations generally include a monitoring period and reporting requirement to ensure ongoing compliance. If a recipient or State Exchange does not come into voluntary compliance and is found in violation of section 1557, OCR can take compliance action by either initiating fund termination proceedings under 45 CFR 80.8 or by any other means authorized by law, including referral to DOJ for enforcement proceedings.

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 § 92.303, with modifications. We are revising § 92.303(a) to read ''. . . administrative enforcement actions concerning discrimination on the basis of race, color, national origin, sex, age, disability, or any combination thereof . . .'' This language applies the same procedural provisions to administrative enforcement actions under section 1557

---

an African American woman to the hospital because they assumed she could not afford the ambulance cost due to her race. *See* U.S. Dep't Health & Hum. Services, Off. for Civil Rts., *HHS Office for Civil Rights Reaches Agreement with Hillsborough County Fire and Rescue in Florida to Improve Access to Care for Communities of Color*, *https://www.hhs.gov/about/news/2023/03/07/hhs-office-for-civil-rights-reaches-agreement-with-hillsborough-county-fire-and-rescue-in-florida.html*. In June of 2022, OCR entered into a Voluntary Resolution Agreement with the University of Southern California (U.S.C.) and Keck Medicine of U.S.C. (collectively, the ''KMUSC Entities'') resolving a compliance review of KMUSC Entities' policies and procedures for responding to sex discrimination complaints made by students, employees, or patients employed by, or participating in, any KMUSC programs or activities receiving Federal financial assistance from HHS. *See* U.S. Dep't Health & Hum. Servs., Off. for Civil Rts., *HHS Voluntary Resolution Agreement with the University of Southern California Settles Title IX Compliance Review*, *https://www.hhs.gov/about/news/2022/06/15/hhs-voluntary-resolution-agreement-with-university-of-southern-california-settles-title-ix-discrimination-complaints.html*.

[396] 29 FR 16298, 16301–03 (Dec. 4, 1964).

regardless of the basis of alleged discrimination, acknowledges that discrimination experienced by individuals may involve multiple bases, and corrects a scrivener's error (an unnecessary placement of the word ''discrimination'' after ''disability''). We are also revising § 92.303(a) to parallel § 92.304, to now provide that the procedural provisions applicable to title VI apply with respect to administrative enforcement actions against health programs and activities of recipients and State Exchanges concerning discrimination on the basis of race, color, national origin, sex, age, and disability discrimination under section 1557 or the part. These procedures are found at 45 CFR 80.6 through 80.11 and part 81 of the subchapter. Additionally, we are replacing the text at proposed § 92.303(b) with new language stating: ''If OCR receives a complaint over which it does not have jurisdiction, it shall promptly notify the complainant and shall make reasonable efforts to refer the complaint to the appropriate Federal Government entity.''

Procedures for Health Programs and Activities Administered by the Department (§ 92.304)

In § 92.304, OCR addressed procedures for all claims of discrimination against the Department under section 1557 or the part, as set forth in § 92.304(a).

Section 92.304(b) proposed making the existing procedures under the section 504 federally conducted regulation at 45 CFR 85.61 and 85.62 applicable to all such claims under Section 1557 for all protected bases (*i.e.,* race, color, national origin, sex, age, and disability).

Section 92.304(c) proposed requiring the Department to provide OCR access to information relevant to determining compliance with section 1557 or the part.

Section 92.304(d) proposed prohibiting the Department from retaliating against an individual or entity for the purpose of interfering with any right secured by section 1557 or the part, or because such individual or entity has participated in an investigation, proceeding, or hearing under section 1557 or the part.

The comments and our responses regarding § 92.304 are set forth below.

Comment: Some commenters recommended that this section explicitly recognize claims of discrimination involving multiple bases, and suggested amending § 92.304(a) to add ''or a combination thereof.'' Some commenters recommended providing clear procedures for the administrative enforcement of such intersectional claims.

Response: OCR agrees that including this language is consistent with the changes we have made throughout the text regarding claims of discrimination involving multiple bases and accepts this proposal with a minor modification, so that the rule reads ''of any combination thereof.'' Further, OCR appreciates the recommendation for providing clear procedures for the administrative enforcement of intersectional claims. As stated in § 92.301, administrative complaints under section 1557 alleging multiple grounds of discrimination are now subject to a single administrative process.

Comment: Commenters on § 92.304(d) supported its prohibition on retaliation by the Department, noting that this provision shows a commitment to preventing discrimination at all levels and ensuring a path to rectifying grievances.

Response: OCR appreciates the support for this provision and, as stated in the preamble, we think it is important to include because individuals should not face retaliation for asserting their civil rights or raising concerns regarding discrimination being experienced by others.

Comment: Some commenters encouraged OCR to be as proactive as possible in enforcing the regulations with respect to the Department's programs.

Response: OCR appreciates the need for proactive enforcement and proactive technical assistance. We will continue working with the Department components in providing technical assistance and assisting them in helping to resolve compliance issues with section 1557.

Summary of Regulatory Changes

For the reasons set forth in the Proposed Rule and considering the comments received, OCR is finalizing the provisions as proposed in § 92.304, with modification. We are revising § 92.304(a) and (b) to read ''. . . discrimination on the basis of race, color, national origin, sex, age, disability, or any combination thereof . . . ,'' consistent with edits made at §§ 92.101(a)(1), 92.207(a) and (b)(1) and (2), and 92.303(a). In addition, as noted above, for clarity, we are revising § 92.304(b) to parallel § 92.303 to now provide that the procedural provisions applicable to section 504 at 45 CFR 85.61 and 85.62 shall apply with respect to administrative enforcement actions against the Department, including Federally-facilitated Exchanges, concerning discrimination on the basis of race, color, national origin, sex, age, or disability under section 1557 or the part. Also, where the section cross-references regulatory provisions that use the term ''handicap,'' the term ''race, color, national origin, sex, age, or disability'' shall apply in its place.

III. Change in Interpretation—Medicare Part B Funding Meets the Definition of Federal Financial Assistance; Responses to Public Comment

The Department's longstanding position has been that Medicare Part B (''Part B'') funding does not meet the definition of ''Federal financial assistance'' for the purpose of title VI, title IX, section 504, the Age Act, and section 1557. *See, e.g.,* 81 FR 31375, 31383 (May 18, 2016). In the 2022 NPRM, we proposed to change that position after evaluating the Part B program and the definition of ''Federal financial assistance'', such that Part B funds will be considered Federal financial assistance when received by providers and suppliers.

The Department sought comment on the impact that this change in position may have on recipients subsidized only by Part B funds that do not receive any other form of Federal financial assistance from the Department. We also invited comment on the amount of time that should be allowed for recipients of Part B funds to come into compliance with the applicable statutes and their implementing regulations. We also sought comment on what resources the Department can provide to assist newly covered entities in coming into compliance.

The comments and our responses regarding this change in interpretation are set forth below.

Comment: Some commenters objected to the proposal. These commenters claimed that interpreting Part B as meeting the definition of ''Federal financial assistance'' would reduce access to care because forcing these providers to implement new requirements will discourage them from participating in federally funded health care programs. Other commenters who opposed this interpretation stated that Part B does not meet the definition of ''Federal financial assistance'' because the program requires participants to pay monthly premiums based on income. In this way, commenters maintained, Part B is merely a private health insurance plan for individuals with low incomes, and is not equivalent to a Federal welfare program. A few commenters discussed that including Part B among the programs to which section 1557 applies is a radical change to what

qualifies as Federal financial assistance, and that such a change will affect other civil rights laws.

Response: The Department's change in interpretation regarding Part B does not alter, change, or expand the definition of ''Federal financial assistance.'' As stated in the 2022 NPRM, the Department is revising its position regarding whether Part B payments constitute Federal financial assistance under the longstanding definition of ''Federal financial assistance'' in regulations implementing section 1557 and the four statutes referenced in section 1557: title VI, title IX, section 504, and the Age Discrimination Act. 87 FR 47828. After evaluating the definition of ''Federal financial assistance,'' the Department has concluded that Part B funds meet that definition. While we disagree that this change in interpretation changes the definition of ''Federal financial assistance,'' we do note that this change means that Part B payments are considered Federal financial assistance with respect to title VI, title IX, section 504, and the Age Discrimination Act, in addition to section 1557.

Moreover, the Department disagrees that Part B is the equivalent of private health insurance and therefore is not Federal financial assistance. Part B confers a benefit or subsidy on the recipient—namely, financial assistance to the provider in exchange for providing health care services. As discussed in the 2022 NPRM, ''the government is assisting providers of services by making available to them a segment of the patient population that either (a) would not have been able to afford any medical services, or (b) would not have been able to afford these specific providers.'' 87 FR 47890. The Federal Government, through Part B, offers providers a reliable source of payment for services given to eligible patients who otherwise would go without care. Although Part B enrollees may pay premiums to receive coverage, the Federal Government covers half of the cost of Part B benefits. Thus, the fact that enrollees may pay for a portion of their coverage does not change the fact that providers receive Federal financial assistance through the program. In this way, Part B is no different than Medicare Part A, which also offers financial assistance to providers and which has long been considered Federal financial assistance. We note, however, that private health insurance may be subject to this rule when a health insurance issuer receives Federal financial assistance for such coverage. For instance, issuers may receive Federal financial assistance through receipt of advance payments of the premium tax credit or cost-sharing reductions for qualified health plans, which are private health insurance plans sold on the Exchanges. Further, when a recipient health insurance issuer is principally engaged in the provision or administration of health insurance coverage or other health-related coverage as set forth under the definition of ''health program or activity'' at § 92.4, all of the issuer's operations are covered, including its other private health insurance coverage, such as coverage sold off the Exchange.

OCR is also unpersuaded by the argument that the Department's change in interpretation will reduce access to care by leading to physician disenrollment from Medicare participation or decreased participation in other federally funded government programs. Indeed, we are unaware of any evidence that supports this concern and commenters did not provide any. As stated in the 2022 NPRM, many providers who receive payments through Part B are already subject to section 1557 and the four civil rights laws referenced in section 1557 through receipt of other Federal financial assistance. 87 FR 47890.

For the reasons provided in the NPRM and restated here, the Department respectfully disagrees with commenters and reiterates its position that funds provided via the current Part B program meet the longstanding definition of ''Federal financial assistance''.

Comment: An overwhelming number of commenters supported the change in interpretation, the result of which is that the Part B funds will be considered Federal financial assistance. Many groups commented that applying section 1557 to Part B will help address past discrimination. For example, commenters discussed that excluding Part B from a Federal financial assistance designation exempted individual providers from any obligation to comply with the Civil Rights Act of 1964. This exemption of the Part B program from title VI's nondiscrimination requirements allowed doctors in many states to continue providing segregated health care services. Commenters stated that failing to consider Part B payments as Federal financial assistance created confusion for patients about whether civil rights laws applied to their individual health providers—many of whom refused to serve individuals on the basis of their race or national origin because title VI did not apply to them. Therefore, commenters suggested that discriminatory history warrants the Department's reassessment of whether Part B payments meet the definition of ''Federal financial assistance''. They also note that this change will align Part B with other portions of the Medicare program and bring uniformity across all Medicare providers, increasing access to quality health care.

Other commenters explained that many of Part B providers already receive other forms of Federal financial assistance, such that this change in interpretation will not subject them to new obligations. Some commenters stated that all providers enrolled in the Part B program are recipients of Federal financial assistance—regardless of whether they are ''participating'' or ''non-participating'' providers—because even those designated as ''non-participating'' agree to provide Medicare-subsidized health services to Part B enrollees.

Many other supportive commenters noted that because funds received under Medicare Part A and Part B are fundamentally similar and Medicare Part A payments have long been considered Federal financial assistance, it is reasonable for the Department to similarly consider Part B payments as Federal financial assistance. Therefore, the commenters argue, considering Part B payments to be Federal financial assistance will allow individuals additional options for bringing discrimination claims against discriminatory conduct in all health care settings.

Response: OCR appreciates commenters' views on the Department's change in interpretation regarding whether Part B payments constitute Federal financial assistance as defined by our civil rights regulations. The Department agrees with commenters that because Part B payments, like those of Medicare Part A, are Federal funds directly or indirectly received by providers, they squarely meet the definition of ''Federal financial assistance''. This position provides uniformity across the Medicare programs and will not only help address patient confusion regarding the funding streams of their respective Medicare programs, but also ensures that the Department is applying the definition of ''Federal financial assistance'' consistently across all of our federally funded programs.

The Department agrees that because many recipients of Part B funds are already recipients of some other form of Federal financial assistance, this change will not impose excessive burdens on those covered entities. For those newly covered entities, however, we are providing a delayed applicability date as discussed below.

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).

those amendments and section 1557. 87 FR 27208. The clarifications finalized in this section of the rule will apply on or after the effective date of this final rule (60 days after publication).

In finalizing amendments to the CMS regulations in this final rule, the Department considered comments received in response to the 2022 NPRM, as well as comments received to similar proposals in the 2023 Payment Notice NPRM (collectively, the ''Proposed Rules''). The Department is also responding to comments we received in response to the Proposed Rules in this final rule. In section C.1. of this preamble, the Department responds to comments applicable to 45 CFR 147.104(e), 155.120(c), 155.220(j), 156.125(b), 156.200(e), and 156.1230(b). Section C.2. provides a summary of regulatory changes for 45 CFR 155.120(c), 155.220(j), 156.200(e), and 156.1230(b); there were no unique comments applicable to those sections. Comments that relate specifically to 45 CFR 147.104 are addressed in section C.3. of this preamble.

As stated in the 2022 NPRM, if any of the provisions at 45 CFR 147.104(e), 155.120(c), 155.220(j), 156.125(b), 156.200(e), and 156.1230(b) are held to be invalid or unenforceable by their terms, or as applied to any person or circumstance, such provision shall be considered severable from its respective section or such application shall be considered severable from any valid or enforceable applications of such provision (87 FR 47895). The determination that a provision is invalid or unenforceable shall not affect either the remainder of its section or any other sections, and the determination that a provision is invalid or unenforceable as applied to any particular person or circumstance shall not affect the application of the provision to other persons not similarly situated or to other dissimilar circumstances. In enforcing the nondiscrimination provisions in the corresponding CMS regulations, the Department will comply with laws protecting the exercise of conscience and religion, including, to the extent applicable, section 1303 of the ACA, the Weldon, Church, and Coats-Snowe amendments, the Religious Freedom Restoration Act (42 U.S.C. 2000bb through 2000bb-4) and all other applicable legal requirements.

1. Comments and Responses to 45 CFR 147.104(e), 155.120(c), 155.220(j), 156.125(b), 156.200(e), and 156.1230(b)

The Department proposed to amend 45 CFR 147.104(e), 155.120(c), 155.220(j), 156.125(b), 156.200(e), and 156.1230(b) by removing the term ''sex'' and revising the term to read ''sex (including sexual orientation and gender identity).'' However, after considering all the public comments submitted in response to the Proposed Rules, the Department is finalizing a revision to the term ''sex'' and adding in its place the phrase ''sex (including discrimination on the basis of sex characteristics, including intersex traits; pregnancy or related conditions; sexual orientation; gender identity; and sex stereotypes).'' This revision is necessary to ensure consistency across the policies and requirements applicable to entities subject to both those amendments and section 1557.

Comment: The majority of commenters to the proposal in the 2023 Payment Notice NPRM expressed broad support for the proposal and agreed that amending the CMS regulations is warranted in light of the well-documented discrimination that LGBTQI+ individuals face in seeking health care and insurance coverage.

Commenters supporting the proposal asserted that all Americans deserve access to affordable, high-quality health care, and that Federal policies and nondiscrimination protections must reinforce equity of care for all patients regardless of socioeconomic and sociodemographic characteristics and insurance coverage. Commenters urged the Department to finalize the proposed nondiscrimination protections in light of persisting trends of pervasive discrimination in insurance coverage. Commenters said that it is well documented that LGBTQI+ individuals continue to face discrimination in seeking health care, and that the nondiscrimination protections will help address barriers to health equity for LGBTQI+ individuals and aid providers in providing effective care.

Many commenters supporting the proposal referred to copious bodies of research, including research identified in the 2022 NPRM, that demonstrate the many ways in which the LGBTQI+ community faces discrimination when seeking health care, resulting in poorer health outcomes. 87 FR 47833–47835 (2022). Commenters asserted that issuers have contributed to this discrimination by employing transgender-specific exclusions to deny coverage for medically necessary treatment and that this was exacerbated by the removal of protections on the basis of sexual orientation and gender identity in the 2020 Rule. Many of these commenters also highlighted how individuals who identify as part of the LGBTQI+ community disproportionately face health disparities and are at higher risk for many conditions.

Response: We firmly believe that clarifying the scope of sex discrimination can lead to improved health outcomes for LGBTQI+ individuals [399] and that these protections are consistent with our broader aim of improving health equity. Finalizing the amendments to the nondiscrimination protections to explicitly prohibit discrimination on the basis of sex characteristics, including intersex traits; pregnancy or related conditions; sexual orientation; gender identity; and sex stereotypes is warranted to help remedy health care discrimination and to better address barriers to health equity for LGBTQI+ individuals.[400] The revisions to 45 CFR 147.104(e), 155.120(c), 155.220(j), 156.125(b), 156.200(e), and 156.1230(b) will support the Department's objective of ensuring consistency against employing discriminatory marketing practices and benefit designs.

Comment: Many of the commenters that supported the proposal in the 2023 Payment Notice NPRM suggested ways in which the Department could further strengthen or clarify the breadth of the nondiscrimination protections, such as by expressly prohibiting discrimination on the basis of sex characteristics, including intersex traits.

Many commenters also recommended that the Department clarify that gender identity discrimination includes discrimination based on gender expression and transgender status. Such commenters stated that entities often perpetuate discrimination against transgender people because of their gender expression or belief that they are transgender rather than their gender identity itself, which is often private information. These commenters argued that the inclusion of ''gender identity'' alone in nondiscrimination protections leaves room for confusion or evasion of legal obligations.[401] Commenters

[399] Brian W. Ward et al., U.S. Dep't of Health & Hum. Servs., Ctrs. for Disease Control & Prevention, *National Health Statistics Report: Sexual Orientation & Health Among U.S. Adults: National Health Interview Survey,* 2013 (2014), *https://www.cdc.gov/nchs/data/nhsr/nhsr077.pdfhttps://www.cdc.gov/nchs/data/nhsr/nhsr077.pdf.*

[400] Thu T. Nguyen et al., *Trends for Reported Discrimination in Health Care in a National Sample of Older Adults with Chronic Conditions,* 33 J. Gen. Internal Med. 291–297 (2017), *https://doi.org/10.1007/s11606-017-4209-5.*

[401] *See* U.S. Dep't of Health & Hum. Servs., *FAQs About Affordable Care Act Implementation (Part XXVI),* 6, Q5 (May 11, 2015), *https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/aca_implementation_faqs26.pdf.* Section 2713 of the PHS Act and its implementing regulations require non-grandfathered group health plans and health insurance issuers offering non-

emphasized that expressly incorporating transgender status into Department regulations would provide additional clarity, and would conform the regulation to contemporary protections against discrimination.

Response: We agree with commenters that discrimination on the basis of sexual orientation and gender identity may present itself as discrimination on the basis of gender expression and transgender status, which are inextricably linked with one's gender identity. We believe that gender expression and transgender status are sufficiently addressed by the inclusion of gender identity in the description of discrimination based on sex that is being finalized.

Comment: Many commenters supported the proposal as consistent with the overarching intent of the ACA to improve access to health coverage and prohibit discrimination in health care, asserting that the removal of protections on the basis of sexual orientation and gender identity in the 2020 Rule frustrates this purpose by creating barriers to comprehensive care. Many commenters affirmed that the Department has broad authority to regulate in this area under various sections of the ACA independent of section 1557. Specifically, commenters acknowledged that section 1321(a) of the ACA [402] gives the Department broad rulemaking authority to regulate Exchanges and QHPs; section 1312(c) [403] gives the Department authority to establish procedures for States to allow agents or brokers to enroll individuals and businesses in QHPs; section 1302(b)(4) [404] directs the Department, in defining EHB, to ''take into account the health care needs of diverse segments of the population, including women, children, persons with disabilities, and other groups''; section 1311(c)(1)(A) [405] directs the Department to establish criteria for QHPs to ensure that they will ''not employ marketing practices or benefit designs that have the effect of discouraging the enrollment in such plan by individuals with significant health needs''; and section 2792 of the PHS Act [406] provides the Department with broad authority to promulgate regulations that may be necessary or appropriate to carry out the provisions of title XXVII of the PHS Act, including the guaranteed availability provisions in section 2702,[407] added to the PHS Act by the ACA.

Response: We agree with commenters that clarifying the scope of sex discrimination aligns with the ACA's goals of improving access to health insurance and removing unreasonable barriers to care. We reiterate that we are relying on authority from sections 1311(c)(1)(A), 1312(e), and 1321(a)(1)(A), (B), and (D) of the ACA, as well as sections 2702 and 2792 of the PHS Act, to support this change. 87 FR 584, 596.

Comment: Some commenters objected to the protections against discrimination on the basis of gender identity, in particular, or stated that the Proposed Rule arbitrarily requires coverage of interventions for individuals diagnosed with gender dysphoria, but not for individuals seeking such procedures for other clinically indicated mental health conditions. Some commenters asserted the proposal is arbitrary and capricious because it requires issuers to provide coverage for a ''one-size-fits-all'' treatment to gender dysphoria that is unsupported by evidence. Such 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: One of the primary goals of the proposals to clarify the scope of sex discrimination is to address the pervasive health care discrimination faced by LGBTQI+ patients.[408] When medically necessary treatments are categorically excluded when sought by transgender enrollees for purposes of gender-affirming care, but the same such treatments are covered for cisgender enrollees, such exclusions may deny transgender individuals access to coverage based on their sex. These types of exclusions, and other types of sex discrimination, can have the effect of discouraging or preventing the enrollment of LGBTQI+ individuals in health insurance coverage.

Issuers generally have discretion in designing their benefits packages, and 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 health insurance issuers include coverage for any particular item or service not already covered. However, to the extent a covered entity provides coverage for a particular health service, the covered entity must provide coverage for the health service to all individuals in a neutral, nondiscriminatory manner consistent with this rule.

Amending these sections to specify discrimination on the basis of sex includes sex characteristics, including intersex traits; pregnancy or related conditions; sexual orientation; gender identity; and sex stereotypes will help 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 their plan and made available to other enrolled individuals. Regulations at 45 CFR 147.104(e), 155.120(c), 155.220(j), 156.125(b), 156.200(e), and 156.1230(b) already prohibit discrimination on a variety of bases, including on the basis of race, color, national origin, present or predicted disability, age, sex, expected length of life, degree of medical dependency, quality of life, or other health conditions. Amending these sections to describe sex discrimination will better clarify nondiscrimination protections for all individuals, while also addressing existing disparities for LGBTQI+ individuals seeking health care.

Comment: Many commenters that objected to the proposed clarification suggested that coverage of gender-affirming care and any corresponding treatments are unsupported by clinical evidence, harmful to patients, and incongruent with the belief that gender is immutably defined by one's biological sex. For example, many commenters asserted that due to the lack of clinical evidence, CMS decided in 2016 not to issue a National Coverage Determination

grandfathered group or individual health insurance coverage to provide coverage for certain recommended preventive health services without imposing any cost-sharing requirements. Under this requirement, the plan or issuer must provide coverage, without cost sharing, for a recommended preventive service that is medically appropriate for the individual, as determined by the individual's attending provider, regardless of the individual's sex assigned at birth, gender identity, or recorded gender.

[402] 42 U.S.C. 18041(a).

[403] 42 U.S.C. 18032(c).

[404] 42 U.S.C. 18022(b)(4),

[405] 42 U.S.C. 13031(c)(1)(A).

[406] 42 U.S.C. 300gg–92

[407] 42 U.S.C. 300gg–1.

[408] U.S. Dep't of Health & Hum. Servs., Ctrs. for Disease Control & Prevention, Nat'l Ctr. for Health Statistics, *Chapter 25: Lesbian, Gay, Bisexual, and Transgender Health, Healthy People* 2020 (2016), *https://www.cdc.gov/nchs/data/hpdata2020/HP2020MCR-C25-LGBT.pdf*; Hudaisa Hafeez et al., *Health Care Disparities Among Lesbian, Gay, Bisexual, and Transgender Youth: A Literature Review,* 9 Cureus e1184 (2017), *https://doi.org/10.7759/cureus.1184*; Karen I. Fredriksen-Goldsen et al., *Health Disparities Among Lesbian, Gay, and Bisexual Older Adults: Results From a Population-Based Study,* 103 a.m. J. Pub. Health 1802–1809 (2013), *https://doi.org/10.2105/AJPH.2012.301110*; Billy A. Caceres et al., *A Systematic Review of Cardiovascular Disease in Sexual Minorities,* 107 a.m. J. Pub. Health e13–e21 (2017), *https://doi.org/10.2105/AJPH.2016.303630.*

(NCD) [409] for coverage of gender-affirming surgery for Medicare beneficiaries with gender dysphoria. Many objecting commenters also claimed that studies that reach different conclusions (for example, any studies showing efficacy or safety of gender-affirming care) are flawed.

Response: We believe that commenters citing the 2016 Medicare NCD decision are incorrectly interpreting the decision. In its final Decision Memorandum on the issue, CMS notes that it declined to issue an NCD specifically on gender-affirming surgery because the clinical evidence is inconclusive, specifically as it relates to the Medicare population (that is, generally individuals 65 or older). CMS clarifies that the result of the decision is not a national coverage prohibition, but rather a continuation of the current policy that coverage decisions for gender-affirming surgery will continue to be made by local Medicare Administrative Contractors (MACs) and Medicare Advantage (MA) plans on a case-by-case basis based on whether gender-affirming surgery is reasonable and necessary for the individual beneficiary after considering the individual's specific circumstances.

Furthermore, the Medicare program did not analyze clinical evidence for counseling or hormone therapy treatments for gender dysphoria and was not making an NCD determination related to counseling, hormone therapy treatments, or any other potential treatment for gender dysphoria. Therefore, not only is the population for which the NCD applies distinct, but so is the scope of the NCD decision itself.

Claims made by opposing commenters regarding assertions of patient harm resulting from gender-affirming care, purported lack of evidence demonstrating efficacy of such care, alleged differences between ''biological sex'' and gender, and hypothetical medical scenarios are not germane to the proposed regulatory text acknowledging that sex discrimination includes discrimination on the basis of sexual orientation or gender identity. While claims about medical evidence and specific treatments may be relevant in evaluating whether a particular action constitutes unlawful discrimination, or whether a particular item or service is medically necessary, such assertions do not speak to the decision to clarify the scope of sex discrimination in the first place. We also acknowledge that there is a robust consensus in the medical community that gender-affirming care is safe, effective, and medically necessary when clinically indicated for a particular individual.

The amendments made concurrent with the 2020 final rule to the nondiscrimination protections in 45 CFR 147.104(e), 155.120(c), 155.220(j), 156.125(b), 156.200(e), and 156.1230(b) were based on an erroneous assertion that the plain statutory meaning of ''sex'' does not encompass sexual orientation and gender identity, which is unsupported by *Bostock.* In addition, the 2020 amendments were based on the incorrect assertion that the denial of basic health care on the basis of gender-identity is not a widespread problem in the United States.

Comment: One commenter asserted that the proposed change to the description of sex discrimination is arbitrary and capricious because the Department did not compute the costs of the impact of the rule against the purported benefits of the proposal.

Response: As we explained in the 2022 NPRM and based on our experience with States selecting a new EHB-benchmark plan pursuant to 45 CFR 156.111,[410] CMS believes there will be minimal costs incurred based on amending these sections to clarify sex discrimination. Because these sections previously prohibited discrimination on the basis of sexual orientation and gender identity, many entities already comply with the prohibition on discrimination, as amended under this final rule. 87 FR 47898. We do not anticipate amending these sections to describe sex discrimination would impose substantial administrative costs on any regulated entities that did not subsequently revise nondiscrimination policies based on the 2020 Rule.[411] On balance, we believe any costs are justified in light of the potentially significant benefits provided by protecting individuals from discrimination based on sex characteristics, including intersex traits; pregnancy or related conditions; sexual orientation; gender identity; and sex stereotypes. We refer readers to our cost benefit analysis in the Regulatory Impact Analysis of this final rule for additional discussion on the minimal cost impacts to plans and issuers to include nondiscrimination protections. 87 FR 47898.

Comment: Some commenters objected to a perceived lack of clarity in the Proposed Rules. Such commenters noted that the Proposed Rules did not appropriately discuss the breadth of which markets would be covered by this proposal, questioning whether it would apply to large group plans, fully insured group health plans sponsored by employers, health insurance issuers and third party administrators of self-insured plans.

Response: The amendments we are finalizing to the nondiscrimination regulations at 45 CFR 147.104(e) apply to health insurance issuers offering non-grandfathered group or individual health insurance coverage, and their officials, employees, agents, and representatives. The nondiscrimination amendments we are finalizing at 45 CFR 155.120(c) apply to States and Exchanges carrying out Exchange requirements. The nondiscrimination amendments we are finalizing at 45 CFR 155.220(j) apply to agents, brokers, or web-brokers that assist with or facilitate enrollment of qualified individuals, qualified employers, or qualified employees, in coverage in a manner that constitutes enrollment through an FFE, or assists individuals in applying for advance payments of the premium tax credit and cost-sharing reductions for QHPs sold through an FFE. The nondiscrimination amendments we are finalizing at 45 CFR 156.200(e) apply to QHPs in the individual and small-group markets. Section 156.125(b) requires issuers providing EHB to comply with the requirements of 45 CFR 156.200(e), thereby extending the application to non-grandfathered health insurance coverage in the individual and small group markets that provide EHBs.

[409] U.S. Dep't of Health & Hum. Servs., Ctrs. for Medicare & Medicaid Servs., *Decision Memo for Gender Dysphoria and Gender Reassignment Surgery* (CAG–00446N) (Aug. 30, 2016), *https://www.cms.gov/medicare-coverage-database/view/ncacal-decision-memo.aspx?proposed=N&ncaid=282.*

[410] *See, e.g.,* U.S. Dep't of Health & Hum. Servs., Ctrs. for Medicare & Medicaid Servs., *Information on Essential Health Benefits (EHB) Benchmark Plans Colorado 2023 EHB- Benchmark Plan Actuarial Report, https://www.cms.gov/marketplace/resources/data/essential-health-benefits.* 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.

[411] State of Cal., Dep't of Ins., *Economic Impact Assessment Gender Nondiscrimination in Health Insurance,* (2012), *http://translaw.wpengine.com/wp-content/uploads/2013/04/Economic-Impact-Assessment-Gender-Nondiscrimination-In-Health-Insurance.pdf*; 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*; Jody L. Herman, The Williams Inst., UCLA Sch. of Law, *Costs 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://williamsinstitute.law.ucla.edu/wp-content/uploads/Herman-Cost-Benefit-of-Trans-Health-Benefits-Sept-2013.pdf*; 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. Gen. Internal Med. 394 (2015), *https://pubmed.ncbi.nlm.nih.gov/26481647/.*

Lastly, the nondiscrimination protections we are finalizing at 45 CFR 156.1230(b) apply to issuers using direct enrollment on an FFE.

Comment: Some commenters noted concerns about how the nondiscrimination protections would apply to health care providers.

Response: The amendments we are finalizing at 45 CFR 147.104(e), 155.120(c), 155.220(j), 156.125(b), 156.200(e), and 156.1230(b) do not apply to health care providers.

Comment: One commenter asked the Department to provide clarity on the interaction between the section 1557 requirement and the 2023 Notice of Benefit and Payment Parameters final rule regarding non-discriminatory benefit design and EHB.

Response: While the requirements of section 1557 and the requirements imposed on EHB are separate requirements, we are finalizing regulatory language in this rule to make compliance easier for entities that are subject to both standards. As we stated in the 2023 Notice of Benefit and Payment Parameters final rule, CMS continues to make refinements to our EHB nondiscrimination policy and will address non-discriminatory benefit design as it relates to EHB in future rulemaking.

Comment: Commenters objecting to a more detailed understanding of sex discrimination raised several legal concerns. Commenters stated that the Department's reliance on *Bostock* v. *Clayton County,* 590 U.S. 644 (2020), is inappropriate, misinterprets *Bostock,* and misapplies the case to section 1557. One commenter asserted that the rule is arbitrary and capricious because it inappropriately applies the title VII framework to health care. Other commenters stated that the proposal is based on a faulty interpretation of title IX. Commenters also asserted that although reverting the nondiscrimination sections to pre-2020 language would allow LGBTQI+ individuals to receive ''medically necessary'' care, the 2020 rule enforces the plain text enacted by the ACA, which prohibited the discrimination on the basis of sex only.

Other commenters cautioned that absent clear congressional authorization, the Department is not justified in promoting the view that sex or gender can be different than the sex assigned to an individual at birth. Other commenters asserted that the rule is arbitrary and capricious because it ignores that a person's sex is determined by biology and does not sufficiently specify what it means by ''sex'' and how it relates to gender dysphoria treatments.

Response: We disagree that the proposal to include nondiscrimination protections is arbitrary and capricious. We are not relying on or applying the title VII framework to the nondiscrimination protections we are finalizing at 45 CFR 147.104(e), 155.120(c), 155.220(j), 156.125(b), 156.200(e), and 156.1230(b), nor are we relying on other Federal civil rights laws for statutory authority. As stated in the Proposed Rule, 87 FR 596, we are relying on authority from sections 1311(c)(1)(A), 1312(e), and 1321(a)(1)(A), (B), and (D) of the ACA to support the amendments at 45 CFR 155.120, 155.220, 156.200, and 156.1230. We also rely on authority from sections 2702 and 2792 of the PHS Act to support the amendments to 45 CFR 147.104 and 156.125. Section 2792 of the PHS Act provides the HHS Secretary with broad rulemaking authority to issue regulations as may be necessary or appropriate to carry out the provisions of title XXVII of the PHS Act, including the guaranteed availability provision in section 2702 of the PHS Act, implemented at 45 CFR 147.104, and the EHB requirements in section 2707(a) of the PHS Act, implemented at 45 CFR 147.150 and 156.125. 87 FR 584, 596. We made these proposals and are finalizing these provisions due in large part to the pervasive health and health care disparities faced by people who identify as part of the LGBTQI+ community.[412]

The aim of this final rule is to address the reality of many consumers in the health care sector and how discrimination on the basis of sex by entities regulated under 45 CFR 147.104(e), 155.120(c), 155.220(j), 156.125(b), 156.200(e), and 156.1230(b) impairs the ability of consumers to access or pay for quality care. We believe these changes are necessary to address the role of discrimination in perpetuating the pervasive health and health care disparities faced by people who identify as part of the LGBTQI+ community.

We also disagree with commenters contesting that these nondiscrimination proposals inappropriately align with *Bostock.* In *Bostock,* the Supreme Court held that discrimination on the basis of sex under title VII of the Civil Rights Act of 1964 includes discrimination on the basis of sexual orientation and gender identity. Under *Bostock's* reasoning, laws that prohibit sex discrimination also prohibit discrimination on the basis of gender identity and sexual orientation.[413]

Furthermore, the inclusion of ''sex stereotypes'' is consistent with the Supreme Court's holding in *Price Waterhouse* v. *Hopkins,* 490 U.S. 228, 250–51 (1989). The inclusion of ''pregnancy or related conditions'' is consistent with the Department's longstanding interpretation of sex discrimination under Title IX.[414] As noted earlier in this preamble, the Department is finalizing these amendments to ensure consistency across the policies and requirements applicable to entities subject to health insurance market and Exchange requirements and those subject to section 1557. Amending CMS nondiscrimination protections to better specify the meaning of sex discrimination is imperative to advancing health equity and ensuring individuals are able to receive health care that is free from discrimination as envisioned under the ACA.

Comment: Many commenters to the 2023 Payment Notice NPRM expressed concerns that the proposal infringed on the First Amendment and would lead to violations of the religious conscience of providers, issuers, brokers, agents, and religiously affiliated hospitals. Some of these commenters objected to the inclusion of sexual orientation or gender identity within nondiscrimination protections altogether. Other commenters asserted that it is unclear how CMS would implement RFRA protections in the context of the nondiscrimination protections, and that this lack of clarity would increase the chance of litigation. A few commenters asked for the final rule to include an exemption for any stakeholders with religious objections (including issuers,

[412] U.S. Dep't of Health & Hum. Servs., Ctrs. for Disease Control & Prevention, Nat'l Ctr. for Health Statistics, Chapter 25: *Lesbian, Gay, Bisexual, and Transgender Health,* Healthy People 2020 (2016), *https://www.cdc.gov/nchs/data/hpdata2020/HP2020MCR-C25-LGBT.pdf*; Hudaisa Hafeez et al., *Health Care Disparities Among Lesbian, Gay, Bisexual, and Transgender Youth: A Literature Review,* 9 Cureus e1184 (2017), *https://doi.org/10.7759/cureus.1184*; Karen I. Fredriksen-Goldsen et al., *Health Disparities Among Lesbian, Gay, and Bisexual Older Adults: Results From a Population-Based Study,* 103 a.m. J. Pub. Health 1802–1809 (2013), *https://doi.org/10.2105/AJPH.2012.301110*; Billy A. Caceres et al., *A Systematic Review of Cardiovascular Disease in Sexual Minorities,* 107 a.m. J. Pub. Health e13–e21 (2017), *https://doi.org/10.2105/AJPH.2016.303630.*

[413] *See, e.g., Grimm* v. *Gloucester Cnty. Sch. Bd.,* 972 F.3d 586, 616 (4th Cir. 2020), *cert. denied,* 141 S. Ct. 2878 (2021) (''Although *Bostock* interprets Title VII of the Civil Rights Act of 1964, 42 U.S.C. 2000e–2(a)(1), it guides our evaluation of claims under Title IX''); E.O. 13988, 86 FR 7023 (2021).

[414] *See* 45 CFR 86.21(c)(2) and (3); 86.40(b)(1), (4), and (5); 86.51(b)(6); 86.57(b) through (d) (Title IX regulation); *see also Conley* v. *Northwest Fla. State Coll.,* 145 F. Supp. 3d 1073 (N.D. Fla. 2015).

plan sponsors, or individual purchasers) or to clarify whether there will be a process for such stakeholders to claim an exemption under RFRA outside of litigation. One commenter requested a process under which issuers or the insured can receive an up-front exemption when they have a religious or conscience-based objection to paying for plans that cover benefits to which they object as being experimental and harmful.

Other commenters believed that the proposal takes the right approach in relation to moral and religious objections.

Response: 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 and fulfill the statutory command of the ACA to prohibit discrimination and remove unreasonable barriers to care. Certain protections already exist in Federal law with respect to religious or moral beliefs, particularly regarding 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 and all other applicable legal requirements. Nothing in the nondiscrimination protections at 45 CFR 147.104(e), 155.120(c), 155.220(j), 156.125(b), 156.200(e), and 156.1230(b) displaces those protections, and an application of this rule will not be required if it would violate Federal religious freedom and conscience laws.

Although some commenters urged CMS to incorporate a categorical religious exemption into this final rule, a blanket religious exemption is not supported by the underlying statutes. We will apply the protections in existing laws in resolving any conflicts between religious beliefs and these nondiscrimination protections. An entity that believes that compliance with any of these provisions would violate their rights under RFRA or the Free Exercise Clause of the First Amendment should contact CMS, which is responsible for evaluating RFRA-based requests for requirements in the programs it operates or oversees.[415] An entity that believes that compliance with any provision of this rule would violate their rights under the religious freedom and conscience laws enforced by HHS's Office for Civil Rights should file a complaint with OCR.

As with any HHS program, if an entity alleges that HHS's actions have substantially burdened its religious exercise, the Department will apply the test set out by RFRA.[416] The RFRA analysis evaluates whether the actions of the Federal Government have substantially burdened an entity's exercise of religion; if so, the question becomes whether the action furthers a compelling interest and is the least restrictive means to further that interest. RFRA provides that when application of a Federal Government rule or other law would substantially burden a person's exercise of religion, the government must afford that person an exemption to the rule unless it can demonstrate that applying the burden to that person furthers a compelling governmental interest and is the least restrictive means of doing so.[417] Accordingly, under RFRA, we would assess whether a particular application of these rules substantially burdened a stakeholder's exercise of religion and, if so, whether the government has a compelling interest in denying the stakeholder's exemption assurance request and whether there are less restrictive alternatives available.[418] The government's compelling interest in prohibiting discrimination on the basis of sex is to improve health outcomes, including for the LGBTQI+ community, and fulfill the statutory command of the ACA to prohibit discrimination. Whether this prohibition imposes a substantial burden on an entity's exercise of religion and whether it is the least restrictive means of advancing the government's interest will depend on specific facts and circumstances.

The amendments we are finalizing at 45 CFR 147.104(e), 155.120(c), 155.220(j), 156.125(b), 156.200(e), and 156.1230(b) prohibit discrimination on the basis of sex in the conduct of health insurance issuers and their officials, employees, agents, and representatives; States and the Exchanges; agents, brokers, or web-brokers that assist with or facilitate enrollment of qualified individuals, qualified employers, or qualified employees; issuers subject to EHB requirements; and QHP issuers.

Lastly, we again reiterate that the amendments we are finalizing at 45 CFR 147.104(e), 155.120(c), 155.220(j), 156.125(b), 156.200(e), and 156.1230(b) do not require regulated entities to cover any particular service not already covered.

2. Health Insurance Exchanges

a. Non-Interference With Federal Law and Nondiscrimination Standards (45 CFR 155.120)

In 45 CFR 155.120 we proposed to amend paragraph (c)(1)(ii) by removing the term ''sex'' and adding in its place the phrase ''sex (including sexual orientation and gender identity).'' We did not receive comments unique to this section.

Summary of Regulatory Changes

We amend 45 CFR 155.120 in paragraph (c)(1)(ii) by removing the term ''sex'' and adding in its place the phrase ''sex (including discrimination on the basis of sex characteristics, including intersex traits; pregnancy or related conditions; sexual orientation; gender identity; and sex stereotypes).''

b. Federally-Facilitated Exchange Standards of Conduct (45 CFR 155.220)

In 45 CFR 155.220 we proposed to amend paragraph (j)(2)(i) by removing the term ''sex'' and adding in its place the phrase ''sex (including sexual orientation and gender identity).'' We did not receive comments unique to this section.

Summary of Regulatory Changes

We amend 45 CFR 155.220 in paragraph (j)(2)(i) by removing the term ''sex'' and adding in its place the phrase ''sex (including discrimination on the basis of sex characteristics, including intersex traits; pregnancy or related conditions; sexual orientation; gender identity; and sex stereotypes).''

c. Essential Health Benefits Package: Prohibition on Discrimination (45 CFR 156.125)

In 45 CFR 156.200 we proposed to amend § 156.200 in paragraph (e) by removing the term ''sex'' and adding in its place the phrase ''sex (including sexual orientation and gender identity).'' Section 156.125(b) would accordingly require issuers providing EHB to comply with such nondiscrimination requirements as it requires that an issuer providing EHB must comply with the requirements of § 156.200(e). We did not receive comments unique to this section.

[415] U.S. Dep't of Health and Hum. Servs., Off. of the Sec'y, Delegation of Authority, 86 FR 67067 (Nov. 24, 2021).

[416] See 86 FR 67067 (Nov. 24, 2021) (delegation of authority under which all HHS components are to ensure full compliance with RFRA and other constitutional requirements).

[417] 42 U.S.C. 2000bb–1(b).

[418] *Fulton* v. *City of Phila.,* 593 U.S. (2021) (''The question, then, is not whether the City [of Philadelphia] has a compelling interest in enforcing its non-discrimination policies generally, but whether it has such an interest in denying an exception to [Catholic Social Services].'').

Summary of Regulatory Changes

Elsewhere in this rule, we amend 45 CFR 156.200 in paragraph (e) by removing the term ''sex'' and adding in its place the phrase ''sex (including discrimination on the basis of sex characteristics, including intersex traits; pregnancy or related conditions; sexual orientation; gender identity; and sex stereotypes).'' Paragraph (b) of 45 CFR 156.125 accordingly requires issuers providing EHB to comply with such nondiscrimination requirements as it states that an issuer providing EHB must comply with the requirements of § 156.200(e).

d. QHP Issuer Participation Standards (45 CFR 156.200)

In 45 CFR 156.200 we proposed to amend paragraph (e) by removing the term ''sex'' and adding in its place the phrase ''sex (including sexual orientation and gender identity).'' We did not receive comments unique to this section.

Summary of Regulatory Changes

We amend 45 CFR 156.200 in paragraph (e) by removing the term ''sex'' and adding in its place the phrase ''sex (including discrimination on the basis of sex characteristics, including intersex traits; pregnancy or related conditions; sexual orientation; gender identity; and sex stereotypes).''

e. Direct Enrollment With the QHP Issuer in a Manner Considered To Be Through the Exchange (45 CFR 156.1230)

In 45 CFR 156.1230 we proposed to amend § 156.1230 in paragraph (b)(2) by removing the term ''sex'' and adding in its place the phrase ''sex (including sexual orientation and gender identity).'' We did not receive comments unique to this section.

Summary of Regulatory Changes

We amend 45 CFR 156.1230 in paragraph (b)(2) by removing the term ''sex'' and adding in its place the phrase ''sex (including discrimination on the basis of sex characteristics, including intersex traits; pregnancy or related conditions; sexual orientation; gender identity; and sex stereotypes).''

3. Prohibition of Discrimination—Group and Individual Health Insurance Markets Guaranteed Availability of Coverage (45 CFR 147.104)

In 45 CFR 147.104 we proposed to amend paragraph (e) by revising ''sex'' to ''sex (including sexual orientation and gender identity).''

The comments and our responses regarding this proposal are set forth below.

Comment: Some commenters requested that CMS clarify that States, including State Attorneys General, may enforce section 1557 to the fullest extent granted by law. That request was in response to CMS' explanation in the Proposed Rule that it was not relying on section 1557 as authority to amend 45 CFR 147.104 because states would not have authority to enforce section 1557 and CMS is of the view that partial reliance on section 1557 could unnecessarily complicate enforcement efforts. 87 FR 47898.

Response: In the Proposed Rule, CMS explained that one of the primary reasons CMS did not propose to rely on section 1557 authority to amend 45 CFR 147.104 was the manner in which § 147.104 is enforced. As discussed in the Proposed Rule, under PHS Act section 2723, States have primary enforcement authority over issuers with respect to regulations that implement title XXVII of the PHS Act, which includes § 147.104. CMS has a responsibility to enforce such regulations if CMS determines that a State is not substantially enforcing or the State notifies CMS that it has not enacted legislation to enforce or is not otherwise enforcing such regulations; otherwise, the State retains primary enforcement authority. Because section 1557 is not codified in title XXVII of the PHS Act, PHS Act section 2723 does not provide States with the authority to enforce section 1557. Therefore, CMS continues to be of the view that partial reliance on section 1557 authority could unnecessarily complicate enforcement efforts of § 147.104.

For this reason and because § 147.104 applies to issuers that may not receive Federal financial assistance such that they would be subject to section 1557, CMS relies on its authorities under sections 2702 and 2792 of the PHS Act when amending § 147.104. Notwithstanding the foregoing, the Department clarifies that although States do not enforce the administrative procedures specified in the section 1557 regulation itself, States may utilize their independent enforcement authorities to pursue violations of law, including applicable Federal laws, by entities within their jurisdictions.

Summary of Regulatory Changes

We amend 45 CFR 147.104 in paragraph (e) by removing the term ''sex'' and adding in its place the phrase ''sex (including discrimination on the basis of sex characteristics, including intersex traits; pregnancy or related conditions; sexual orientation; gender identity; and sex stereotypes).''

V. Executive Order 12866 and Related Executive Orders on Regulatory Review

A. Regulatory Impact Analysis

We have examined the impacts of the final rule under E.O. 12866, E.O. 14094, E.O. 13563, the Regulatory Flexibility Act (5 U.S.C. 601–612), the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), and E.O. 13132 on Federalism. E.O.s 12866 and 13563 direct us to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). Section 3(f) of E.O. 12866 (as amended by E.O. 14094) defines a ''significant regulatory action'' as any regulatory action that is likely to result in a rule that may: (1) have an annual effect on the economy of $200 million or more (adjusted every 3 years by the Administrator of the Office of Information and Regulatory Affairs (OIRA) for changes in gross domestic product); or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, territorial, or Tribal governments or communities; (2) create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raise legal or policy issues for which centralized review would meaningfully further the President's priorities or the principles set forth in this Executive order, as specifically authorized in a timely manner by the Administrator of OIRA in each case. This final rule is a significant regulatory action, under sec. 3(f)(1) of E.O. 12866 (as amended by E.O. 14094).

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. 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 are certifying that the final rule will not have a significant economic impact on a substantial number of small entities.

The Unfunded Mandates Reform Act of 1995 (section 202(a)) generally

requires us to prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing ''any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any 1 year.'' The current threshold after adjustment for inflation is $177 million, using the most current (2022) Implicit Price Deflator for the Gross Domestic Product. This final rule is not subject to the Unfunded Mandates Reform Act because it falls under an exception for regulations that establish or enforce any statutory rights that prohibit discrimination on the basis of race, color, religion, sex, national origin, age, or disability.[419]

E.O. 13132 on Federalism establishes certain requirements that an agency must meet when it promulgates a Proposed Rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has federalism implications. In considering the principles in and requirements of E.O. 13132, the Department has determined that the final rule would not significantly affect the rights, roles, and responsibilities of the States.

The Congressional Review Act (CRA) defines a ''major rule'' as any rule that the Administrator of OIRA of the Office of Management and Budget finds has resulted in or is likely to result in: (A) ''an annual effect on the economy of $100,000,000 or more''; (B) ''a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions''; or (C) ''significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic and export markets.'' 5 U.S.C. 804(2). Based on the analysis of this final rule under E.O. 12866, this rule is expected qualify under 5 U.S.C. 804(2)(A). The Department will comply with the CRA's requirements to inform Congress.

The Background and Reasons for the final rulemaking sections at the beginning of this preamble contains a summary of this final rule and describes the reasons it is needed.

1. Public Comments

Comment: OCR received some comments discussing the cost of notices and taglines[420] in addition to requests that OCR work with the health care industry to develop future regulations. One commenter explained how the cost of including taglines averages up to $8.91 per month per covered entity and upwards of $2 million a year for the health insurance industry. Another health insurer commenter stated that they have spent over $16 million on notices and taglines since 2016 and estimated that they have spent over $3 million in 2022 alone. However, neither commenter provided data explaining the source or more detail on the cost estimates. Another commenter noted that the Proposed Rule does not adequately answer complaints received in prior 1557 rulemakings on the frequency and volume of materials related to the notice and tagline sections of the rule but did not provide any data with their comment.

Response: Based on costs estimated in this analysis, OCR derives a monthly cost of notices ranging from $21.28 to $26.60 per entity depending on the prevalence of electronic delivery. These cost estimates include the total notices of nondiscrimination and notices of availability of language assistance services and auxiliary aids and services (''Notices of Availability''); OCR therefore finds the commenter's estimate of $8.91 per month for Notices of Availability as plausible and consistent with the estimates in section 2 of the Regulatory Impact Analysis. OCR also notes that the cost estimates that are given are averages, and it is expected that there will be some entities that would have costs that are well above or below average. Furthermore, it is expected that large entities would have higher than average costs due to the increased number of notices they would send to individuals.

Comment: A few commenters expressed general concerns on the potential for an increase in premiums and costs within the health care industry. Commenters suggested the final rule would create a moral hazard for individuals or made general statements without data that increasing coverage of goods and services would increase costs and resulting premiums. Other commenters focused on the harm to small business the rule would cause from raising the insurance costs for low-income individuals that small businesses employ. Commenters argued this would lead to layoffs of said employees and limit what services would be available.

Response: As discussed in section 2 of the RIA, OCR expects that there is a possibility of increased premiums and costs due to the rule, but the possible increase is expected to be a small percentage of the current costs due to the low utilization of gender-affirming care and supply of specialists capable of offering said services. OCR does not expect the final rule to have a significant economic impact on small entities based on the analysis in the Regulatory Flexibility Act (RFA).

Comment: A couple of commenters were concerned that the rule would make it more difficult for small entities to compete and remain compliant, which would give a competitive advantage to larger entities in the industry and lead to more consolidation of supplier and provider markets.

Response: OCR appreciates the concerns raised by these commenters; however, as discussed in the RFA, OCR does not expect a significant impact of costs on a substantial number of small entities.

Comment: A few commenters claimed that the final rule would lead to lower innovation within the health care industry due to an increased need to spend funds fighting discrimination instead of medical research.

Response: As discussed in section 2 of the RIA, OCR estimates that additional costs from the inclusion of nondiscrimination requirements will be a small percentage of the total cost due to the limited number of individuals that would seek gender-affirming care, thereby limiting any potential decrease in available funds for medical research.

Comment: A few commenters expressed concern that the final rule would limit rural health care because it would make it more difficult for rural entities to stay compliant and would worsen their financial positions, potentially resulting in closures.

Response: As discussed in section 2 of the RIA, OCR estimates that the costs associated with the final rule would be a small percentage increase in overall costs. Furthermore, OCR reviewed relevant literature and found no studies which suggested that rural hospitals would be particularly impacted by expanded health care services. Finally, as discussed in the small entity analysis section of this RIA, OCR does not estimate a significant economic impact on a substantial number of small entities.

Comment: Several commenters expressed concern that the final rule would lead to fewer health care professionals in the industry for a

[419] 2 U.S.C. 1503(2).

[420] Commenters referred to ''taglines,'' which were required in the 2016 Rule at former § 92.8(d). This final rule does not require ''taglines'' but instead requires a notice of availability of language assistance services and auxiliary aids and services (referred to as ''Notice of Availability'') at § 92.11.

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).

publication. This revision resulted in adjusted cost estimates that are consistent with the RIA presented in this final rule. The estimates covered the employees' time for reviewing and completing the collections required.

Consistent with the NPRM, the collections of information proposed by this final rule relate to §§ 92.5 (Assurances required); 92.7 (Designation and responsibilities of a Section 1557 Coordinator); 92.9 (Training); 92.10 (Notice of nondiscrimination); and 92.11 (Notice of availability of language assistance services and auxiliary aids and services). Respondents to this proposed information collection would include a variety of covered entities with a health program or activity including hospitals, ambulatory surgical centers, skilled nursing facilities, and physicians' offices. For a more detailed discussion concerning the potential costs' implications related to these collections of information, please see the Regulatory Impact Analysis.

1. ICRs Regarding Assurances (§ 92.5)

Section 92.5 retains the assurances obligations from the 2016 and 2020 Rules for covered entities to submit an assurance of compliance to the Department. As stated in the NPRM, OCR has previously obtained PRA approval (OMB control # 0945–0008) for this reporting requirement via an update to HHS Form 690 (Consolidated Civil Rights Assurance Form), separate from this rulemaking. The requirement to sign and submit an assurance of compliance currently exists under section 1557 and other civil rights regulations (title VI, section 504, title IX, and the Age Act). Since the Department provides an online portal through which covered entities submit attestation of Assurance of Compliance, the Department has determined that this requirement imposes no additional reporting or recordkeeping requirements under the PRA.

OCR did not receive any comments in response to the ICRs related to this policy. Please see the prior preamble discussion for our responses to the general comments related to this provision. OCR is finalizing this ICR as proposed.

2. ICRs Regarding Section 1557 Coordinator (§ 92.7) and Training (§ 92.9)

Section 92.7 requires covered entities with 15 or more employees designate a section 1557 Coordinator to coordinate their efforts to comply with and carry out their responsibilities under section 1557. The burden to coordinate efforts to comply with and carry out the responsibilities under section 1557 was estimated in the NPRM, at an annualized burden of 10 hours per covered entity to store complaints and the associated records required under § 92.8(c)(2) each year. We assumed that administrative or clerical support personnel would perform these functions. The mean hourly wage for this occupation was $17.38 per hour, which we double to account for overhead and other indirect costs. In the 2022 NPRM, OCR estimated the number of covered entities with more than 15 employees to be approximately 15 percent or 41,250. Although in the 2022 NPRM, OCR estimated that the costs of retaining records related to grievances filed at all covered entities would be $14.3 million annually (($17.38 × 2) × 10 × 41,250), we noted that this estimation approach may overstate the costs if many covered entities already retain complaint information.

OCR has adjusted our estimated respondent burden in this request to reflect baseline conditions based on updated information available at the time of the final rule's publication. No changes were made to estimated personnel or staff time or to the assumption that administrative or clerical support personnel would perform these functions. The mean hourly wage for this occupation, however, has increased to $19.02 per hour, which we double to account for overhead and other indirect costs. The Department estimates the number of covered entities with more than 15 employees to be approximately 15 percent or 63,950. Although 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 burden for documenting employee training as required under § 92.9(c) is the cost of covered entity staff time to (a) create training attendance forms; and (b) store the training sign-up sheet. The labor cost would include 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 in subsequent years. In the NPRM, we estimated that administrative or clerical support personnel would perform these functions. The mean hourly wage for this occupation was $17.38 per hour. The labor cost was $6.0 million in the first year (($17.38 × 1.25) × 275,002 covered entities). In the 2022 NPRM, we estimated that the cost in subsequent years would be $4.8 million, which would represent an annual allotment of one (1) hour (($17.38 × 1) × 275,002 covered entities).

OCR has adjusted our estimated respondent burden in this request to reflect updated baseline conditions based on updated information not available at the time of the publication of the NPRM. No changes were made to the estimated personnel or staff time or to the estimate that administrative or clerical support personnel would perform these functions. The mean hourly wage for this occupation, however, increased to $19.02 per hour. The estimated labor cost of documenting employee training would be $12.6 million in the first year (($19.02 × 2) × 1.25 × 266,297 covered entities). We estimate that the cost in subsequent years would be $10.1 million, which would represent an annual allotment of one (1) hour ((($19.02 × 2) × 1) × 266,297 covered entities).

OCR did not receive any comments in response to the ICRs related to this policy. Please see the prior preamble discussion for our responses to the general comments related to this provision. OCR is finalizing these ICRs as proposed.

3. ICRs Regarding Notice of Nondiscrimination (§ 92.10) and Notice of Availability of Language Assistance Services and Auxiliary Aids and Services (§ 92.11)

Under §§ 92.10 and 92.11, OCR requires covered entities to notify the public of their nondiscrimination requirements, as well as the availability of language assistance services and auxiliary aids and services.

Section 92.10 requires covered entities to provide a Notice of Nondiscrimination relating to its heath programs or activities to beneficiaries of its health programs and activities and members of the public. To minimize the burden on covered entities, the provision proposes a covered entity may combine the content of the notice required by this section with the notice required by title VI, section 504, title IX, and the Age Act implementing regulations.

Section 92.11 requires covered entities to notify the public of their nondiscrimination requirements, as well as the availability of language assistance services and auxiliary aids and services. A covered entity must provide a Notice of Availability that, at minimum, states that the covered entity provides language assistance services and auxiliary aids and services free of charge

in its health programs and activities, in compliance with section 1557. This notice must be provided to beneficiaries of the covered entity's health program or activity and members of the public. The notice must be provided in English and at least the top 15 languages spoken by persons with LEP of the relevant State or States in which a covered entity operates (including territories) and must be provided in alternate formats for individuals who request auxiliary aids and services to ensure effective communication.

OCR also received comments on the cost of Notices of Nondiscrimination and Notices of Availability (referred to as ''taglines'' in the 2016 and 2020 Rules). One commenter explained how the cost of including taglines averages up to $8.91 per month per covered entity and upwards of $2 million a year for the health insurance industry. Another commenter stated that they have spent over $16 million on notices and taglines since 2016, and estimate that they have spent over $3 million in 2022 alone. As we noted in the RIA, neither commenter provided sources for their data nor additional detail on their cost estimates. Another commenter noted that previous complaints on the frequency and volume of materials related to the notice and tagline sections of the rule were not addressed, but no data were provided with their comment.

Based on costs estimated in the RIA, OCR derives a monthly cost of Notices of Nondiscrimination and Notices of Availability from $21.28 and $26.60 per entity depending on the prevalence of electronic delivery. These cost estimates include the total Notices of Nondiscrimination and Notices of Availability and therefore OCR finds the commenter's estimate of $8.91 per month for Notices of Availability as plausible and consistent with the estimates in the RIA. OCR also notes that these cost estimates are averages. It is expected that some entities, including larger entities, may have higher than average costs due to the increased number of notices they would send to individuals.

Both types of notices are required (1) on an annual basis; (2) upon request; (3) at a conspicuous location on the homepage of the covered entity's health program or activity website; and (4) at conspicuous physical locations where the health program or activity interacts with the public.

In the NPRM, OCR estimated the burden for responding to the proposed notice requirements would be 34 minutes and that administrative or clerical support personnel would perform these functions. Because it was difficult to determine the exact number of communications that would be required to contain the notices anticipated under the 2022 NPRM, our cost estimates reflected a wide range of uncertainty in the cost. In the 2022 NPRM, the Department estimated an adjusted annual primary cost total of $4.5 million, with a range of costs between $2.7 million and $25.0 million. These costs would occur in each year of the time horizon of the analysis.

OCR has adjusted our estimated respondent burden in this request to reflect updated baseline conditions based on updated information not available at the time of the publication of the NPRM. Because it is difficult to determine the exact number of communications that would be required to contain the notices anticipated under the 2022 NPRM, our cost estimates reflect a wide range of uncertainty in the cost. OCR notes that the majority of associated costs for these requirements are from the materials, such as paper and ink, used in the notices and these costs are assumed to vary with the length of notices. No changes were made to the estimate that administrative or clerical support personnel would perform these functions. The estimated personnel and staff time, however, increased to 1.34 hours per year to perform these functions. The mean hourly wage for this occupation increased to $19.02 per hour, which we double to account for overhead and other indirect costs. The estimated labor cost to notify the public of their nondiscrimination requirements, as well as availability of language assistance services and auxiliary aids and services, would be $13.5 million (($19.02 × 2) × 1.34) × 266,297 covered entities). The Department estimates the total associated costs for these requirements as an adjusted annual total of $53.2 million, with a range of costs between $35.5 million and $292.6 million. These costs would occur in each year of the time horizon of the analysis.

OCR did not receive any comments in response to the ICRs related to § 92.10, and received the comments discussed above in response to ICRs related to § 92.11. Please see the prior preamble discussion for our responses to the general comments related to this provision. OCR is finalizing the ICRs for §§ 92.10 and 92.11 as proposed.

We have submitted a copy of this final rule to OMB for its review of the rule's ICRs. These requirements are not effective until they have been approved by OMB.

TABLE 1—SUMMARY OF ESTIMATED ANNUALIZED BURDEN

Information collection	Number of respondents	Responses frequency (average)	Total responses	Burden hours per response (average)	Hourly rate	Burden cost [470]
§ 92.7 Coordination Efforts	[471] 63,950/ 266,297	1	330,247	[472] 10/1.25	[473] $38.04	$24,326,580/ 12,662,422
§§ 92.10 & 92.11 Notice	266,297	[474] 1	266,297	1.34	38.04	13,574,117
Total application collection	330,247	.....	596,544	12.59	.....	50,563,119

[470] The figures in this column are averages based on a range. Large entities with more than 15 employees may require more hours than those provided here due to their size and complexity, while small entities may require fewer hours to conduct certain compliance activities.

[471] Covered entities with 15 or more employees would be required to coordinate the retention of grievance complaints for no less than three years. We have estimated that this provision would apply to approximately 63,950 covered entities. All covered entities would be required to document employee training on section 1557. We estimated that this would apply to approximately 266,297 covered entities.

[472] We have estimated that covered entities with 15 or more employees would spend approximately 10 hours on efforts to coordinate their compliance efforts under section 1557 as required under § 92.7. We estimate that all covered entities would spend approximately 1.25 hours documenting employee training as required under § 92.9.

[473] The $38.04 wage, which includes $19.02 plus 100 percent for benefits, applies to the category ''Administrative or Clerical Support Personnel.''

[474] Because it is difficult to determine the exact number of communications which would be required to contain the notices anticipated under the Proposed Rule, our number of responses per respondent estimate reflects this uncertainty.

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

provision(s) of this part to specific contexts, procedures, or health care services shall not be required where such protections apply.

(b) *Assurance of religious freedom and conscience exemption.* A recipient that seeks assurance consistent with paragraph (a) of this section regarding the application of particular provision(s) of this part to specific contexts, procedures, or health care services may do so by submitting a notification in writing to the Director of OCR. Notification may be provided by the recipient at any time, including before an investigation is initiated or during the pendency of an investigation. The notification must include:

(1) The particular provision(s) of this part from which the recipient asserts they are exempt under Federal religious freedom or conscience protections;

(2) The legal basis supporting the recipient's exemption should include the standards governing the applicable Federal religious freedom and conscience protections, such as the provisions in the ACA itself; the Church, Coats-Snowe, and Weldon Amendments; the generally applicable requirements of the Religious Freedom Restoration Act (RFRA); or any other applicable Federal laws; and

(3) The factual basis supporting the recipient's exemption, including identification of the conflict between the recipient's religious or conscience beliefs and the requirements of this part, which may include the specific contexts, procedures, or health care services that the recipient asserts will violate their religious or conscience beliefs overall or based on an individual patient matter.

(c) *Temporary exemption.* A temporary exemption from administrative investigation and enforcement will take effect upon the recipient's submission of the notification—regardless of whether the assurance is sought before or during an investigation. The temporary exemption is limited to the application of the particular provision(s) in this part as applied to the specific contexts, procedures, or health care services identified in the notification to OCR.

(1) If the notification is received before an investigation is initiated, within 30 days of receiving the notification, OCR must provide the recipient with email confirmation acknowledging receipt of the notification. OCR will then work expeditiously to reach a determination of recipient's notification request.

(2) If the notification is received during the pendency of an investigation, the temporary exemption will exempt conduct as applied to the specific contexts, procedures, or health care services identified in the notification during the pendency of OCR's review and determination regarding the notification request. The notification shall further serve as a defense to the relevant investigation or enforcement activity regarding the recipient until the final determination of recipient's exemption assurance request or the conclusion of the investigation.

(d) *Effect of determination.* If OCR makes a determination to provide assurance of the recipient's exemption from the application of certain provision(s) of this part or that modified application of certain provision(s) is required, OCR will provide the recipient its determination in writing, and if granted, the recipient will be considered exempt from OCR's administrative investigation and enforcement with regard to the application of that provision(s) as applied to the specific contexts, procedures, or health care services provided. The determination does not otherwise limit the application of any other provision of this part to the recipient or to other contexts, procedures, or health care services.

(e) *Appeal.* A recipient subject to an adverse determination of its request for an exemption assurance may appeal OCR's determination under the administrative procedures set forth at 45 CFR part 81. The temporary exemption provided for in paragraph (c) of this section will expire upon a final decision under 45 CFR part 81.

(f) *Final agency action.* A determination under this section is not final for purposes of judicial review until after a final decision under 45 CFR part 81.

§ 92.303 Procedures for health programs and activities conducted by recipients and State Exchanges.

(a) The procedural provisions applicable to title VI apply with respect to administrative enforcement actions against health programs and activities of recipients and State Exchanges concerning discrimination on the basis of race, color, national origin, sex, age, disability, or any combination thereof, under section 1557 or this part. These procedures are found at 45 CFR 80.6 through 80.11 and 45 CFR part 81.

(b) If OCR receives a complaint over which it does not have jurisdiction, it shall promptly notify the complainant and shall make reasonable efforts to refer the complaint to the appropriate Federal Government entity.

(c) When a recipient or State Exchange fails to provide OCR with requested information in a timely, complete, and accurate manner, OCR may, after attempting to reach voluntary resolution, find noncompliance with section 1557 or this part and initiate appropriate enforcement procedures, found at 45 CFR 80.8, including beginning the process for fund suspension or termination and taking other action authorized by law.

§ 92.304 Procedures for health programs and activities administered by the Department.

(a) The procedural provisions applicable to section 504 shall apply with respect to administrative enforcement actions against the Department, including Federally-facilitated Exchanges, concerning discrimination on the basis of race, color, national origin, sex, age, disability, or any combination thereof, under section 1557 or this part. These procedures are found at 45 CFR 85.61 and 85.62. Where this section cross-references regulatory provisions that use the term ''handicap,'' the term ''race, color, national origin, sex, age, or disability, or any combination thereof,'' shall apply in its place.

(b) The Department must permit access by OCR to its books, records, accounts, other sources of information, and facilities as may be pertinent to ascertain compliance with section 1557 or this part. Where any information required of the Department is in the exclusive possession of any other agency, institution or person, and the other agency, institution or person fails or refuses to furnish this information, the Department shall so certify and shall set forth what efforts it has made to obtain the information. Asserted considerations of privacy or confidentiality may not operate to bar OCR from evaluating or seeking to enforce compliance with section 1557 or this part. Information of a confidential nature obtained in connection with compliance evaluation or enforcement shall not be disclosed except where necessary under the law.

(c) The Department must not intimidate, threaten, coerce, retaliate, or otherwise discriminate against any individual or entity for the purpose of interfering with any right or privilege secured by section 1557 or this part, or because such individual or entity has made a complaint, testified, assisted, or participated in any manner in an investigation, proceeding or hearing under section 1557 or this part. The identity of complainants must be kept confidential by OCR in accordance with applicable Federal law.

PART 147—HEALTH INSURANCE REFORM REQUIREMENTS FOR THE GROUP AND INDIVIDUAL HEALTH INSURANCE MARKETS

■ 16. The authority citation for part 147 continues to read as follows:

Authority: 42 U.S.C. 300gg through 300gg–63, 300gg–91, 300gg–92, and 300gg–111 through 300gg–139, as amended, and section 3203, Pub. L. 116–136, 134 Stat. 281.

■ 17. Amend § 147.104 by revising paragraph (e) to read as follows:

§ 147.104 Guaranteed availability of coverage.

* * * * *

(e) *Marketing.* A health insurance issuer and its officials, employees, agents and representatives must comply with any applicable State laws and regulations regarding marketing by health insurance issuers and cannot employ marketing practices or benefit designs that will have the effect of discouraging the enrollment of individuals with significant health needs in health insurance coverage or discriminate based on an individual's race, color, national origin, present or predicted disability, age, sex (which includes discrimination on the basis of sex characteristics, including intersex traits; pregnancy or related conditions; sexual orientation; gender identity; and sex stereotypes), expected length of life, degree of medical dependency, quality of life, or other health conditions.

* * * * *

PART 155—EXCHANGE ESTABLISHMENT STANDARDS AND OTHER RELATED STANDARDS UNDER THE AFFORDABLE CARE ACT

■ 18. The authority citation for part 155 continues to read as follows:

Authority: 42 U.S.C. 18021–18024, 18031–18033, 18041–18042, 18051, 18054, 18071, and 18081–18083.

■ 19. Amend § 155.120 by revising paragraph (c)(1)(ii) to read as follows:

§ 155.120 Non-interference with Federal law and non-discrimination standards.

* * * * *

(c) * * *

(1) * * *

(ii) Not discriminate based on race, color, national origin, disability, age, 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).

* * * * *

■ 20. Amend § 155.220 by revising paragraph (j)(2)(i) to read as follows:

§ 155.220 Ability of States to permit agents and brokers and web-brokers to assist qualified individuals, qualified employers, or qualified employees enrolling in QHPs.

* * * * *

(j) * * *

(2) * * *

(i) Provide consumers with correct information, without omission of material fact, regarding the Federally-facilitated Exchanges, QHPs offered through the Federally-facilitated Exchanges, and insurance affordability programs, and refrain from marketing or conduct that is misleading (including by having a direct enrollment website that HHS determines could mislead a consumer into believing they are visiting *HealthCare.gov*), coercive, or discriminates based on race, color, national origin, disability, age, 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);

* * * * *

PART 156—HEALTH INSURANCE ISSUER STANDARDS UNDER THE AFFORDABLE CARE ACT, INCLUDING STANDARDS RELATED TO EXCHANGES

■ 21. The authority citation for part 156 continues to read as follows:

Authority: 42 U.S.C. 18021–18024, 18031–18032, 18041–18042, 18044, 18054, 18061, 18063, 18071, 18082, and 26 U.S.C. 36B.

■ 22. Amend § 156.200 by revising paragraph (e) to read as follows:

§ 156.200 QHP issuer participation standards.

* * * * *

(e) *Non-discrimination.* A QHP issuer must not, with respect to its QHP, discriminate on the basis of race, color, national origin, disability, age, 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).

* * * * *

■ 23. Amend § 156.1230 by revising paragraph (b)(2) to read as follows:

§ 156.1230 Direct enrollment with the QHP issuer in a manner considered to be through the Exchange.

* * * * *

(b) * * *

(2) The QHP issuer must provide consumers with correct information, without omission of material fact, regarding the Federally-facilitated Exchanges, QHPs offered through the Federally-facilitated Exchanges, and insurance affordability programs, and refrain from marketing or conduct that is misleading (including by having a direct enrollment website that HHS determines could mislead a consumer into believing they are visiting *HealthCare.gov*), coercive, or discriminates based on race, color, national origin, disability, age, 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).

[FR Doc. 2024–08711 Filed 4–26–24; 4:15 pm]

BILLING CODE 4153–01–P

Exhibit B

Comment of the State of Tennessee and Nineteen Co-Signing States, HHS-OS-2022-0012-68650 (Oct. 3, 2022)

STATE OF TENNESSEE

Office of the Attorney General

Jonathan Skrmetti
Attorney General and Reporter

P.O. Box 20207
Nashville, TN 37202
Telephone: (615) 741-3491
Facsimile: (615) 741-2009

October 3, 2022

SUBMITTED ELECTRONCIALLY
VIA REGULATIONS.GOV

The Honorable Xavier Becerra
Secretary of Health & Human Services
U.S. Dept. of Health & Human Services
200 Independence Avenue S.W.
Washington, D.C. 20201

Dear Secretary Becerra:

Tennessee and the undersigned State Attorneys General appreciate the opportunity to comment on the Notice of Proposed Rulemaking from the Department of Health and Human Services ("HHS"). *See* Notice of Proposed Rulemaking. Nondiscrimination in Health Programs and Activities, 87 Fed. Reg. 47824 (proposed Aug. 4, 2022) ("Proposed Rule"). Like HHS, Tennessee has a keen interest in the interpretation and enforcement of Section 1557 of the Patient Protection and Affordable Care Act—which has broad effects on healthcare in Tennessee, including Tennessee's successful Medicaid program.

Unfortunately, HHS's proposed interpretation of Section 1557's prohibition of discrimination "on the basis of sex," language incorporated from Title IX, does not comport with the statute as enacted by Congress. Simply put, the statutory text does not prohibit discrimination on the basis of "gender identity" or "sexual orientation." Congress alone possesses the authority to legislate. While the proposed regulations purport to interpret the law, they actually change its

meaning in a way that intrudes on Congress's exclusive domain. Your agency cannot rewrite the law.

Tennessee and the co-signing States have been at the forefront of challenging this Administration's attempts to rewrite Congress's statutes by executive fiat. Just recently, Tennessee and nineteen other States secured a preliminary injunction against similar examples of agency overreach including (1) a "technical assistance document" that the EEOC Chair unilaterally issued in an attempt to expand the meaning of "sex" in Title VII;[1] and (2) the U.S. Department of Education's Interpretation[2] and Fact Sheet[3] adopting a similarly unlawful interpretation of Title IX. *See Tennessee v. United States Dep't of Educ.*, No. 3:21-CV-308, 2022 WL 2791450, at *24 (E.D. Tenn. July 15, 2022) (enjoining EEOC guidance and interpretive rule for unlawfully misconstruing federal law and failure to adhere to Administrative Procedure Act requirements). The Eastern District of Tennessee warned that the agencies' attempted rulemaking "creates rights for students and obligations for regulated entities not to discriminate based on sexual orientation or gender identity that appear nowhere in *Bostock*, Title IX," or existing regulations. *Id.* at *21.

Similarly, just days ago, Texas obtained vacatur of the EEOC "technical assistance document" and HHS's own "guidance" attempting to require—under Section 1557—recipients of federal healthcare funding to engage in purported "gender affirming care" on minors.[4] *See* Opinion and Order, *Texas v. EEOC*, No. 2:21-cv-194 (N.D. Tex. Oct. 1, 2022), ECF 74.

The Proposed Rule here fails to heed the warnings from these rulings—not to mention other litigation enjoining similar attempts to interpret Section 1557 in ways contrary to the plain meaning of its statutory text.

Accordingly, HHS should hew to the regulations that it promulgated in 2020, which adhere to the law enacted by Congress. *See* Nondiscrimination in Health and Health Education Programs or Activities, Delegation of Authority, 85 Fed. Reg. 37160 (June 19, 2020) ("2020 Rule"). If your agency instead continues with this attempt to rewrite the law by executive fiat, HHS will face yet more litigation challenging this Administration's regulatory overreach.[5]

---

[1] *See* EEOC, Protections Against Employment Discrimination Based on Sexual Orientation or Gender Identity, NVTA 2021-1 (June 15, 2021), https://bit.ly/3zgP7iP.

[2] Enforcement of Title IX of the Education Amendments of 1972 With Respect to Discrimination Based on Sexual Orientation and Gender Identity in Light of *Bostock v. Clayton County*, 86 Fed. Reg. 32,637 (June 22, 2021).

[3] U.S. Dep't of Justice & U.S. Dep't of Educ., Confronting Anti-LGBTQI+ Harassment in Schools, https://bit.ly/3sQjZnM.

[4] U.S. Dep't of Health and Human Servs. Off. for Civil Rights, HHS Notice and Guidance on Gender Affirming Care, Civil Rights, and Patient Privacy (March 2, 2022), https://bit.ly/3UTIEWd.

[5] *E.g.*, *Franciscan All., Inc. v. Becerra*, 47 F.4th 368 (5th Cir. 2022) (affirming permanent injunction on RFRA grounds against future HHS attempts to require medical providers to perform abortions or gender-transition procedures); *Christian Employers All. v. EEOC*, No. 1:21-CV-195,

I. *Bostock*'s Limited Reach.

The Proposed Rule is the latest agency action designed to address the President's directive to agency heads to promulgate regulations conferring new protections outside the scope of federal civil rights statutes, ostensibly based on the Supreme Court's holding in *Bostock v. Clayton County*, 140 S. Ct. 1731, 1737 (2020). *See* Executive Order on Preventing and Combating Discrimination on the Basis of Gender Identity or Sexual Orientation, 86 Fed. Reg. 7023 (Jan. 20, 2021).[6]

In *Bostock*, the Supreme Court decided a narrow question: Whether Title VII's precisely-worded protection for employment discrimination "because of . . . sex" prohibits an employer from "fir[ing] someone simply for being homosexual or transgender." 140 S. Ct. at 1753. In a 6-3 decision, the Court concluded that an employer "who fires an individual merely for being gay or transgender" violates Title VII. *Id.* at 1754. That decision, however, was cabined in various ways that limit its applicability to other statutes.

Broadly, the *Bostock* majority expressly noted that "other federal or state laws that prohibit sex discrimination"—like Section 1557—were not "before" the Court, and thus the Court would "not prejudge any such question" about what the text of those statutes requires. *Id.* at 1753. Thus, the *Bostock* majority itself disclaimed the decision's applicability to other statutory schemes.

Moreover, even within the context of the statute at issue in *Bostock*, the majority recognized the narrow limitations of its holding.

First, the *Bostock* majority declined to opine about what constituted unlawful discrimination "because of sex" under its Title VII interpretation. Specifically, the majority did "not purport to address" certain forms of sex-separated facilities or services like "bathrooms, locker rooms, or anything else of the kind." *Id.* at 1753.

Second, the *Bostock* majority emphasized that its interpretation of Title VII would have to accord with religious-liberty protections under the U.S. Constitution and the Religious Freedom Restoration Act. *Id.* at 1753-54.

2022 WL 1573689 (D.N.D. May 16, 2022) (challenge to predecessor to Proposed Rule: HHS's Notification of Interpretation); *Neese v. Becerra*, No. 2:21-CV-163-Z, 2022 WL 1265925 (N.D. Tex. Apr. 26, 2022) (same).

[6] "Under *Bostock*'s reasoning, laws that prohibit sex discrimination—including Title IX of the Education Amendments of 1972, . . . Fair Housing Act . . . , and section 412 of the Immigration and Nationality Act, . . . along with their respective implementing regulations—prohibit discrimination on the basis of gender identity or sexual orientation, so long as the laws do not contain sufficient indications to the contrary." Executive Order, 86 Fed. Reg. at 7023.

Third, the *Bostock* majority recognized "that homosexuality and transgender *status* are distinct concepts from sex." *Id.* at 1746-47 (emphasis added). Thus, the majority did not redefine "sex" to include "sexual orientation" and "gender identity."

II. Regulatory and Litigation Background.

This is the latest installment in HHS's whipsawing between interpretations of Section 1557's prohibition of discrimination "on the basis of sex." This latest interpretation reverses course from HHS's comprehensive 2020 analysis of Section 1557's plain statutory requirements. This inconsistent and chaotic regulatory approach demonstrates the wisdom of the Founders in assigning lawmaking to the people's representatives in Congress and not to the whim of whoever happens to hold executive power at a given time.

Generally, Section 1557 draws its anti-discrimination provision from Title IX: "Section 1557 clearly incorporates Title IX's prohibition of sex discrimination." *Franciscan All. Inc. v. Burwell*, 227 F. Supp. 3d 660, 686 (N.D. Tex. Dec. 31, 2016).[7] And under Title IX, Congress prohibited discrimination "on the basis of sex." 20 U.S.C. § 1681(a).

A. 2016 Rule. In 2016—before the *Bostock* majority interpreted Title VII—HHS defined Section 1557's prohibition of discrimination "on the basis of sex" to "encompass[ ] discrimination on the basis of gender identity": "an individual's internal sense of gender, which may be male, female, neither, or a combination of male and female." 2020 Rule, 85 Fed. Reg. at 37161 (quoting Nondiscrimination in Health Programs and Activities, 81 Fed. Reg. 31375, 31384 (May 18, 2016)). Thus, the 2016 rule also "imposed several requirements regarding medical treatment and coverage on the basis of gender identity."[8] *Id.*

B. Litigation Enjoining 2016 Rule. In a comprehensive opinion, the Northern District of Texas enjoined HHS's enforcement of this regulation nationwide in relevant part. *Franciscan All.*, 227 F. Supp. 3d at 696; *accord* 2020 Rule, 85 Fed. Reg. at 37163 ("On December 31, 2016, the U.S. District Court for the Northern District of Texas preliminarily enjoined, on a nationwide basis, portions of the 2016 Rule that had interpreted Section 1557 to prohibit discrimination on the basis of gender identity and termination of pregnancy.").

Section 1557—like Title IX—reflects "Congress['s] inten[t] to prohibit sex discrimination on the basis of the biological differences between males and females." *Franciscan All.*, 227 F.

---

[7] *Accord* 42 U.S.C. § 18116(a) ("[A]n individual shall not, on the ground prohibited under . . . title IX of the Education Amendments of 1972 (20 U.S.C. 1681 et seq.) . . . be excluded from participation in, be denied the benefits of, or be subjected to discrimination under, any health program or activity, any part of which is receiving Federal financial assistance, 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 this title (or amendments).").

[8] Notably, HHS did not define sex discrimination to include discrimination on the basis of sexual orientation, except in cases "where the evidence establishes that the discrimination is based on gender stereotypes." 2016 Rule 82 Fed. Reg. at 31390.

Supp. 3d at 687 (citing 20 U.S.C. § 1681); *accord Neese*, 2022 WL 1265925, at *12 ("Title IX presumes sexual dimorphism in section after section, requiring equal treatment for each 'sex.'").

The court concluded that "Congress's intent in enacting Section 1557 is clear because the statute explicitly incorporates Title IX's prohibition of sex discrimination." *Franciscan All.*, 227 F. Supp. 3d at 687. Rather than create a new body of nondiscrimination law, Section 1557 ". . . incorporates the grounds of four longstanding federal nondiscrimination statutes," including Title IX. *Id.*, at 671.

And the "text of Title IX indicates Congress's binary definition of 'sex'" is defined by biological sex—and not gender identity. *Id.* at 687; *see also* 20 U.S.C. § 1681 ("students of one sex"; "both sexes"; "students of the other sex"). The court provided extensive support for the proposition that when Congress enacted Title IX in 1972, "the term 'sex' was commonly understood to refer to the biological differences between males and females." [9] *Id.* at 688 (collecting definitions); *accord Neese*, 2022 WL 1265925, at *12 (same).

The Northern District of Texas also concluded that Congress's 2010 enactment of Section 1557—which incorporated Title IX's antidiscrimination provisions—did not alter the court's interpretation. In 2010: "(1) Congress knew how but did not use language indicating as much, and (2) in 2010 no federal court or agency had interpreted Title IX sex discrimination to include gender identity." *Franciscan All.*, 227 F. Supp. 3d at 688.

C. 2020 Rule. In 2020—with the benefit of *Franciscan Alliance*'s analysis and *after* the Supreme Court's Title VII decision in *Bostock*—HHS determined that its 2016 Rule was faulty. Section 1557's protections from discrimination "on the basis of sex" reflected that "'[s]ex' according to its original and ordinary public meaning refers to the biological binary of male and female that human beings share with other mammals." 2020 Rule, 85 Fed. Reg. at 37178.

Primarily, HHS concluded that its 2016 Rule was inconsistent with statutory text and thus imposed "essentially legislative changes that the Department lacked the authority to make." *Id.* at 37161-62. And HHS recognized that the 2016 Rule "imposed new requirements for care related to gender identity and termination of pregnancy that Congress has never required, and prevented covered entities from drawing reasonable and/or medically indicated distinctions on the basis of sex." *Id.* at 37162.

HHS also revised "[t]en provisions in CMS regulations, all of which cover entities that are also subject to Section 1557" to "delet[e] the provisions on sexual orientation and gender identity." *Id.* at 37162. In addition to Section 1557's failure to include "sexual orientation" as a protected

[9] Even among those who used the term "gender identity" around the time of Title IX's enactment, they recognized the difference between "sex" and "gender identity." *Franciscan All.*, 227 F. Supp. 3d at 688 (collecting authorities). Further, other portions of Title IX "authorize[] covered institutions to provide different arrangements for each of the sexes." *Id.* at 688 (citing 20 U.S.C. § 1686).

class, "distinctions on the basis of sexual orientation may be sex-neutral and apply equally to both sexes, which would mean that they do not burden anyone on the basis of sex." *Id.* at 37194.

For both gender identity and sexual orientation, the Agency concluded that "[m]uch as the reasonable distinctions on the basis of sex discussed above are not illegitimate sex stereotypes, so too, distinctions on the basis of sexual orientation do not as such constitute sex stereotyping." *Id.*

At bottom, "[g]iven Congress's decision not to extend civil rights protections on the basis of sexual orientation" and gender identity "in the field of health and human services, the Department believes that State and local governments are best equipped to balance the multiple competing considerations involved in what remain a contentious and fraught set of questions." *Id.* at 37194.

* * *

Just two years after HHS's well-reasoned decision to return to Congress's plain meaning, HHS has reversed course again. First, HHS issued its Notification of Interpretation, and certain affected parties immediately—and successfully—challenged HHS's reversion to its incorrect interpretation. *E.g.*, *Christian Employers All. v. EEOC*, 2022 WL 1573689; *Neese*, 2022 WL 1265925. Now, HHS seeks comment on a new proposed rule which shares similar defects to the agency's prior failed effort.

III. Defects in Proposed Rule.

In *Bostock*, Justice Kavanaugh recognized that "[h]ealthcare benefits may emerge as an intense battleground under the Court's holding." 140 S. Ct. at 1781 (Kavanaugh, J., dissenting) (collecting cases).

With the Proposed Rule here, Justice Kavanaugh's prediction has come true. For reasons evident in Section 1557's plain text and statutory context—and for reasons that HHS identified in 2020 and the reviewing court recognized in 2016—the Proposed Rule's attempts to contort Congress's demands are unlawful. Thus, without substantial alteration, the Proposed Rule will join a long list of unlawful agency actions.[10]

A. Improper Reliance on *Bostock* over Title IX's Text. Rather than developing from Title IX's plain text, the Proposed Rule is over-reliant on inapposite judicial precedent.

[10] HHS may not promulgate regulations that violate Section 1557. *E.g.*, *Children's Health Def. v. FCC*, 25 F.4th 1045, 1052 (D.C. Cir. 2022). The Proposed Rule is not a permissible reading of the statute and instead constitutes an unlawful exercise of Congress's legislative authority that exceeds the agency's jurisdiction. *See* 5 U.S.C. § 706(2)(B)-(C) (allowing a court to set aside agency action that is "contrary to constitutional right [or] power" or "in excess of statutory jurisdiction, authority, or limitations"); U.S. Const. art. I, § 1 ("All legislative Powers herein granted shall be vested in . . . Congress.").

After President Biden directed that agencies conform their regulations to the *Bostock* majority's interpretation, *see* 86 Fed. Reg. at 7023, the Proposed Rule unsurprisingly relies in large part on *Bostock's* analysis of Title VII. Proposed Rule, 87 Fed. Reg. at 47829 (noting the *Bostock* decision as reason to depart from 2020 Rule).

As an initial matter, *Bostock* expressly noted that "other federal or state laws that prohibit sex discrimination"—like Section 1557 and Title IX—were not "before" the Court and thus the Court would "not prejudge any such question" about what the text of those statutes requires. *Bostock*, 140 S. Ct. at 1753.

Thus, as many federal courts have held, "the rule in *Bostock* extends no further than Title VII." *Pelcha v. MW Bancorp, Inc.*, 988 F.3d 318, 324 (6th Cir. 2021) ("[T]he Court in Bostock was clear on the narrow reach of its decision and how it was limited only to Title VII itself."). And "it does not follow that principles announced in the Title VII context automatically apply in the Title IX context." *Meriwether v. Hartop*, 992 F.3d 492, 510 n.4 (6th Cir. 2021); *see also* U.S. Dep't of Educ., Memorandum for Kimberly M. Richey Acting Assistant Secretary of the Office for Civil Rights Re: *Bostock v. Clayton Cty.*, 140 S. Ct. 1731 (2020), at 1-4 (Jan. 8, 2021) (*Bostock* did not interpret Title IX and "does not affect the meaning of 'sex' as that term is used in Title IX").

Bostock is especially inapplicable here because Title IX's text is fundamentally different from Title VII: Title IX prohibits discrimination "on the basis of sex," 20 U.S.C. § 1681(a) (emphasis added), rather than "because of . . . sex," 42 U.S.C. § 2000e-2(a)(1).

Bostock concluded that Title VII's precise textual formulation imposed a but-for causation requirement in which biological sex can only be one reason among many for employment termination. 140 S. Ct. at 1739; *id.* at 1741-42 ("if changing the employee's sex would have yielded a different choice by the employer—a statutory violation has occurred," even if the primary reason for the termination was the employee's gender identity or sexual orientation).

Title IX, by contrast, prohibits only discrimination "on the basis of sex." That language clarifies that biological sex must be *the reason* for the discrimination; mere "but for" causation will not suffice. "A statutory provision's use of the definite article 'the,' . . . indicates that Congress intended the term modified to have a singular referent." *SEC v. KPMG LLP*, 412 F. Supp. 2d 349, 387-88 (S.D.N.Y. 2006); *accord Rumsfeld v. Padilla*, 542 U.S. 426, 434 (2004). Thus, the discrimination prohibited in Title IX must be based on sex itself, not based on distinct concepts such as sexual orientation and gender identity.

B. Ignoring Contextual Sources of Meaning. The Proposed Rule also fails to grapple with Title IX's broader contextual understanding of sex and sex discrimination. Title IX's meaning comes from its terms, "read in context," and in light of "the problem Congress sought to solve." *Goldstein v. SEC*, 451 F.3d 873, 878 (D.C. Cir. 2006) (quoting *PDK Labs. Inc. v. DEA*, 362 F.3d 786, 796 (D.C. Cir. 2004)).

Critically, Title IX's use of the term "sex" not only necessarily means biological sex, but also reflects a view of biological sex in which discrimination must be based on biological sex itself. "Sex" in Title IX refers only to biological sex, and not gender identity or sexual orientation. The word "sex" in Title IX must be read "in accord with the ordinary public meaning of ['sex'] at the time of [Title IX was] enact[ed]." *Bostock*, 140 S. Ct. at 1738. And at that time, "virtually every dictionary definition of 'sex' referred to the physiological distinctions between males and females." *Grimm v. Gloucester Cnty. Sch. Bd.*, 972 F.3d 586, 632 (4th Cir. 2020) (Niemeyer, J. dissenting), *cert. denied*, 141 S. Ct. 2878 (2021); *see also Adams v. Sch. Bd. of St. Johns Cnty.*, 3 F.4th 1299, 1322 (11th Cir. 2021) (W. Pryor, C.J., dissenting) (collecting dictionary definitions from time of enactment), *vacated upon granting en banc review*, 9 F.4th 1369; *Franciscan All.*, 227 F. Supp. 3d at 688 (same); *accord Frontiero v. Richardson*, 411 U.S. 677, 686 (1973) (plurality opinion) ("sex . . . is an immutable characteristic determined solely by the accident of birth"). In 1961, the Oxford English Dictionary defined "Sex" as "[t]he sum of those differences in the structure and function of the reproductive organs on the ground of which beings are distinguished as male and female, and of the other physiological differences consequent on these." 9 Oxford English Dictionary 578 (1961). In 1970, the American College Dictionary defined "Sex" to mean "the sum of the anatomical and physiological differences with reference to which the male and the female are distinguished." The American College Dictionary 1109 (1970). A year later, Webster's Third New International Dictionary defined "Sex" to mean "the sum of the morphological, physiological, and behavioral peculiarities of living beings that subserves biparental reproduction." Webster's Third New International Dictionary 2081 (1971). The year after Title IX became law, Random House defined "Sex" as "either the male or female division of a species, esp. as differentiated with reference to the reproductive functions." The Random House College Dictionary 1206 (rev. ed. 1973). And a few years after that, the American Heritage Dictionary defined "Sex" as "[t]he property of quality by which organisms are classified according to their reproductive functions." American Heritage Dictionary 1187 (1976). Each of these sources indicate that Title IX uses "sex" as a reference to the categories of "male" and "female," which "simply are not physiologically the same." *Bauer v. Lynch*, 812 F.3d 340, 350 (4th Cir. 2016) (citing and discussing *United States v. Virginia*, 518 U.S. 515 (1996)).

Title IX repeatedly uses the biological binary of sex. For example, Title IX speaks of permitting sex-based discrimination among ''Men's'' and ''Women's'' associations and organizations for ''Boy[s]'' and ''Girls,'' "the membership of which has traditionally been limited to persons of one [or the other] sex." 20 U.S.C. § 1681(a)(6)(B). The statute also describes how an institution may change "from . . . admit[ting] only students of one sex" (that is, male or female) "to . . . admit[ting] students of both sexes," (male and female). 20 U.S.C. § 1681(a)(2).[11] Title IX thus treats "sex" as having two biological possibilities: male or female. The Affordable Care Act also uses this biological binary. For example, Section 1558 of the Affordable Care Act—the

[11] Consequently, the Department of Education has always construed the term "sex" in Title IX to mean biological sex—not gender identity. *E.g.*, 85 Fed. Reg. 30,178 (May 19, 2020) ("Title IX and its implementing regulations include provisions that presuppose sex as a binary classification. . . . In promulgating regulations to implement Title IX, the Department expressly acknowledged physiological differences between the male and female sexes.").

provision immediately following Section 1557—uses this biological binary in amending the Fair Labor Standards Act to prohibit an employer from discriminating in certain ways "against any employee with respect to *his or her* compensation, terms, conditions, or other privileges of employment." Pub. L. No. 111-148, § 1558, 124 Stat. 119, 261 (2010), codified at 29 U.S.C. § 218c (emphasis added).

Further, Title IX makes clear that not all disparate treatment *based on biological differences* is unlawful discrimination.[12] In other words, sex discrimination under Title IX—and thus under Section 1557—does not arise merely from the "but-for" analysis employed by the *Bostock* majority. *Bostock*, 140 S. Ct. at 1742 ("Just as sex is necessarily a but-for *cause* when an employer discriminates against homosexual or transgender employees, an employer who discriminates on these grounds inescapably intends to rely on sex in its decisionmaking.").

Specifically, Title IX—unlike Title VII addressed in *Bostock*—expressly permits sex-based separation. *E.g.*, 20 U.S.C. § 1686 ("nothing contained herein shall be construed to prohibit any educational institution receiving funds under this Act, from maintaining separate living facilities for the different sexes"); *see Tennessee*, 2022 WL 2791450, at *21 ("Title IX does allow for sex-separation in certain circumstances."); *Franciscan All.*, 227 F. Supp. 3d at 688 ("For example, in § 1686 Congress authorized covered institutions to provide different arrangements for each of the sexes.").[13]

It makes perfect sense to import Title IX's understanding of "sex"—and sex discrimination—into Section 1557, which governs "health programs." Much like in the educational context where differential treatment on the basis of sex may be warranted (in facilities or on sports teams), healthcare also requires different treatment based on biological realities. Men and women have different health needs based on biological sex. As Justice Ginsburg recognized—especially in healthcare contexts—"[p]hysical differences between men and women . . . are enduring" and the "two sexes are not fungible"; they have "inherent differences." *United States v.*

---

[12] Not only does this analysis help define what constitutes unlawful discrimination, it also demonstrates that Congress meant for "sex" to mean "biological sex."

[13] Both HHS and the Department of Education's implementing regulations have long provided that parties regulated by Title IX may provide sex-separated facilities and teams. 34 C.F.R. § 106.33 (allowing "separate toilet, locker room, and shower facilities on the basis of sex, but such facilities provided for students of one sex shall be comparable to such facilities provided for students of the other sex"); *id.* § 106.41(b) (covered institutions "may operate or sponsor separate teams for members of each sex where selection for such teams is based upon competitive skill or the activity involved is a contact sport"); 45 C.F.R. § 86.32(b) (allowing "separate housing on the basis of sex"); *id.* § 86.33 (allowing "separate toilet, locker room, and shower facilities on the basis of sex, but such facilities provided for students of one sex shall be comparable to such facilities provided for students of the other sex"); *id.* § 86.41(b) (allowing "separate teams for members of each sex where selection for such teams is based upon competitive skill or the activity involved is a contact sport").

Virginia, 518 U.S. 515, 533 (1996) (quoting *Ballard v. United States*, 329 U.S. 187, 193 (1946); *Califano v. Webster*, 430 U.S. 313, 320 (1977) (per curiam)).

Indeed, the Proposed Rule itself recognizes that discrimination on the basis of pregnancy is unlawful sex discrimination—which can only be true if unlawful discrimination under Section 1557 were based on biological differences between the sexes. Proposed Rule, 87 Fed. Reg. at 47848; *see also* 2020 Rule, 85 Fed. Reg. at 7179-80 ("Section 1557's protection against discrimination 'on the basis of sex' covers women's health issues including pregnancy, uterine cancer, and prenatal and postpartum services. That assumption is correct: These issues are protected under Section 1557 because of the ordinary and biological meaning of 'sex.'").

In response to the overwhelming evidence that Title IX (and thus Section 1557) does not support HHS's preferred interpretation, the preamble of the Proposed Rule contends that Section 1557 only incorporates the "grounds" of illegal discrimination from Title IX—*i.e.*, the protected classes or "bases"—but not Title IX's definition of sex discrimination. Proposed Rule, 87 Fed. Reg. at 47840.

This unduly narrow interpretation has two flaws.

First, it disregards the most important takeaway from Title IX's other provisions: Title IX's various exclusions help to define what the term "sex" does—and does *not*—mean. And "sex" does not mean "sexual orientation" and "gender identity."

Second, the Proposed Rule does not explain why Section 1557 incorporating the "grounds" for discrimination does *not* incorporate the broader scope of Title IX's prohibitions, as well as Title IX's religious exemption which is integral to properly interpreting the scope of Title IX.

C. The Proposed Rule's Effects on Regulated Parties and Others. Another defect in the Proposed Rule is the effect it will have on regulated parties and others and the Proposed Rule's failure to consider those effects.

First, the Proposed Rule's prohibition of "gender-identity" discrimination will likely compel speech in the form of requiring regulated parties to use preferred pronouns—as compared to pronouns reflecting biological sex. *E.g.*, *Meriwether*, 992 F.3d at 507 (noting First Amendment problems with compelling people to use pronouns affirming that "[p]eople can have a gender identity inconsistent with their sex at birth").[14] Furthermore, under the Proposed Rule, both public and private healthcare providers and organizations would be compelled to provide and post nondiscrimination notices that convey the federal government's messages about controversial topics, such as gender identity and abortion, without regard for the providers' and organizations'

[14] Moreover, some gender dysphoric or transgender individuals prefer novel pronouns to the traditional masculine or feminine pronouns. *See United States v. Varner*, 948 F.3d 250, 256-57 (5th Cir. 2020) (declining to use a litigant's "preferred pronouns" and providing a chart of preferred pronouns that includes "such neologisms" as fae/faer/faers/faerself, per/per/pers/perself, ve/ver/vis/verself, and xe/xem/xyr/xyrs/xemself, ze/hir/hirs/hirself).

views on those topics. *See Bongo Prods., LLC v. Lawrence*, No. 3:21-cv-00490, 2022 WL 1557664, at *1, *16-17 (M.D. Tenn. May 17, 2022) (ruling that a government cannot compel others to affirm the government's position on a controversial topic relating to gender identity).

Second, the Proposed Rule may encourage regulated parties to insert themselves into constitutionally protected family affairs. As the Supreme Court has concluded, "[t]here [is] a 'private realm of family life which the state cannot enter,' that has been afforded both substantive and procedural protection[s]" under our Constitution. *Smith v. Org. of Foster Fams. for Equal. & Reform*, 431 U.S. 816, 842 (1977) (citation and footnotes omitted) (quoting *Prince v. Massachusetts*, 321 U.S. 158, 166 (1944)). Thus parents may "bring up" their children as they deem fit, including through instruction on matters of behavior and ethics. *See M.L.B. v. S.L.J.*, 519 U.S. 102, 116 (1996) (citing *Meyer v. Nebraska*, 262 U.S. 390 (1923)). In this regard, the Treasury and General Government Appropriations Act of 1999 requires federal agencies to issue a Family Policymaking Assessment for any rule that may affect family well-being. *See* Pub. L. No. 105-277, Div. A, § 654, 112 Stats. 2681-480, 2681-528 (1998), codified at 5 U.S.C. § 601 (note). HHS must conduct an analysis of the NPRM's impact on families, which it has not done.

Third, the Proposed Rule offers little assurance that the religious beliefs and practices of all will be respected. To be sure, various proposed regulations pay lip service to the Religious Freedom Restoration Act's requirements, and they purport to establish an exemption process for religious objections. *See* Proposed Rule, 87 Fed. Reg. at 47911, 47918-19. To many religious adherents, however, those promises for exemptions and exceptions ring hollow. *E.g.*, *Little Sisters of the Poor Saints Peter & Paul Home v. Pennsylvania*, 140 S. Ct. 2367, 2375-78 (2020) (detailing the tortured history of the Little Sisters of the Poor); *Franciscan All., Inc.*, 47 F.4th at 380 (affirming the permanent injunction of the HHS's attempts to require the Franciscan Alliance to provide gender-identity treatment due to their religious beliefs). The Proposed Rule's case-by-case approach to religious exemptions inverts the process; puts the burden of compliance on regulated entities to justify such exemptions; chills the exercise of religion; and permits arbitrary and capricious oversight of such requests for exemption by government employees who lack training on the Frist Amendment, RFRA, statutory protections for religious exercise, and religious liberty issues. The proposed requirements may well cause healthcare providers to stop providing certain types of healthcare services and treatment, to stop accepting Medicaid (or Medicare)[15] patients, or to leave (or not enter) the medical profession completely. Religious or religiously motivated healthcare organizations and professional tend to provide a significant amount of healthcare to minority and other underserved and low-income populations and in medically underserved areas, such as inner cities and rural and frontier areas. As a result, this could impact access to care and negatively impact health equity considerations and our States' Medicaid programs. HHS needs to

[15] In this regard, HHS takes the unprecedented step of redefining Medicare Part B as providing federal financial assistance to healthcare professionals who merely accept Medicare reimbursement for providing services to elderly Americans.

consider and address the impact and effects on low-income and rural peoples of such reduced access to healthcare.[16]

Fourth, to the extent that the Proposed Rule governs federal funding, "[t]he legitimacy of Congress' power to legislate under the spending power . . . rests on whether the State voluntarily and knowingly accepts the terms of the contract." *Pennhurst State Sch. & Hosp. v. Halderman*, 451 U.S. 1, 17 (1981) (quotation marks omitted). Congress, through Section 1557, did not unambiguously prohibit discrimination based on sexual orientation or "gender identity," and thus HHS cannot now impose that requirement on receipt of federal funds, including Medicaid funds. And even if HHS could interpret Section 1557 to impose such a requirement, which it cannot, such a new requirement putting existing funds at risk would be unconstitutionally coercive. *See Nat'l Fed'n of Indep. Bus. V. Sebelius*, 567 U.S. 519, 581 (2012) (opinion of Roberts, C.J.).

D. Reliance on Currently Enjoined Department of Education Interpretation. Finally, the Proposed Rule is also defective because it relies on the very Department of Education Interpretation that the Eastern District of Tennessee preliminarily enjoined. 47 Fed. Reg. at 47828 & n.46 (citing the Interpretation in the Summary of the Proposed Rule as a "Federal agency interpretation[]" that HHS aims to make its regulations "consistent with"). The Proposed Rule, published *after* the Eastern District of Tennessee's order, does not even acknowledge the existence of the injunction.

As the Eastern District of Tennessee held, the Department of Education Interpretation unlawfully attempted to "create[] rights for students and obligations for regulated entities not to discriminate based on sexual orientation or gender identity that appear nowhere in *Bostock*, Title IX, or" existing regulations. *Tennessee*, 2022 WL 2791450, at *21. So too is the Proposed Rule an attempt to stretch HHS's power beyond the text of the statute Congress enacted.

HHS provided no justification in the Proposed Rule for attempting to make its regulations consistent with an Interpretation that the Department of Education itself is not allowed to implement against twenty States. The Department of Education agrees that it may "not cite, reference, treat as binding, or otherwise rely upon" the Interpretation in any enforcement action against the twenty States. Notice of Compliance at 2, *Tennessee v. U.S. Dep't of Educ.*, No. 3:21-CV-308 (E.D. Tenn. Aug. 25, 2022), ECF No. 97. There is no reason for HHS to rely on the enjoined Interpretation either. If HHS insists on pursuing its rulemaking proposal, it must "make appropriate changes" to the proposed rule, *Mann Constr., Inc. v. United States*, 27 F.4th 1138, 1142 (6th Cir. 2022), that acknowledge how the Proposed Rule unlawfully attempted to create rights and obligations that appear nowhere in *Bostock*, Title IX, Section 1557, or existing regulations.

* * *

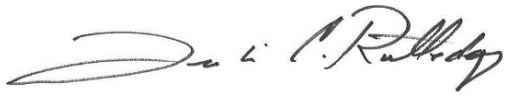
[16] In this regard, HHS should also explain how the Proposed Rule does not violate Section 1554 of the Affordable Care Act, codified at 42 U.S.C. § 18114.

Thank you for consideration of these concerns. We value our close working relationship with your agency and the good works we have been able to achieve together, but the Proposed Rule raises serious concerns that HHS will exceed its statutory authority and promulgate unlawful regulations. If necessary, Tennessee and the co-signing States will take action to safeguard the rights of their residents.

Sincerely,

Jonathan Skrmetti
Tennessee Attorney General and Reporter

Steve Marshall
Alabama Attorney General



Leslie Rutledge
Arkansas Attorney General

Chris Carr
Georgia Attorney General

Lawrence G. Wasden
Idaho Attorney General

Todd Rokita
Indiana Attorney General

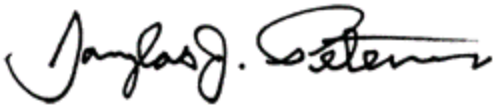
Derek Schmidt
Kansas Attorney General

Daniel Cameron
Kentucky Attorney General

Jeff Landry
Louisiana Attorney General

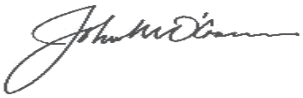
Lynn Fitch
Mississippi Attorney General

Austin Knudsen
Montana Attorney General



Douglas J. Peterson
Nebraska Attorney General

Dave Yost
Ohio Attorney General



John M. O'Connor
Oklahoma Attorney General

Alan Wilson
South Carolina Attorney General

Mark Vargo
South Dakota Attorney General

Ken Paxton
Texas Attorney General

Sean D. Reyes
Utah Attorney General

Jason S. Miyares
Virginia Attorney General

Patrick Morrisey
West Virginia Attorney General

JS 44 (Rev. 03/24)

CIVIL COVER SHEET

1:24cv161 LG-BWR

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. *(SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)*

I. (a) PLAINTIFFS

State of Tennessee, et al.

(b) County of Residence of First Listed Plaintiff Davidson County, TN
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorneys *(Firm Name, Address, and Telephone Number)*
Steven Griffin, Senior Counsel for Strategic Litigation
P.O. Box 20207, Nashville, TN 37202; 615-741-3491

DEFENDANTS

Xavier Becerra, et al.

County of Residence of First Listed Defendant
(IN U.S. PLAINTIFF CASES ONLY)
NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

Attorneys *(If Known)*

II. BASIS OF JURISDICTION *(Place an "X" in One Box Only)*

- ☐ 1 U.S. Government Plaintiff
- ☐ 3 Federal Question *(U.S. Government Not a Party)*
- ☒ 2 U.S. Government Defendant
- ☐ 4 Diversity *(Indicate Citizenship of Parties in Item III)*

III. CITIZENSHIP OF PRINCIPAL PARTIES *(Place an "X" in One Box for Plaintiff and One Box for Defendant)*
(For Diversity Cases Only)

	PTF	DEF		PTF	DEF
Citizen of This State	☐ 1	☐ 1	Incorporated *or* Principal Place of Business In This State	☐ 4	☐ 4
Citizen of Another State	☐ 2	☐ 2	Incorporated *and* Principal Place of Business In Another State	☐ 5	☐ 5
Citizen or Subject of a Foreign Country	☐ 3	☐ 3	Foreign Nation	☐ 6	☐ 6

IV. NATURE OF SUIT *(Place an "X" in One Box Only)*
Click here for: Nature of Suit Code Descriptions.

CONTRACT
- ☐ 110 Insurance
- ☐ 120 Marine
- ☐ 130 Miller Act
- ☐ 140 Negotiable Instrument
- ☐ 150 Recovery of Overpayment & Enforcement of Judgment
- ☐ 151 Medicare Act
- ☐ 152 Recovery of Defaulted Student Loans (Excludes Veterans)
- ☐ 153 Recovery of Overpayment of Veteran's Benefits
- ☐ 160 Stockholders' Suits
- ☐ 190 Other Contract
- ☐ 195 Contract Product Liability
- ☐ 196 Franchise

REAL PROPERTY
- ☐ 210 Land Condemnation
- ☐ 220 Foreclosure
- ☐ 230 Rent Lease & Ejectment
- ☐ 240 Torts to Land
- ☐ 245 Tort Product Liability
- ☐ 290 All Other Real Property

TORTS

PERSONAL INJURY
- ☐ 310 Airplane
- ☐ 315 Airplane Product Liability
- ☐ 320 Assault, Libel & Slander
- ☐ 330 Federal Employers' Liability
- ☐ 340 Marine
- ☐ 345 Marine Product Liability
- ☐ 350 Motor Vehicle
- ☐ 355 Motor Vehicle Product Liability
- ☐ 360 Other Personal Injury
- ☐ 362 Personal Injury - Medical Malpractice

PERSONAL INJURY
- ☐ 365 Personal Injury - Product Liability
- ☐ 367 Health Care/ Pharmaceutical Personal Injury Product Liability
- ☐ 368 Asbestos Personal Injury Product Liability

PERSONAL PROPERTY
- ☐ 370 Other Fraud
- ☐ 371 Truth in Lending
- ☐ 380 Other Personal Property Damage
- ☐ 385 Property Damage Product Liability

CIVIL RIGHTS
- ☐ 440 Other Civil Rights
- ☐ 441 Voting
- ☐ 442 Employment
- ☐ 443 Housing/ Accommodations
- ☐ 445 Amer. w/Disabilities - Employment
- ☐ 446 Amer. w/Disabilities - Other
- ☐ 448 Education

PRISONER PETITIONS

Habeas Corpus:
- ☐ 463 Alien Detainee
- ☐ 510 Motions to Vacate Sentence
- ☐ 530 General
- ☐ 535 Death Penalty

Other:
- ☐ 540 Mandamus & Other
- ☐ 550 Civil Rights
- ☐ 555 Prison Condition
- ☐ 560 Civil Detainee - Conditions of Confinement

FORFEITURE/PENALTY
- ☐ 625 Drug Related Seizure of Property 21 USC 881
- ☐ 690 Other

LABOR
- ☐ 710 Fair Labor Standards Act
- ☐ 720 Labor/Management Relations
- ☐ 740 Railway Labor Act
- ☐ 751 Family and Medical Leave Act
- ☐ 790 Other Labor Litigation
- ☐ 791 Employee Retirement Income Security Act

IMMIGRATION
- ☐ 462 Naturalization Application
- ☐ 465 Other Immigration Actions

BANKRUPTCY
- ☐ 422 Appeal 28 USC 158
- ☐ 423 Withdrawal 28 USC 157

INTELLECTUAL PROPERTY RIGHTS
- ☐ 820 Copyrights
- ☐ 830 Patent
- ☐ 835 Patent - Abbreviated New Drug Application
- ☐ 840 Trademark
- ☐ 880 Defend Trade Secrets Act of 2016

SOCIAL SECURITY
- ☐ 861 HIA (1395ff)
- ☐ 862 Black Lung (923)
- ☐ 863 DIWC/DIWW (405(g))
- ☐ 864 SSID Title XVI
- ☐ 865 RSI (405(g))

FEDERAL TAX SUITS
- ☐ 870 Taxes (U.S. Plaintiff or Defendant)
- ☐ 871 IRS—Third Party 26 USC 7609

OTHER STATUTES
- ☐ 375 False Claims Act
- ☐ 376 Qui Tam (31 USC 3729(a))
- ☐ 400 State Reapportionment
- ☐ 410 Antitrust
- ☐ 430 Banks and Banking
- ☐ 450 Commerce
- ☐ 460 Deportation
- ☐ 470 Racketeer Influenced and Corrupt Organizations
- ☐ 480 Consumer Credit (15 USC 1681 or 1692)
- ☐ 485 Telephone Consumer Protection Act
- ☐ 490 Cable/Sat TV
- ☐ 850 Securities/Commodities/ Exchange
- ☐ 890 Other Statutory Actions
- ☐ 891 Agricultural Acts
- ☐ 893 Environmental Matters
- ☐ 895 Freedom of Information Act
- ☐ 896 Arbitration
- ☒ 899 Administrative Procedure Act/Review or Appeal of Agency Decision
- ☐ 950 Constitutionality of State Statutes

V. ORIGIN *(Place an "X" in One Box Only)*

☒ 1 Original Proceeding ☐ 2 Removed from State Court ☐ 3 Remanded from Appellate Court ☐ 4 Reinstated or Reopened ☐ 5 Transferred from Another District *(specify)* ☐ 6 Multidistrict Litigation - Transfer ☐ 8 Multidistrict Litigation - Direct File

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing *(Do not cite jurisdictional statutes unless diversity)*:
APA, 5 U.S.C. § 706; Declaratory Judgment Act, 28 U.S.C. § 2201; Section 1557 of the ACA, 42 U.S.C. § 18116

Brief description of cause:
Plaintiffs seek injunctive and declaratory relief to set aside a final rule issued by Defendant HHS regarding nondiscrimination in healthcare.

VII. REQUESTED IN COMPLAINT:

☐ CHECK IF THIS IS A **CLASS ACTION** UNDER RULE 23, F.R.Cv.P.

DEMAND $ Injunctive & Declarator

CHECK YES only if demanded in complaint:
JURY DEMAND: ☐ Yes ☒ No

VIII. RELATED CASE(S) IF ANY *(See instructions):*

JUDGE U.S. District Judge Keith Starrett DOCKET NUMBER 5:24-cv-48-KS-LGI

DATE
05/30/2024

SIGNATURE OF ATTORNEY OF RECORD
Steven Griffin

FOR OFFICE USE ONLY

RECEIPT # 5418349 AMOUNT $405.00 APPLYING IFP JUDGE MAG. JUDGE