[ORAL ARGUMENT NOT SCHEDULED]

No. 20-5331

**IN THE UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT**

WHITMAN-WALKER CLINIC, INC., et al.,

Plaintiff-Appellees,

v.

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, et al.,

Defendants-Appellants.

On Appeal from the United States District Court
for the District of Columbia

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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

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1377 R Street NW
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Case No.

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

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Plaintiffs,

v.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
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ALEX M. AZAR II, in his official capacity as Secretary of U.S. Department of Health and Human Services,
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Washington, D.C. 20201;

ROGER SEVERINO, in his official capacity as Director, Office for Civil Rights, U.S. Department of Health and Human Services,
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Washington, D.C. 20201; and

SEEMA VERMA, in her official capacity as Administrator for the Centers for Medicare and Medicaid Services, U.S. Department of Health and Human Services,
7500 Security Boulevard,
Baltimore, MD 21244,

Defendants.

INTRODUCTION

1. A person's access to health care should not be contingent on their sex, gender identity, transgender status, sexual orientation, race, national origin, age, disability, or religion. When people go to a doctor's office, hospital, or an emergency room seeking treatment, they expect and are entitled to receive care appropriate to meet their health needs without regard to who they are or the type of health care they seek.

2. Yet, in the midst of a global pandemic, the Trump Administration's Department of Health and Human Services ("HHS") has sought to diminish protections from discrimination in health care because of a person's sex, gender identity, transgender status, sexual orientation, race, national origin, age, or disability.

3. HHS has taken these actions notwithstanding and despite the decision of the Supreme Court of the United States on June 15, 2020 holding that discrimination on the basis of a person's transgender status or sexual orientation is discrimination on the basis of sex. *See Bostock v. Clayton Cty., Ga.*, 590 U.S. ___, 2020 WL 3146686 (June 15, 2020).

4. As of the filing of this Complaint, and in less than six months, approximately 2.25 million people in the United States have tested positive for COVID-19, resulting in approximately 120,000 deaths to date.[1] The United States is facing a public health crisis. During these difficult times, Americans need the security and peace of mind that they will be able to access the health care they need and require. The government should be doing everything within its capacity to protect and preserve the safe and effective delivery of health care to all patients regardless of their sex, gender identity, transgender status, sexual orientation, race,

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[1] Centers for Disease Control and Prevention, *Coronavirus Disease 2019 (COVID-19): Cases in the U.S.*, https://perma.cc/38HG-JUBB (last visited June 21, 2020).

national origin, age, or disability. Yet, HHS is doing exactly the opposite, adopting positions that fly in the face of its stated mission to "enhance and protect the health and well-being of all Americans by providing for effective health and human services."[2]

5. Recognizing the paramount importance of providing people with prompt, effective, and nondiscriminatory access to health care, Congress has taken repeated and concerted efforts to improve access to health care and bar discrimination within the health care industry.

6. Section 1557 of the Patient Protection and Affordable Care Act ("ACA"), 42 U.S.C. § 18116, specifically and explicitly protects against discrimination in the provision of health care services. Section 1557 prohibits discrimination based on sex, race, color, national origin, age, and disability.

7. In 2016, HHS promulgated a final rule, developed over the course of six years and two notice-and-comment periods, to implement the nondiscrimination requirements of Section 1557. *See* Nondiscrimination in Health Programs and Activities, 81 Fed. Reg. 31,376 (May 18, 2016) (formerly codified at 45 C.F.R. pt. 92) (the "2016 Final Rule"). Consistent with Section 1557's nondiscrimination mandate, the 2016 Final Rule made clear that health care providers and insurers may not discriminate against lesbian, gay, bisexual, transgender, and queer ("LGBTQ") people in making medical and coverage decisions. Doing so constitutes discrimination on the basis of sex, which the 2016 Final Rule specifically defined to include discrimination on the basis of gender identity and sex stereotyping, among other criteria.

[2] U.S. Dep't of Health & Human Servs., *About HHS*, HHS.GOV, https://perma.cc/CY5N-RBPH.

8. The 2016 Final Rule also included specific guidance about how Section 1557's sex discrimination prohibition applies to transgender people, including access to and coverage of gender-affirming health services.

9. In addition, the 2016 Final Rule confirmed, based on the plain statutory language of Section 1557, that all enforcement mechanisms available under the statutes listed in Section 1557 are available to any person regardless of the person's protected characteristic, establishing a unitary legal standard for all violations of the statute. It also confirmed that Section 1557 prohibits not only intentional discrimination, but conduct and practices that have the effect of subjecting individuals to discrimination on the basis of their sex.

10. Since the 2016 Final Rule went into effect, it has led to a dramatic decrease in discriminatory policies and practices.[3]

11. Now, however, with next-to-no legal, medical, or reasoned policy foundation, and contrary to the opinions of professional medical and public health organizations,[4] HHS has issued a revised regulation under Section 1557 (the "Revised Rule") that rolls back the 2016 Final Rule and limits the protections for LGBTQ people, among others. *See* Nondiscrimination in Health and Health Education Programs or Activities, Delegation of Authority, 85 Fed. Reg.

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[3] *See, e.g.*, Sharita Gruberg and Frank J. Bewkes, *The ACA's LGBTQ Nondiscrimination Regulations Prove Crucial*, Center for American Progress (Mar. 7, 2018), https://perma.cc/CTP2-UMEJ.

[4] *See*, *e.g.*, Letter from James L. Madara, MD, Exec. Vice President/CEO, American Medical Association, to The Hon. Alex M. Azar II, Sec'y, U.S. Dep't Health & Hum. Servs. (Aug. 13, 2019), https://perma.cc/9N7N-JJ3G; Letter from Saul Levin, MD, MPA, FRCP-E, CEO & Med. Dir., American Psychiatric Association, to Sec'y Alex Azar II, U.S. Dep't Health & Hum. Servs. (Aug. 9, 2019), https://perma.cc/YUG9-E6SW; Letter from Katherine B. McGuire, Chief Advocacy Officer, American Psychological Association, to U.S. Dep't Health & Hum. Servs. (Aug. 13, 2019), https://perma.cc/LE65-6Q63.

37,160 (June 19, 2020) (to be codified at 42 C.F.R. pts. 438, 440, & 460 and 45 C.F.R. pts. 86, 92, 147, 155, & 156).

12. Although the Revised Rule cannot change the law, it is part of the Trump Administration's concerted and aggressive effort to undermine protections for LGBTQ people, including Section 1557's nondiscrimination protections and the regulatory structure and administrative processes the 2016 Final Rule established. Multiple provisions in the Revised Rule threaten to confuse and mislead patients, health care providers, and insurers and will result in increased discrimination and substantial harm to precisely those vulnerable communities that Section 1557 is intended to protect, like LGBTQ people and their families.

13. Relying on essentially one federal district court opinion, the Revised Rule arbitrarily and capriciously repeals entirely the 2016 Final Rule's definition of discrimination on the basis of sex, which specifically included discrimination based on gender identity and sex stereotyping, as well as related provisions prohibiting discrimination against transgender individuals. The elimination of this definition not only invites health care insurers and providers to discriminate against LGBTQ people seeking health care, but it also introduces substantial confusion among health care providers and insurers regarding their legal obligations and the right of the populations they serve to be free from sex discrimination, particularly in light of the Supreme Court's decision in *Bostock* v. *Clayton County, Georgia*, 590 U.S. __, 2020 WL 3146686, which held that discrimination based on transgender status or sexual orientation "necessarily entails discrimination based on sex." *Id.* at *11.

14. The Revised Rule, which HHS publicly released three days prior to the Supreme Court's ruling in *Bostock*, recognizes that "a holding by the U.S. Supreme Court on the meaning of 'on the basis of sex' under Title VII will likely have ramifications for the definition of 'on the

basis of sex' under Title IX," because "Title VII case law has often informed Title IX case law with respect to the meaning of discrimination 'on the basis of sex.'" 85 Fed. Reg. 37,168. However, undeterred from their goal to foster discrimination against LGBTQ people, HHS published the Revised Rule, without any changes, four days after the Supreme Court's decision in *Bostock*.

15. To be clear, *Bostock*'s holding that discrimination on the basis of sexual orientation or transgender status constitutes discrimination on the basis of sex forecloses HHS's attempts to deny the full protection of Section 1557 to LGBTQ individuals and patients in health care settings.

16. The Revised Rule also eliminates the unitary legal standard for enforcement of violations of Section 1557, replacing it with a fractured approach that will complicate and make it more difficult to bring discrimination claims under Section 1557, particularly claims of intersectional discrimination. The Revised Rule's elimination of the explicit recognition of private rights of action and the availability of compensatory damages under Section 1557 also will confuse the public and mislead individuals into not asserting their legal rights.

17. In addition, the Revised Rule imports broad and sweeping exemptions for discrimination based on personal religious or moral beliefs from the identified statutes in Section 1557 *and* other statutes, including the Religious Freedom Restoration Act (42 U.S.C. § 2000bb *et seq*.), which Section 1557 does not reference. These exemptions invite individual health care providers, health care entities, and insurers across the country to opt out of treating patients, including many transgender patients, if they believe doing so would compromise their faith.

18. These exemptions will adversely affect health care providers that serve and treat the LGBTQ community and their LGBTQ patients because (1) their individual health care

employees may decline to serve patients based on religious objections, and (2) their ability to refer patients to other providers will be impaired, as the Revised Rule would invite discrimination against their LGBTQ patients.

19. HHS's attempt to create new religious exemptions in Section 1557 is contrary to law and endangers patients' health in the name of advancing the religious beliefs of those who are entrusted with caring for them—a result sharply at odds with HHS's stated mission to "enhance and protect the health and well-being of all Americans" and to "provid[e] for effective health and human services."[5]

20. The Revised Rule also arbitrarily and capriciously eliminates the requirement that covered entities post notices informing individuals about nondiscrimination requirements and their rights and also cuts back the safeguards that the 2016 Final Rule implemented for patients with Limited English Proficiency ("LEP"), weakening protections for LEP patients and depriving families and individuals of adequate care.

21. In addition, the Revised Rule limits the scope of Section 1557, cutting back on the entities subject to Section 1557. Despite the plain language of Section 1557, the Revised Rule excludes health programs and activities that HHS funds but are not established or administered under Title I of the ACA and health insurance plans outside of Title I of the ACA that do not receive Federal financial assistance. Not only is this action inconsistent with Section 1557, it will cause drastic reductions in protections for LGBTQ people.

22. The Revised Rule also amends a series of unrelated regulations issued under statutes other than Section 1557 by deleting references to sexual orientation and gender identity discrimination. HHS does not have the authority to make these changes within the rulemaking

[5] U.S. Dep't of Health & Human Servs., *About HHS*, HHS.GOV, https://perma.cc/CY5N-RBPH.

challenged, and these changes are not supported by any analysis or evidence. The Revised Rule is intended only to send a message that a person's LGBTQ identity is not recognized and LGBTQ people can be subjected to discrimination.

23. The Revised Rule's cost-benefit analysis is fatally flawed, incomplete, and unreasonable. Specifically, HHS fails to account for the increased costs to patients, insurers, and the health care system at large stemming from discrimination against LGBTQ and other patients.

24. The Revised Rule, if allowed to go into effect, will undermine the progress achieved so far in eradicating health care discrimination against LGBTQ people in a broad array of health care programs and entities by inviting health care insurers and providers once again to discriminate against them, while also discouraging LGBTQ people from seeking health care in the first instance.

25. In adopting the Revised Rule, HHS acted arbitrarily and capriciously, in excess of its statutory authority, and not in accordance with the law in violation of the Administrative Procedure Act ("APA") (5 U.S.C. § 551 *et seq.*). The Revised Rule also violates the Equal Protection Guarantee and Due Process Clause of the Fifth Amendment, and the Free Speech and Establishment Clauses of the First Amendment to the United States Constitution.

26. The Revised Rule is causing and will continue to cause irreparable harm to LGBTQ people and health care providers. The Revised Rule should be declared unlawful, enjoined, and vacated.

JURISDICTION AND VENUE

27. This Court has jurisdiction pursuant to 28 U.S.C. § 1331, as this action arises under the laws of the United States and United States Constitution; 28 U.S.C. § 1346, as a civil action against the United States founded upon the Constitution, an Act of Congress, or an

executive regulation; and 28 U.S.C. § 1361, as an action to compel an officer or agency to perform a duty owed to plaintiffs.

28. Jurisdiction also is proper under the Administrative Procedure Act, 5 U.S.C. §§ 701-706. Defendants' issuance of the Revised Rule on June 19, 2020, constitutes a final agency action that is subject to judicial review under 5 U.S.C. §§ 702, 704, and 706.

29. An actual controversy exists between the parties within the meaning of 28 U.S.C. § 2201(a), and this Court may grant declaratory, injunctive, and other relief pursuant to 28 U.S.C. §§ 2201-2202 and 5 U.S.C. §§ 705-706.

30. Venue is proper in this district under 28 U.S.C. § 1391(b)(1), (b)(2), & (e)(1) because at least one plaintiff resides in this judicial district, a substantial part of the events or omissions giving rise to this action occurred in this district, and each defendant is an agency of the United States or an officer of the United States sued in their official capacity.

PARTIES

A. Plaintiffs

31. Plaintiffs are two private health care facilities that provide health care services to LGBTQ people and many individuals and families with LEP (Whitman-Walker Clinic, Inc. d/b/a Whitman-Walker Health and the Los Angeles LGBT Center) ("private health care provider plaintiffs"); two organizations that provide a wide range of services to the LGBTQ community, including people and families with LEP (the TransLatin@ Coalition and Bradbury-Sullivan LGBT Community Center) ("LGBTQ-services plaintiffs"); two national associations of health professionals (American Association of Physicians for Human Rights d/b/a GLMA: Health Professionals Advancing LGBTQ Equality and AGLP: The Association of LGBTQ Psychiatrists) ("health professional association plaintiffs"); and three individual physicians and

one behavioral health provider who work for the private health care provider plaintiffs ("individual provider plaintiffs").

32. The private health care provider plaintiffs (Whitman-Walker Health and the Los Angeles LGBT Center) and the individual provider plaintiffs assert claims on their own behalf and also on behalf of their patients and recipients of services, who face barriers to asserting their own claims and protecting their own interests.

33. The LGBTQ-services plaintiffs (the TransLatin@ Coalition and the Bradbury-Sullivan LGBT Community Center) assert claims on their own behalf and also on behalf of the recipients of their services who face barriers to asserting their own claims and protecting their own interests.

34. The TransLatin@ Coalition also asserts claims on behalf of its transgender and gender nonconforming members, including members who are leaders of affiliated community organizations serving Latinx transgender and gender nonconforming people.

35. The health professional association plaintiffs (GLMA and AGLP) assert claims on their own behalf and on behalf of their members and also on behalf of the LGBTQ patients whose interests they represent and the patients whom their members treat who face barriers to asserting their own claims and protecting their own interests.

36. Plaintiffs assert different but complementary interests and share the common objective of maintaining an effective, functioning health care system that protects patients' dignity and their rights to access health services. Plaintiffs also support providing informed access to comprehensive, medically appropriate care to LGBTQ patients, including gender-affirming care for transgender persons, without discrimination based on a patient's sex, gender

identity, transgender status, or sexual orientation and in accordance with medical and ethical standards of care.

37. Plaintiff **Whitman-Walker Clinic, Inc. d/b/a Whitman-Walker Health**, a Federally Qualified Health Center located in Washington, D.C., has a special mission to serve the LGBTQ community and persons living with HIV of every sexual orientation and gender. More than 280 medical, behavioral health and dental professionals, lawyers and paralegals, support staff and administrators provide a range of services, including medical and community health care, transgender care and services, behavioral-health services, dental-health services, legal services, insurance-navigation services, and youth and family support. In 2019, Whitman-Walker provided health care services to 20,760 individuals. More than 10% of those individuals identified as transgender or gender nonconforming. Almost 45% of health care patients – and 60% of those who provided information on their sexual orientation – identified as lesbian, gay, bisexual, or otherwise non-heterosexual. More than 9% of patients had limited English proficiency. Whitman-Walker receives various forms of federal funding from HHS and from institutions affiliated with or funded by HHS, including but not limited to funds under the Public Health Services Act ("PHSA"), direct grants, funding under the Ryan White Comprehensive AIDS Resources Emergency Act of 1990, 42 U.S.C. § 300ff *et seq.* ("Ryan White funding"), funds under the 340B Drug Discount Program, and research grants from the Centers for Disease Control and Prevention and the National Institutes of Health, and Medicaid and Medicare reimbursements. Whitman-Walker also receives funds from the Health Resources and Service Administration ("HRSA") and is a Federally Qualified Heath Center. In 2019, Whitman-Walker's federally funded research contracts and grants totaled more than $7 million. Whitman-Walker is subject to Section 1557 of the ACA and the Revised Rule.

38. Plaintiff **Dr. Sarah Henn** is the Chief Health Officer of Whitman-Walker. Dr. Henn oversees all health care-related services at Whitman-Walker and maintains a panel of patients for whom she provides direct care. Whitman-Walker's patient population, including patients to whom Dr. Henn provides direct care and whose care she oversees, includes many patients who have experienced refusals of health care or who have been subjected to disapproval, disrespect, or hostility from medical providers outside of Whitman-Walker because of their actual or perceived sexual orientation, gender identity, or transgender status. Many of Dr. Henn's patients and those whose care she oversees are, therefore, apprehensive or fearful of encountering stigma and discrimination in health care settings because of their past experiences. Such experiences will increase as a result of the Revised Rule. In addition to overseeing medical care of patients and working with her own patients, Dr. Henn oversees Whitman-Walker's Research Department and is personally involved in a number of clinical research projects, including as the Leader of Whitman-Walker's Clinical Research Site for the AIDS Clinical Trials Group funded by the National Institutes of Health.

39. Plaintiff **Dr. Randy Pumphrey** is Senior Director of Behavioral Health at Whitman-Walker. As Senior Director of Behavioral Health, Dr. Pumphrey oversees Whitman-Walker's portfolio of mental-health services and substance-use-disorder-treatment services and maintains a panel of patients for whom he provides direct behavioral health care. In 2019, Whitman-Walker provided mental-health or substance-use-disorder-treatment services to more than 1,800 patients, many of whom identify as LGBT or are living with HIV. Many, if not most, of the patients to whom Dr. Pumphrey provides direct care and whose behavioral health care he oversees face considerable stigma and discrimination as people living with HIV, sexual or gender minorities, or people of color. They have experienced difficulty finding therapists or

other mental-health or substance-use-disorder professionals who are understanding and welcoming of their sexual orientation, gender identity, or transgender status. These experiences of discrimination will increase as a result of the Revised Rule.

40. Plaintiff **The TransLatin@ Coalition** is a nationwide 501(c)(3) nonprofit membership organization that advocates for the interests of transgender and gender nonconforming individuals, particularly Latinx people, and provides direct services to the transgender community, including leadership development, educational services, and employment services. The TransLatin@ Coalition currently has a presence in Los Angeles, California; Washington, D.C.; Chicago, Illinois; New York, New York; Atlanta, Georgia; Houston, Texas; and Tucson, Arizona. The TransLatin@ Coalition has thousands of individual members across the United States, including transgender and gender nonconforming Latinx individuals who have experienced or fear discrimination based on their sex, transgender status, national origin, or LEP status in health care. This includes individual transgender and gender nonconforming Latinx members like Bamby Salcedo, who resides in California, and Arianna Lint, who resides in Florida. Ms. Salcedo and Ms. Lint have experienced discrimination in health care because of their transgender status and fear the Revised Rule will make it more likely they will encounter discrimination in health care again. The TransLatin@ Coalition's membership also includes leaders of affiliated community organizations that serve Latinx transgender and gender nonconforming people across the country, such as Arianna's Center headquartered in Florida and with offices in Puerto Rico, Community Estrella in Georgia, and the Fundación Latinoamericana de Accion Social (FLAS) in Texas. The Coalition and its members advocate for policy changes at the local, state, and federal levels, and conducts research regarding homelessness, health and health care, and employment in the transgender Latinx

community. Through its Center for Violence Prevention & Transgender Wellness, the Coalition also provides direct services to transgender, gender nonconforming, and intersex people in the City of Los Angeles. Many of the members of the Coalition and the individuals they and the Coalition serve are immigrants, some living with HIV/AIDS. The Coalition and its members serve many communities in which English is not the primary language spoken and a number of individuals in these communities are not fluent in English.

41. Plaintiff **Los Angeles LGBT Center** is located in Los Angeles, California. Its mission is to build a world in which LGBT people thrive as healthy, equal, and complete members of society. The LA LGBT Center offers programs, services, and advocacy spanning four broad categories: health, social services and housing, culture and education, and leadership and advocacy. The LA LGBT Center has more than 750 employees and provides services to more LGBT people than any other organization in the world, with about 500,000 client visits per year, including LEP patients. LA LGBT Center receives funds under the PHSA. Approximately 80% of the LA LGBT Center's funding originates from the federal government, including but not limited to Ryan White funding; direct funding from the Centers for Disease Control and Prevention; discounts under the 340B Drug Discount Program; grants under section 330 of the PHSA; grants from HRSA's Bureau of Primary Health Care under which the LA LGBT Center is a Federally Qualified Health Center; and Medicaid and Medicare reimbursements. The LA LGBT Center is an entity subject to Section 1557 of the ACA and the Revised Rule.

42. Plaintiff **Dr. Robert Bolan** is the Chief Medical Officer of the LA LGBT Center. He oversees the delivery of health care for over 20,000 patients who come to the LA LGBT Center and personally treats approximately 300 patients. More than 90% of these patients identify as LGBT, many of them coming from different areas of California and other States to

obtain services in a safe and affirming environment. Dr. Bolan also oversees the LA LGBT Center's Research Department. Dr. Bolan and the providers he supervises treat patients who identify as transgender and who require gender-affirming treatment, including medically necessary health care for gender dysphoria. Many of Dr. Bolan's patients and many of the patients of the providers he supervises at the LA LGBT Center already have experienced traumatic and discriminatory denials of health care based on their sexual orientation, gender identity, transgender status, or HIV status at the hands of providers outside the LA LGBT Center, including by health care providers who have expressed religious or moral objections to treating them. These experiences will increase as a result of the Revised Rule.

43. Plaintiff **Dr. Ward Carpenter** is the Co-Director of Health Services at the LA LGBT Center. Dr. Carpenter is a nationally recognized expert in the field of transgender medicine. In his role as Co-Director of Health Services, Dr. Carpenter oversees the healthcare of more than 25,000 patients who come to the LA LGBT Center and personally treats 150 patients. All of Dr. Carpenter's patients identify within the LGBT community and approximately 30% are people living with HIV. These patients come from different areas of California and other States to obtain services in a safe and affirming environment. Dr. Carpenter's patient population is disproportionately low-income and experiences high rates of chronic medical conditions, homelessness, unstable housing, and extensive trauma history. In addition, many of Dr. Carpenter's patients, as well as the patients of the other medical providers he supervises at the Center, already have experienced traumatic and discriminatory denials of healthcare based on their sexual orientation, gender identity, transgender status, or HIV status at the hands of providers outside the LA LGBT Center, including by healthcare providers who have expressed

religious or moral objections to treating them. These experiences will increase as a result of the Revised Rule.

44. Plaintiff **Bradbury-Sullivan LGBT Community Center** is a 501(c)(3) nonprofit organization based in Allentown, Pennsylvania, and incorporated in Pennsylvania. It is dedicated to securing the health and well-being of LGBTQ people of the Greater Lehigh Valley. It provides a variety of programs and services for the LGBTQ community, including HIV/STI testing, health care-enrollment events, health promotion programs for LGBTQ adults and youth, support groups, and a free legal clinic. Bradbury-Sullivan Center also provides referrals to LGBT-welcoming health care providers. Patrons of Bradbury-Sullivan Center often seek health care services from other health care organizations, including religiously affiliated organizations. Bradbury-Sullivan Center works with patrons who have experienced discriminatory treatment when seeking health care services from such organizations, and it advocates on behalf of those patrons by providing referrals to LGBT-welcoming agencies and providers, training agencies to provide LGBT-welcoming services, and, when necessary, communicating with agencies to inform them of their legal obligations to serve LGBT people. Bradbury-Sullivan Center also conducts research documenting health disparities in the LGBT community and performs related community-education efforts to improve public health within the LGBT community. Bradbury-Sullivan Center receives pass-through funding from HHS through the Assistance Programs for Chronic Disease Prevention and Control, State Public Health Approaches to Ensuring Quitline Capacity funded in part by Prevention and Public Health Fund, State Physical Activity and Nutrition, Injury Prevention and Control Research and State and Community Based Programs, National State-Based Tobacco Control Programs, Maternal and Child Health Services Block Grant, and in the past also has received Ryan White funding.

45. Plaintiff **American Association of Physicians For Human Rights, Inc. d/b/a GLMA: Health Professionals Advancing LGBTQ Equality** (formerly known as the Gay & Lesbian Medical Association) is a 501(c)(3) nonprofit membership organization based in Washington, D.C. and incorporated in California. GLMA is a national organization committed to ensuring health equity for lesbian, gay, bisexual, transgender, queer, and all sexual and gender minority individuals, and equality for health professionals in such communities in their work and learning environments. To achieve this mission, GLMA utilizes the scientific expertise of its diverse multidisciplinary membership to inform and drive advocacy, education, and research. GLMA works with professional accreditation bodies and health professional associations on standards, guidelines, and policies that address LGBTQ health and protect individual patient health and public health in general. GLMA also represents the interests of hundreds of thousands of LGBTQ health professionals and millions of LGBTQ patients and families across the United States. GLMA's membership includes approximately 1,000 member physicians, nurses, advanced practice nurses, physician assistants, researchers and academics, behavioral health specialists, health-profession students, and other health professionals throughout the country. Their practices represent the major health care disciplines and a wide range of health specialties, including primary care, internal medicine, family practice, psychiatry, pediatrics, obstetrics/gynecology, emergency medicine, neurology, and infectious diseases.

46. Plaintiff **AGLP: The Association of LGBTQ Psychiatrists** is a 501(c)(3) nonprofit membership organization based in Philadelphia, Pennsylvania. AGLP is a national organization of 450 LGBTQ+ psychiatrists that educates and advocates on LGBTQ mental-health issues. It is the oldest association of LGBTQ+ professionals in the country. AGLP represents the interests of its members, LGBTQ+ patients, and the patients whom AGLP

members treat in working to influence policies relevant to the LGBTQ+ community and advocating for its members' patients. AGLP's goals are to foster a fuller understanding of LGBTQ+ mental-health issues; research and advocate for the best mental healthcare for the LGBTQ community; develop resources to promote LGBTQ mental health; create a welcoming, safe, nurturing, and accepting environment for members; and provide valuable and accessible services to our members. AGLP also assists medical students and residents in their professional development; encourages and facilitates the presentation of programs and publications relevant to LGBTQ concerns at professional meetings; and serves as liaison with other minority and advocacy groups within the psychiatric community. Some of the institutions in which AGLP's members work receive various forms of federal funding directly or indirectly via federal programs. AGLP's members therefore are subject to Section 1557 of the ACA and the Revised Rule.

B. Defendants

47. Defendant **United States Department of Health and Human Services** is a cabinet department of the federal government, headquartered in the District of Columbia. HHS promulgated the Revised Rule and is responsible for its enforcement. HHS is an "agency" within the meaning of the APA. 5 U.S.C. § 551(1).

48. Defendant **Alex M. Azar, II** is the Secretary of HHS. He is sued in his official capacity. Secretary Azar is responsible for all aspects of the operation and management of HHS, including the adoption, administration, and enforcement of the Revised Rule, and with implementing and fulfilling HHS's duties under the United States Constitution and the APA.

49. Defendant **Roger Severino** is the Director of the Office of Civil Rights ("OCR") at HHS. He is sued in his official capacity. Director Severino is responsible for all aspects of the operation and management of OCR, including the adoption, administration, and enforcement

of the Revised Rule. As an HHS law enforcement agency, OCR is supposed to ensure equal access to health and human services by enforcing civil rights laws such as Section 1557.

50. Defendant **Seema Verma** is the Administrator for the Centers for Medicare and Medicaid Services ("CMS"), a component of HHS. She is sued in her official capacity. Administrator Verma is responsible for all aspects of the operation and management of CMS, including the adoption, administration, and enforcement of the Revised Rule as it pertains to regulations relating to the establishment and operation of ACA exchanges; in the marketing and design practices of health insurance issuers under the ACA; in the administration, marketing, and enrollment practices of Qualified Health Plans ("QHPs") under the ACA; in beneficiary enrollment and the promotion and delivery of services under Medicaid; and in the delivery of services under the Programs for All-Inclusive Care for the Elderly ("PACE").

FACTUAL ALLEGATIONS

I. Discrimination Against Transgender People Prior to the Affordable Care Act

51. Before the Affordable Care Act was enacted in 2010 during the Obama Administration, HHS documented many forms of discrimination against transgender people in accessing health care services, insurance coverage, and facilities.

52. The administrative record documents and demonstrates that, prior to the enactment of the ACA, transgender people experienced significant discrimination from entities providing health care, even for routine medical care. HHS reported that "[f]or transgender individuals, a major barrier to receiving care is a concern over being refused medical treatment based on bias against them." 81 Fed. Reg. 31,376, 31,460. For example, "[i]n a 2010 report, 26.7% of transgender respondents reported that they were refused needed health care. A 2011 survey revealed that 25% of transgender individuals reported being subject to harassment in medical settings." *Id.*

53. Some entities providing insurance or health care discriminated against transgender patients by refusing to cover medically necessary treatments for gender dysphoria in accordance with accepted standards of care. Gender dysphoria is a serious medical condition codified in the Diagnostic and Statistical Manual of Mental Disorders (DSM-V) and International Classification of Diseases (ICD-11). The criteria for diagnosing gender dysphoria are set forth in the DSM-V (302.85). The World Professional Association for Transgender Health ("WPATH") publishes widely accepted standards of care for treating gender dysphoria. Leading medical organizations and federal courts have recognized the WPATH Standards of Care as the authoritative standards of care. The overwhelming consensus among medical experts and every major medical organization is that treatments for gender dysphoria, including surgical procedures, are effective, safe, and medically necessary when clinically indicated to alleviate gender dysphoria.

54. Prior to the enactment of the ACA, however, insurance companies routinely excluded coverage for transition-related care based on the misguided assumption that such treatments were cosmetic and experimental. Today, medical consensus recognizes that such exclusions have no basis in medical science.[6]

55. Those discriminatory exclusions prevented transgender people from obtaining medically necessary treatment for gender dysphoria. *See* 81 Fed. Reg. at 31,460. As a result, transgender people were more likely to lack health insurance and suffer significant health disparities, including high rates of untreated mental health needs, suicide attempts, and HIV. *Id.*

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[6] *See* Decision No. 2576, National Coverage Determination 140.3: Transsexual Surgery at 18 (Docket No. A-13-87) (U.S. Dep't of Health & Human Servs. Appeals Bd. App. Div. 2014), https://perma.cc/3BGA-F9DH.

II. Section 1557 of the Affordable Care Act

56. On March 23, 2010, Congress enacted the Patient Protection and Affordable Care Act ("ACA"), Pub. L. No. 111-148, 124 Stat. 119 (2010), recognizing the importance of providing patients with prompt and nondiscriminatory access to medical care and to information about all treatment options.

57. Section 1554 of the ACA provides:

> Notwithstanding any other provision of this Act, the Secretary of Health and Human Services shall not promulgate any regulation that—
>
> (1) creates any unreasonable barriers to the ability of individuals to obtain appropriate medical care;
>
> (2) impedes timely access to healthcare services;
>
> (3) interferes with communications regarding a full range of treatment options between the patient and the provider;
>
> (4) restricts the ability of healthcare providers to provide full disclosure of all relevant information to patients making healthcare decisions;
>
> (5) violates the principles of informed consent and the ethical standards of healthcare professionals; or
>
> (6) limits the availability of healthcare treatment for the full duration of a patient's medical needs.

42 U.S.C. § 18114.

58. Section 1557 of the ACA protects against discrimination in the provision of health care services. It provides, in relevant part:

> Except as otherwise provided for in this title [I] (or an amendment made by this title), an individual shall not, on the ground prohibited under title VI of the Civil Rights Act of 1964 (42 U.S.C. 2000d et seq.), title IX of the Education Amendments of 1972 (20 U.S.C. 1681 et seq.), the Age Discrimination Act of 1975 (42 U.S.C. 6101 et seq.), or section 794 of Title 29 [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 this title [I] (or amendments). The enforcement mechanisms provided for and available under such title VI, title IX, section 794, or such Age Discrimination Act shall apply for purposes of violations of this subsection.

42 U.S.C. § 18116(a).

59. Section 1557 prohibits discrimination based on sex, including discrimination based on a patient's gender identity, transgender status, sexual orientation, and failure to conform to sex stereotypes, all of which are forms of sex discrimination. It also prohibits discrimination on the basis of race, color, national origin, age, and disability.

60. Section 1557 provides that "[t]he enforcement mechanisms provided for and available under such title VI, title IX, section 794, or such Age Discrimination Act shall apply for purposes of violations of this subsection." *Id.* § 18116(a).

61. Section 1557 further provides that the Secretary of HHS "may promulgate regulations to implement this section." *Id.* § 18116(c).

62. The ACA covers nearly every health care provider in the country.

III. The 2016 Final Rule

63. On May 18, 2016, HHS published a final rule implementing Section 1557. *See* Nondiscrimination in Health Programs and Activities, 81 Fed. Reg. 31,376 (May 18, 2016) (formerly codified at 45 C.F.R. pt. 92) (the "2016 Final Rule"). A copy of the 2016 Final Rule is attached as **Exhibit 1**.

64. In implementing Section 1557's prohibition of discrimination "on the basis of . . . sex," the 2016 Final Rule defined "on the basis of sex" to include "discrimination on the basis of

. . . sex stereotyping, and gender identity." 81 Fed. Reg. at 31,467 (formerly codified at 45 C.F.R. § 92.4).[7]

65. The 2016 Final 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.* In the 2016 Final Rule, HHS emphasized that "even where it is permissible to make sex-based distinctions, individuals may not be excluded from health programs and activities for which they are otherwise eligible based on their gender identity." 81 Fed. Reg. at 31,409.

66. The 2016 Final Rule defined "sex stereotypes" as

> stereotypical notions of masculinity or femininity, including expectations of how individuals represent or communicate their gender to others, such as behavior, clothing, hairstyles, activities, voice, mannerisms, or body characteristics. These stereotypes can include the expectation that individuals will consistently identify with only one gender and that they will act in conformity with the gender-related expressions stereotypically associated with that gender. Sex stereotypes also include gendered expectations related to the appropriate roles of a certain sex.

81 Fed. Reg. at 31,468 (formerly codified at 45 C.F.R. § 92.4).

67. In defining "on the basis of sex" to include "discrimination on the basis of . . . sex stereotyping, and gender identity," HHS explained that "courts, including in the context of Section 1557, have recognized that sex discrimination includes discrimination based on gender

[7] Although OCR stated in 2016 "that current law is mixed on whether existing Federal nondiscrimination laws prohibit discrimination on the basis of sexual orientation as a part of their prohibitions on sex discrimination," 81 Fed. Reg. at 31388, the Supreme Court now has definitively answered this question by holding in *Bostock* that "it is impossible to discriminate against a person for being homosexual or transgender without discriminating against that individual based on sex." 2020 WL 3146686, at *7.

identity. Thus, we proposed to adopt formally this well-accepted interpretation of discrimination 'on the basis of sex.'" 81 Fed. Reg. at 31,387-88.

68. The 2016 Final Rule also prohibited discrimination based on association – that is, it prohibited discrimination against a person on the basis of the sex, race, color, national origin, age, or disability of "an individual with whom the individual or entity is known or believed to have a relationship or association." 81 Fed. Reg. at 31,472 (formerly codified at 92 C.F.R. § 209). HHS explained that a "prohibition on associational discrimination is consistent with longstanding interpretations of existing antidiscrimination laws, whether the basis of discrimination is a characteristic of the harmed individual or an individual who is associated with the harmed individual." 81 Fed. Reg. at 31,439. It also is consistent with the Age Discrimination Act, which includes a specific prohibition of discrimination based on association with an individual with a disability. *Id.*; *see also* 42 U.S.C. § 12182(b)(1)(E); 28 C.F.R. § 35.130(g).

69. The 2016 Final Rule also recognized that Section 1557 not only prohibits intentional discrimination on the basis of sex, it also prohibits conduct and practices "that *have the effect of subjecting individuals to discrimination* on the basis of sex," which can give rise to disparate impact claims. 81 Fed. Reg. at 31,470 (formerly codified at 45 C.F.R. § 92.101(b)(3)(ii)) (emphasis added).

70. The 2016 Final Rule applied to "every health program or activity, any part of which receives Federal financial assistance provided or made available by the Department; every health program or activity administered by the Department; and every health program or activity administered by a Title I entity." 81 Fed. Reg. at 31,466 (formerly codified at 45 C.F.R.

§ 92.2(a)). HHS estimated that the rule would "likely cover almost all licensed physicians because they accept Federal financial assistance." 81 Fed. Reg. at 31,445.

71. With respect to health care insurance providers or employee benefits plans, the 2016 Final Rule specifically required covered entities to treat individuals consistent with their gender identity. *See* 81 Fed. Reg. at 31,471 (formerly codified at 45 C.F.R. § 92.206). And it prohibited covered entities from having or implementing "a categorical coverage exclusion or limitation for all health care services related to gender transition," 81 Fed. Reg. at 31,472 (formerly codified at 45 C.F.R. § 92.207(b)(4)), because such an exclusion is "discriminatory on its face," 81 Fed. Reg. at 31,456. In adopting these provisions, HHS explained that blanket "exclusions of coverage for all care related to gender dysphoria or associated with gender transition" were "outdated and not based on current standards of care." 81 Fed. Reg. at 31,429.

72. The "range of transition-related services" the 2016 Final Rule contemplated were "not limited to surgical treatments and may include, but [were] not limited to, services such as hormone therapy and psychotherapy, which may occur over the lifetime of the individual." 81 Fed. Reg. at 31,435-36.

73. Consistent with the plain language of Section 1557, which provides that the "enforcement mechanisms provided for and available under such title VI, title IX, section 794, *or* such Age Discrimination Act shall apply for purposes of violations" of Section 1557, 42 U.S.C. § 18116(a) (emphasis added), the 2016 Final Rule adopted a unitary legal standard for addressing discrimination in health care and enforcing Section 1157. The 2016 Final Rule provided: "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, *or* the Age Discrimination Act of 1975 shall apply for purposes of

Section 1557 as implemented by this part." 81 Fed. Reg. at 31,472 (formerly codified at 45 C.F.R. § 92.301) (emphasis added).

74. In the preamble to the 2016 Final Rule, HHS clarified that *all* enforcement mechanisms available under the statutes listed in Section 1557 are available for purposes of Section 1557 enforcement, regardless of an individual's protected characteristic or characteristics. Otherwise, different enforcement mechanisms and standards would apply depending on whether an individual's claim is based on her sex, race, age, or disability. 81 Fed. Reg. at 31,439-40. HHS thus interpreted Section 1557 as "authorizing a private right of action for claims of disparate impact discrimination on the basis of any of the criteria enumerated in the legislation." *Id.* at 31,440.

75. The 2016 Final Rule also specifically recognized that a private right of action is available under Section 1557 and compensatory damages are available. *See* 81 Fed. Reg. at 31,472 (formerly codified at 45 C.F.R. §§ 92.301(b), 92.302(d)). HHS explained that its "interpretation of Section 1557 as authorizing compensatory damages is consistent with our interpretations of Title VI, Section 504, and Title IX." 81 Fed. Reg. at 31,440.

76. The 2016 Final Rule did not incorporate Title IX's blanket religious exemption because Section 1557 "contains no religious exemption." 81 Fed. Reg. at 31,380. In declining to import Title IX's religious exemption, HHS further explained that "Title IX and its exemption are limited in scope to educational institutions, and there are significant differences between the educational and health care contexts that warrant different approaches." *Id.* HHS noted that "a blanket religious exemption could result in a denial or delay in the provision of health care to individuals and in discouraging individuals from seeking necessary care, with serious and, in some cases, life threatening results." *Id.*

77. After a careful and deliberate analysis, HHS determined that a "more nuanced approach in the health care context" was warranted. *Id*. The 2016 Final Rule provided: "Insofar as the application of any requirement under this part would violate applicable Federal statutory protections for religious freedom and conscience, such application shall not be required." 81 Fed. Reg. at 31,466 (formerly codified at 45 C.F.R. § 92.2(b)(2)).

78. The 2016 Final Rule also included provisions to ensure that the approximately 25 million Americans who are Limited English Proficient (LEP)[8] have access to the health care they need. The 2016 Final Rule required health care providers and other covered entities to post nondiscrimination notices and include taglines in the top 15 languages spoken throughout the state with all significant publications and communications. *See* 81 Fed. Reg. at 31,469 (formerly codified at 45 C.F.R. § 92.8).

79. The 2016 Final Rule also included standards that governed access to language assistance services for LEP individuals by requiring that language interpreters be "qualified" and that when covered entities video interpretation services to LEP individuals, it be real-time and high quality. *See* 81 Fed. Reg. at 31,470-71 (formerly codified at 45 C.F.R. § 92.201).

80. The promulgation of the 2016 Final Rule led to a decrease in discriminatory policies and practices.[9] For example, a recent study of 37 states in the federal marketplace

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[8] U.S. Census Bureau, *Language Spoken at Home*, American Community Survey 2018 1-Year Estimates Subject Tables, tbl. S1601 (2018), https://perma.cc/Z452-RSWR; U.S. Census Bureau, Characteristics of People by Language Spoken at Home, American Community Survey 2018 1-Year Estimates Subject Tables, tbl. S1603, https://perma.cc/R59J-HG4K.

[9] *See* Gruberg & Bewkes, *The ACA's LGBTQ Nondiscrimination Regulations Prove Crucial*, https://perma.cc/CTP2-UMEJ.

showed that, in 2019, 97% of plans did not contain blanket exclusions of transition-related care.[10]

IV. The Trump Administration's Proposed Revision to the 2016 Final Rule

81. On June 14, 2019, the Trump Administration issued a Notice of Proposed Rulemaking, proposing to "make substantial revisions" to the 2016 Final Rule, including repealing certain provisions. *See* Notice of Proposed Rulemaking, *Nondiscrimination in Health and Health Education Programs or Activities*, 84 Fed. Reg. 27,846, 27,848 (June 14, 2019) ("Proposed Rule").

82. In an attempt to explain why it was reversing course merely three years after the 2016 Final Rule went into effect, HHS stated it was revising the implementing regulations "to better comply with the mandates of Congress, address legal concerns, relieve billions of dollars in undue regulatory burdens, further substantive compliance, reduce confusion, and clarify the scope of Section 1557 in keeping with existing civil rights statutes and regulations prohibiting discrimination on the basis of race, color, national origin, sex, age, and disability." 84 Fed. Reg. at 27,846.

83. HHS further claimed that the 2016 Final Rule "exceeded its authority under Section 1557, adopted erroneous and inconsistent interpretations of civil rights law, caused confusion, and imposed unjustified and unnecessary costs." *Id.* at 27,849.

84. These purported justifications do not withstand scrutiny.

85. HHS received nearly 200,000 comments during the public comment period. The comments that HHS received identified and expressed concerns about many of HHS's proposed

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[10] Out2Enroll, *Summary of Findings: 2020 Marketplace Plan Compliance with Section 1557*, https://perma.cc/WU25-C9BN. This finding is consistent with summaries from 2017, 2018, and 2019.

revisions, including many of the same issues that form the basis of this complaint. Commenters emphasized that the following actions, taken individually or combined, will cause immediate and irreparable harm to LGBTQ people and their families:

a. Eliminating the definition of "on the basis of sex" and the specific prohibition on discrimination on the basis of gender identity and sex stereotyping is arbitrary and capricious, not the result of reasoned decision-making, contrary to law, and invites covered health care providers and insurers to discriminate against transgender people;

b. Eliminating a unitary legal standard for enforcing violations of Section 1557 and replacing it with a fractured and complex set of procedures is contrary to the plain language of Section 1557 and Congress's intent, and will complicate and make it more difficult to bring discrimination claims, particularly claims of intersectional discrimination;

c. Incorporating sweeping religious exemptions is contrary to the statutory language of Section 1557 and will create significant burdens on patients and providers;

d. Eliminating notice requirements and critical language access provisions that ensure LEP individuals can access necessary health care is arbitrary and capricious, contrary to statutory intent, and will make it more difficult for LEP patients to understand their health care rights, communicate with doctors and other health care workers, and navigate complex insurance and medical documents with specialized terminology, and cause an increase in patients who will delay or not seek care at all;

e. Excluding from Section 1557 health programs and activities that HHS administers but are not established under Title I of the ACA and health insurance plans outside of Title I of the ACA that do not receive Federal financial assistance is inconsistent with Section 1557 and will cause drastic reductions in protections for LGBTQ people;

f. Eliminating gender identity and sexual orientation protections in unrelated regulations is procedurally improper, arbitrary and capricious, and contrary to law; and

g. Eliminating protections relating to discrimination on the basis of association is arbitrary and capricious and contrary to law.

V. The Revised Rule

86. Despite the significant concerns raised during the comment period, HHS published the Revised Rule in the Federal Register on June 19, 2020, making only "minor and primarily technical corrections." *See* Nondiscrimination in Health and Health Education Programs or Activities, Delegation of Authority, 85 Fed. Reg. 37,160, 37,161 (June 19, 2020). A copy of the Revised Rule is attached as **Exhibit 2** and incorporated by reference.

87. In adopting the Revised Rule, HHS failed to address adequately many of the serious issues commenters raised, including concerns that the proposed elimination of the definition of "on the basis of sex," which the 2016 Final Rule defined to include gender identity and sex stereotyping, would invite discrimination against LGBTQ people. *See* 85 Fed. Reg. at 37,165, 37,180.

88. Relying essentially on one federal district court opinion—*Franciscan Alliance, Inc.* v. *Burwell*, 227 F. Supp. 3d 660 (N.D. Tex. 2016)—which the preamble cites more than 40 times, HHS takes the position that "the ordinary public meaning of the term 'sex' in Title IX is

unambiguous" and refers to a "biological binary meaning of sex," 85 Fed. Reg. at 37,178-80, and discrimination on the basis of sex under Title IX does not encompass discrimination on the basis of gender identity or sex stereotyping, 85 Fed. Reg. at 37,183-86.

89. HHS explicitly rejected comments urging it to wait until the Supreme Court decided *Bostock* and related cases because of the potential implications for the Revised Rule. *See* 85 Fed. Reg. at 37,168. Despite acknowledging that "a holding by the U.S. Supreme Court on the meaning of 'on the basis of sex' under Title VII will likely have ramifications for the definition of 'on the basis of sex' under Title IX," because "Title VII case law has often informed Title IX case law with respect to the meaning of discrimination 'on the basis of sex,'" *id.*, HHS stated it was sticking with the position the federal government had taken in *Bostock* and related cases that "discrimination 'on the basis of sex' in Title VII and Title IX does not encompass discrimination on the basis of sexual orientation or gender identity," *id.*

90. HHS further asserted that even if the Supreme Court determined that the prohibition on sex discrimination in Title VII encompassed gender identity and sexual orientation, such a ruling may not fully address the implications for the health care context. 85 Fed. Reg. at 37,168.

91. Among other revisions, the Revised Rule:

a. Repeals the definition of "on the basis of sex" and the specific prohibition of discrimination on the basis of gender identity and sex stereotyping, *see* 85 Fed. Reg. at 37,161-62;

b. Repeals the unitary legal standard for enforcing violations of Section 1557 and eliminates provisions recognizing a private right of action and compensatory damages, *see* 85 Fed. Reg. at 37,162;

c. Incorporates sweeping religious exemptions, *see id.*;

d. Repeals notice requirements and access to language provisions, *see id.*;

e. Excludes from the scope of Section 1557 certain health programs and activities and health insurance plans, *see id.*;

f. Repeals gender identity and sexual orientation protections in unrelated regulations, *see id.*; and

g. Repeals provisions relating to discrimination on the basis of association, *see id*.

92. These changes are arbitrary and capricious, not the process of reasoned decision-making, contrary to the statutory language and Congress's intent, not in accordance with law, in excess of HHS's statutory authority, and unconstitutional.

VI. HHS's Repeal of the Definition of "On the Basis of Sex" and Protections Against Discrimination on the Basis of Gender Identity and Sex Stereotyping Is Arbitrary and Capricious and Contrary to Law

93. Section 1557 prohibits sex discrimination. In line with that prohibition, the 2016 Final Rule included a definition of "on the basis of sex" that explicitly prohibited discrimination on the basis of gender identity and sex stereotyping, among other grounds. *See* 81 Fed. Reg. at 31,467 (formerly codified at 45 C.F.R. § 92.4).

94. The Revised Rule repeals entirely the 2016 Final Rule's definition of discrimination "on the basis of sex," without providing a different definition. Although HHS's Notice of Proposed Rulemaking stated HHS was declining to define the term because "of the likelihood that the Supreme Court will be addressing the issue in the near future," 84 Fed. Reg. at 27,857, HHS did not wait for the Supreme Court to decide whether discrimination on the basis of "sex" encompasses discrimination against LGBTQ people.

95. Instead, it staked its elimination of the definition of "on the basis of sex" on the *Franciscan Alliance* decision and the government's position in the *Bostock* litigation "that discrimination 'on the basis of sex' in Title VII and Title IX does not encompass discrimination on the basis of sexual orientation or gender identity." 85 Fed. Reg. at 37,168.

96. The Supreme Court now has conclusively rejected that position, holding "it is impossible to discriminate against a person for being homosexual or transgender without discriminating against that individual on the basis of sex." *Bostock*, 2020 WL 3146686, at *7. *Bostock*'s conclusion that discrimination "on the basis of sex" encompasses claims of discrimination based on transgender status and sexual orientation affirms the validity of the substantial body of case law that formed the basis of the 2016 Final Rule. *See* 81 Fed. Reg. at 31,387-90, 31,392.

97. The Revised Rule's repeal of the definition of "on the basis of sex" and elimination of the protections for LGTBQ people against discrimination is contrary to law and will invite health care insurers and providers to discriminate against LGBTQ people seeking health care. It also introduces substantial confusion among health care providers and insurers regarding their legal obligations and the right of the populations they serve to be free from discrimination, particularly in light of the Supreme Court's ruling in *Bostock*.

98. The Revised Rule also eliminates the provisions in the 2016 Final Rule specifically requiring covered entities to treat individuals consistent with their gender identity and prohibiting covered entities from having or implementing "a categorical coverage exclusion or limitation for all health care services related to gender transition." *Compare* 81 Fed. Reg. at 31,471-72 (formerly codified at 45 C.F.R. §§ 92.101(b)(3)-(4)), *with* 85 Fed. Reg. at 37,187-88.

99. HHS claims this provision inappropriately interfered with the ethical and medical judgment of health professionals. *See* 85 Fed. Reg. at 37,187-88. However, as the 2016 Final Rule demonstrates, prohibiting the exclusion or denial of health programs or activities on the basis of an individual's LGBTQ status does not prevent medical providers from providing appropriate medical advice.

100. The Revised Rule also eliminates the provision in the 2016 Final Rule that prohibited a covered entity from discriminating against an individual based on those with whom they are known or believed to have a relationship or to be associated. *Compare* 81 Fed. Reg. at 31,472 (formerly codified at 45 C.F.R. § 92.209), *with* 85 Fed. Reg. at 37,199-200. The 2016 Final Rule grounded this provision on a thorough examination of existing case law. *See* 81 Fed. Reg. at 31,438-39.

101. Former Section 92.209 accurately reflected current law. HHS has provided no good reason to eliminate it. Its decision to do so is arbitrary and capricious and contrary to the law, in violation of the APA.

VII. The Revised Rule's Repeal of the Unitary Standard Is Arbitrary and Capricious and Contrary to Law

102. Section 1557 provides: "The enforcement mechanisms provided for and available under such title VI, title IX, section 794, *or* such Age Discrimination Act shall apply for purposes of violations of [Section 1557]." 42 U.S.C. § 18116(a) (emphasis added). Congress's use of the disjunctive "or" indicates that the enforcement mechanisms applicable under any of the incorporated statutes are available to every claim of discrimination under Section 1557, regardless of the particular type of discrimination.

103. During the notice-and-comment period on the 2016 Final Rule, commenters pointed to the plain language of Section 1557 and asked HHS to "clarify that all enforcement

mechanisms available under the statutes listed in Section 1557 are available to each Section 1557 plaintiff, regardless of the plaintiff's protected class. Thus, for example, an individual could bring a race claim under the Age Act procedure and an age claim under the Title VI procedure." 81 Fed. Reg. at 31,439.

104. As commenters emphasized, by enacting Section 1557, Congress intended to create a new health-specific, anti-discrimination cause of action subject to a singular standard regardless of a person's protected characteristic. Otherwise, different enforcement mechanisms and standards would apply depending on whether an individual's claim is based on their sex, race, national origin, age, or disability, in which case a person who faces intersectional discrimination – that is, discrimination based on more than one ground – would have different remedies and enforcement mechanisms for the same conduct under the same law. *Id.* at 31,439-40.

105. In response, HHS stated: "OCR interprets Section 1557 as authorizing a private right of action for claims of disparate impact on the basis of any of the criteria enumerated in the legislation." *Id.* at 31,440.

106. The 2016 Final Rule specified, consistent with this interpretation, that Section 1557 not only prohibits intentional discrimination on the basis of sex, but also conduct and practices "that *have the effect of subjecting individuals to discrimination* on the basis of sex" – conduct that can give rise to disparate impact claims based on sex. 81 Fed. Reg. at 31,470 (formerly codified at 45 C.F.R. § 92.101(b)(3)(ii)) (emphasis added).

107. The 2016 Final Rule implemented Section 1557's directives regarding enforcement by promulgating 45 C.F.R. § 92.301, which provided: "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, *or* the Age Discrimination Act of 1975 shall apply for purposes of Section 1557 as interpreted by this part." 81 Fed. Reg. at 31,472 (formerly codified at 45 C.F.R. § 92.301(a)) (emphasis added).

108. In addition, the 2016 Final Rule specified that a private right of action is available under Section 1557 and compensatory damages are available. *See* 81 Fed. Reg. at 31,472 (formerly codified at 45 C.F.R. §§ 92.301(b), 92.302(d)). HHS explained that its "interpretation of Section 1557 as authorizing compensatory damages is consistent with our interpretations of Title VI, Section 504, and Title IX." 81 Fed. Reg. at 31,440.

109. Under these regulations, individuals bringing claims of intersectional discrimination, i.e., discrimination based on multiple characteristics, would not need to litigate their claims under different standards and different enforcement mechanisms.

110. The Revised Rule, however, without reasoned explanation, rejects the 2016 Final Rule's establishment of a unitary legal standard and enforcement mechanism under Section 1557, limiting the remedies available from claims of discrimination based on a characteristic listed in Section 1557 to only those remedies available under the statute from which the characteristic was incorporated. HHS acknowledged commenters raised concerns about intersectional discrimination but brushed them aside by noting that OCR accepts complaints that allege discrimination based on more than one protected status. 85 Fed. Reg. at 37,199-200.

111. HHS claims the 2016 Final Rule applied the enforcement mechanisms in existing statutes "in a confusing and inconsistent manner," 85 Fed. Reg. at 37,202, and resulted in "a new patchwork regulatory framework unique to Section 1557 covered entities," 85 Fed. Reg. at 37,162.

112. The 2016 Final Rule accomplished precisely the opposite. It established a consistent, unitary legal standard and enforcement mechanism as Section 1557 contemplates. It is HHS's arbitrary and capricious elimination of a unitary standard that creates a confusing and patchwork approach, applying different remedies and enforcement mechanisms to discriminatory conduct that arises under a single statute – Section 1557.

113. The Revised Rule also eliminates, without providing a reasoned explanation, the provisions in the 2016 Final Rule expressly recognizing a private right of action to "challenge a violation of Section 1557 or this part." *Compare* 81 Fed. Reg. at 31,472 (formerly codified 45 C.F.R. § 92.302(d)), *with* 85 Fed. Reg. at 37,203.

114. HHS eliminated the private right of action provision even though the existence of such a right is clear from the statutory language of Section 1557, which explicitly references and incorporates the "enforcement mechanisms" of four civil rights laws, all of which have a private right action, and even though every court that has ruled on the question has held that the statutory language of Section 1557 confers a private right of action.

115. The Revised Rule also eliminates, without providing a reasoned explanation, § 92.301(b) of the 2016 Final Rule that recognized "[c]ompensatory damages for violations of Section 1557 are available in appropriate administrative and judicial actions brought under this rule." 81 Fed. Reg. at 31,472 (formerly codified 45 C.F.R. § 301(b)). The only justification HHS offers is that "the Department has concluded that its enforcement of Section 1557 should conform to the Department of Justice's Title VI Manual," which states that "under applicable Federal case law, compensatory damages are generally unavailable for claims based solely on a Federal agency's disparate impact regulations." 85 Fed. Reg. at 37,202.

116. HHS ignores entirely its own statement in the preamble to the 2016 Final Rule that its interpretation of Section 1557 as authorizing compensatory damages was consistent with HHS's "interpretations of Title VI, Section 504, and Title IX," as providing for compensatory damages. *See* 81 Fed. Reg. at 31,440. HHS's elimination of the provision recognizing the availability of compensatory damages also is inconsistent with controlling U.S. Supreme Court decisions holding that damages are available under these civil rights statutes.

117. HHS's unreasonable interpretation of Section 1557 is arbitrary, capricious, and contrary to law in that it fails to follow the statutory language of Section 1557 and apply each of the "enforcement mechanisms" available under each of the civil rights statutes incorporated into Section 1557 to every claim of discrimination arising under Section 1557 regardless of the basis. HHS's arbitrary and capricious elimination of provisions recognizing a private right of action under Section 1557 and the availability of compensatory damages likewise is contrary to the plain language of the statute and the law.

118. Although HHS cannot change the law, its fracturing of the consolidated procedures established in the 2016 Final Rule undermines Congress's intent to create a new, health-specific anti-discrimination cause of action and will make it more difficult to bring discrimination claims under Section 1557. HHS's elimination of the private right of action and compensatory damages provisions also will confuse the public and mislead some persons into not asserting their legal rights.

VIII. The Revised Rule's Incorporation of Sweeping Religious Exemptions Conflicts with the Statutory Language of Section 1557 and Is Inappropriate in the Health Care Context

119. The 2016 Final Rule included a provision stating that covered entities do not have to comply with Section 1557 if doing so would violate applicable federal statutory protections

for religious conscience and freedom. *See* 81 Fed. Reg. at 31,466 (formerly codified at 45 C.F.R. § 92.2(b)(2)).

120. HHS considered incorporating Title IX's blanket religious exemptions into Section 1557, but after careful consideration and deliberation, HHS declined to do so in the 2016 Final Rule. 81 Fed. Reg. at 31,379-80. Title IX's religious exemption by its terms applies only to educational institutions and programs, not health care providers or health plans. It protects religiously-controlled educational institutions and programs from requirements that violate their religious tenets. *See* 20 U.S.C. § 1681(a)(3); 34 C.F.R. § 106.12. For example, religious schools that believe only men can be priests, rabbis, or ministers are not required to admit women to training programs for the priesthood, rabbinate, or ministry.

121. In declining to import Title IX's blanket religious exemption into Section 1557, HHS explained that Section 1557, unlike Title IX, does not include a religious exemption. It further explained that Title IX's blanket exemption would be inappropriate in the health care setting because it is framed for educational institutions, which are very different from health care settings, and those differences "warrant different approaches." 81 Fed. Reg. at 31,380.

122. HHS noted that, unlike the educational context where individuals may select a religious educational institution by choice, in the health care context, individuals may have limited or no choice of providers. *Id.* In addition, "a blanket religious exemption could result in a denial or delay in the provision of health care to individuals and in discouraging individuals from seeking necessary care, with serious and, in some cases, life threatening results." *Id.*

123. HHS determined that a "more nuanced approach in the health care context" was warranted. *Id.* As a result, the 2016 Final Rule provided: "Insofar as the application of any requirement under this part would violate applicable Federal statutory protections for religious

freedom and conscience, such application shall not be required." 81 Fed. Reg. at 31,466 (formerly codified at 45 C.F.R. § 92.2(b)(2)).

124. The Revised Rule upends this nuanced and carefully considered approach by explicitly identifying and incorporating sweeping religious exemptions from a number of different statutes. Not only does the Revised Rule incorporate the Title IX religious exemptions, it also incorporates "definitions, exemptions, affirmative rights, or protections" from unrelated statutes. 85 Fed. Reg. at 37,245 (to be codified at 45 C.F.R. § 92.6(b)).

125. The inclusion of sweeping religious exemptions in Section 1557 is contrary to the statutory language of Section 1557, which by its terms does not incorporate any exemptions from Title IX or any other statute. Section 1557 expressly incorporates the enforcement mechanisms from four civil rights statutes, but pointedly does not incorporate the religious exemptions from Title IX or any other statute.

126. Religiously affiliated hospitals and health care systems occupy a large and growing percentage of health care markets. The Revised Rule's sweeping religious exemptions to Section 1557's prohibitions on discrimination will invite these institutions to allow their religious beliefs to determine patient care, contrary to medical standards and the health of an increasing number of individuals.

127. The Revised Rule also invites individual health care providers to deny care to LGBTQ patients on the basis of their individual religious beliefs. It prioritizes the protection of individual conscience and religious freedom rights over ensuring that LGBTQ people receive the health care to which they are entitled. *See* 85 Fed. Reg. at 37,206.

128. The Revised Rule's religious exemptions disproportionately harm LGBTQ people, who often are refused health care because of their sexual orientation or gender identity.

According to a 2018 study, 8% of LGBTQ people were refused health care because of their sexual orientation, and 29% of transgender people were denied care because of their gender identity.[11]

129. When LGBTQ people are denied care, it becomes difficult and sometimes impossible to find another provider, especially for those who live in rural areas and for transgender people. In one recent study, 18% of LGBTQ people said it would be very difficult if not impossible to find the same type of service in another hospital. Outside of a metropolitan area, 41% of respondents stated that, if they were denied treatment, it would be very difficult if not impossible to find the same service at a different location.[12]

130. These religious exemptions also will frustrate the ability of organizations who provide health care to LGBTQ patients to accomplish their missions. Individual health care providers employed by these organizations may choose to deny care to LGBTQ patients, claiming that doing so would violate their religious beliefs. This denial of care would harm the ability of these organizations to treat their patients effectively. These exemptions also would impair the ability of these organizations to refer their LGBTQ patients to other health care providers because they would be unsure whether these providers would invoke these exemptions to deny care to LGBTQ patients.

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[11] Shabab Ahmed Mirza & Caitlin Rooney, *Discrimination Prevents LGBTQ People From Accessing Health Care*, Center for American Progress (Jan. 18, 2018), https://perma.cc/ZG7E-7WK8.

[12] *Id.*

IX. The Revised Rule's Elimination of Notices of Nondiscrimination Rights and Language Access Provisions Is Arbitrary and Capricious and Contrary to Statutory Intent

131. More than 25 million Americans are of LEP, meaning they speak, read, or write English less than "very well."[13] An estimated 6.5 million LEP adults are uninsured.[14]

132. The 2016 Final Rule contained a number of provisions to ensure that LEP patients understand their rights and are able to communicate fully and effectively with their providers and other health care staff. The 2016 Final Rule required covered entities to provide notice of nondiscrimination policies, including notice of availability of and how to access language assistance services. 81 Fed. Reg. at 31,469 (formerly codified at 45 C.F.R. § 92.8(a)).

133. In addition, covered entities were required to include taglines on all significant documents in the top fifteen languages spoken by individuals with LEP in their state. 81 Fed. Reg. at 31,469 (formerly codified at 45 C.F.R. § 92.8(d)(1)). Taglines are short statements that inform individuals of their right to language assistance and how to seek such assistance.

134. The 2016 Final Rule also required that a covered entity with at least 15 employees designate a specific individual or individuals with responsibility to oversee compliance with Section 1557, including LEP efforts, and investigate complaints and concerns and establish and adhere to a specific grievance procedure. 81 Fed. Reg. at 31,469 (formerly codified at 45 C.F.R. § 92.7).

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[13] *See* U.S. Census Bureau, *Language Spoken at Home*, American Community Survey 2018 1-Year Estimates Subject Tables, tbl. S1601 (2018), https://perma.cc/Z452-RSWR; U.S. Census Bureau, *Characteristics of People by Language Spoken at Home*, American Community Survey 2018 1-Year Estimates Subject Tables, tbl. S1603, https://perma.cc/R59J-HG4K.

[14] *See* Letter from Kathy Ko Chin, President & CEO, Asian & Pacific Islander American Health Forum, to Roger Severino, Dir., Office of Civil Rights, U.S. Dep't Health & Hum. Servs., at 21 (Aug. 13, 2019), https://perma.cc/6HWW-6833.

135. The Revised Rule repeals §§ 92.7 and 92.8 of the 2016 Final Rule, eliminating the notice and tagline requirements and the requirement to designate a specific individual to oversee Section 1557 compliance, including LEP efforts, and grievance procedure requirements. *See* 85 Fed. Reg. at 37,204.

136. The elimination of the notice, tagline, and LEP requirements is arbitrary and capricious and will result in some LEP patients failing to understand or assert their rights. It also will result in some LEP patients failing to receive adequate care because of the difficulties patients may have in understanding their providers or other staff, undermining the purpose and intent of the nondiscrimination provisions of Section 1557.

137. HHS has not explained how individuals will know about their rights and how elimination of notices will not deny LEP individuals meaningful access to health care.

X. The Revised Rule's Attempt to Narrow paduthe Scope of Health Programs and Activities Subject to Section 1557 is Arbitrary and Capricious and Contrary to Law

138. The plain language of Section 1557 prohibits discrimination based on sex, race, color, national origin, age, and disability 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] (or amendments).

42 U.S.C. § 18116(a).

139. The 2016 Final Rule correctly interpreted Section 1557 to cover all health-related operations and programs of any health care or health insurance provider, if any part of its operations receives Federal financial assistance; any other health program or activity that HHS administers; or any health insurance exchange or other entity established under ACA Title I or health insurance-exchange-related insurance plan.

140. The Revised Rule attempts to limit the scope of Section 1557 in two principal ways. First, it applies Section 1557's nondiscrimination protections only to health programs or activities of HHS that are administered under Title I of the ACA, not to other health programs and activities that HHS administers. 85 Fed. Reg. at 37,244 (to be codified at 45 C.F.R. § 92.3(a)(2)). Such a limitation excludes from Section 1557 numerous HHS health programs and activities, including health programs and activities of the Centers for Medicare and Medicaid Services, the Centers for Disease Control and Prevention, the National Institutes of Health, and the Substance Abuse and Mental Health Services Administration.

141. The Revised Rule's interpretation of the scope of Section 1557 is inconsistent with and contradicts the plain language of Section 1557, which states that it applies to "any program or activity that is administered by an Executive Agency." 42 U.S.C. § 18116(a). It does not limit Section 1557 to health programs and activities established or administered under ACA Title I.

142. Second, the Revised Rule erroneously declares that health insurers are not a "health program or activity" under Section 1557 and not subject to Section 1557's nondiscrimination prohibitions because, now according to HHS, they are not "principally engaged in the business of providing healthcare." 85 Fed. Reg. at 37,244-45 (to be codified at 45 C.F.R. § 92.3(c)).

143. By declaring that health insurance providers are not principally engaged in the business of providing health care, HHS purports to exclude health insurance providers from the requirements of Section 1557, except for plans offered on the Health Insurance Marketplace or Federally-facilitated Marketplace created under Title I and insurance plans outside of Title I that receive Federal financial assistance. For those health insurers that operate plans outside of Title I

but receive Federal financial assistance, the Revised Rule further limits the application of Section 1557 to only those operations that receive Federal financial assistance—all other operations of the insurer are excluded. 85 Fed. Reg. at 37,244 (to be codified at 45 C.F.R. § 92.3(b)).

144. This Revised Rule exempts many plans, products, and operations of many health insurance issuers, such as self-funded group health plans, the Federal Employees Health Benefits (FEHB) Program, and short-term limited duration insurance plans. 85 Fed. Reg. at 37,173-74.

145. To support its new interpretation, HHS contends that providing "health insurance" is different than providing "healthcare" and points to the definitions of "healthcare" and "health insurance" in unrelated statutes to support its distinction. 85 Fed. Reg. at 37,172-73.

146. But Section 1557 covers "health programs and activities," not just direct health care. Health insurance clearly is a health-related program or activity. It is what enables the vast majority of Americans to access health care. Indeed, health insurance companies design the health care individuals receive by determining benefits offered and establishing formularies, payment structures, and networks. They also conduct prior authorization and establish and evaluate other clinical coverage criteria, as well as exercise considerable control over the health care of enrollees—deciding which providers a patient may see, what hospitals they may visit, and what treatments or medications they may receive.

147. Neither the plain language of Section 1557 nor HHS's effort to rely on unrelated statutes supports HHS's unreasonable assertion that "healthcare" is different than "health insurance." Section 1557 explicitly provides that it covers "health programs and activities." Its scope is not limited to direct health care.

XI. The Revised Rule Arbitrarily and Capriciously Eliminates Gender Identity and Sexual Orientation Protections in Unrelated Regulations

148. The Revised Rule amends a series of unrelated regulations that had identified gender identity and sexual orientation as prohibited bases of discrimination, including regulations related to Medicaid State Plans, Programs for All-Inclusive Care for the Elderly (PACE), and ACA state health insurance exchanges and plans. The Revised Rule eliminates protections against gender identity and sexual orientation discrimination in those regulations. 85 Fed. Reg. at 37,218-22, 37,243.

149. These regulations were not issued pursuant to Section 1557 and do not interpret Section 1557. They were promulgated by CMS pursuant to the authority granted by several unrelated statutes. These unrelated regulations were not promulgated pursuant to HHS's authority to implement regulations under Section 1557.

150. For example, the Revised Rule amends regulations regarding Medicaid State Plans and Medicaid contractors, 42 C.F.R. §§ 438.3(d)(4), 438.206 (c)(2), and 440.262, which were issued pursuant to HHS's authority under Section 1902 of the Social Security Act to implement Section 1902(a)(19). That section directs HHS to "provide such safeguards as may be necessary to assure that eligibility for care and services under the [Medicaid] plan will be determined, and such care and services will be provided, in a manner consistent with simplicity of administration and the best interest of the recipients." 42 U.S.C. § 1396a(a)(19); *see also* Medicaid and Children's Health Insurance Program (CHIP) Programs, 81 Fed. Reg. 27,498, 27,538-39, 27,666 (May 6, 2016).

151. Prior to the Revised Rule, 42 C.F.R. § 438.3(d)(4) provided: "The MCO, PIHP, PAHP, PCCM or PCCM entity will not discriminate against individuals eligible to enroll on the basis of race, color, national origin, sex, sexual orientation, gender identity, or disability and will

not use any policy or practice that has the effect of discriminating on the basis of race, color, or national origin, sex, sexual orientation, gender identity, or disability." The Revised Rule amends § 438.3(d)(4) to state: "The MCO, PIHP, PAHP, PCCM or PCCM entity will not discriminate against individuals eligible to enroll on the basis of race, color, national origin, sex, or disability and will not use any policy or practice that has the effect of discriminating on the basis of race, color, or national origin, sex, or disability." 85 Fed. Reg. at 37,243 (to be codified at 42 C.F.R. § 438.3(d)(4)).

152. PACE is a program for services for frail community-dwelling elderly persons, most of whom are Medicaid and Medicare dual eligible, to keep them in the community rather than moving to nursing homes. *See* 42 C.F.R. §§ 460.98, 460.112. HHS added sexual orientation to the list of protected categories of persons eligible for PACE services in 2006, explaining that "we do not believe anyone should be denied enrollment in PACE because of discrimination of any kind." Medicare and Medicaid Programs; Programs of All-Inclusive Care for the Elderly (PACE); Program Revisions, 71 Fed. Reg. 71,244, 71,295 (Dec. 8, 2006).

153. Prior to the Revised Rule, 42 C.F.R. § 460.98(b)(3) provided: "The PACE organization may not discriminate against any participant in the delivery of required PACE services based on race, ethnicity, national origin, religion, sex, age, sexual orientation, mental or physical disability, or source of payment." The Revised Rule amends 42 C.F.R. § 460.98(b)(3) to state: "The PACE organization may not discriminate against any participant in the delivery of required PACE services based on race, ethnicity, national origin, religion, sex, age, mental or physical disability, or source of payment." 85 Fed. Reg. at 37,243 (to be codified at 42 C.F.R. § 460.98(b)(3)). The Revised Rule also eliminates protections against sexual orientation

discrimination in 42 C.F.R. § 460.112(a). 85 Fed. Reg. at 37,220, 37,243 (to be codified at 42 C.F.R. § 460.112(a)).

154. Prohibitions of discrimination on the basis of sexual orientation and gender identity were added to regulations regarding group and individual market health insurance plans subject to the ACA and to ACA-created health insurance exchanges and qualified health plans. These prohibitions were added to further the ACA's aim of expanding insurance coverage, which discriminatory marketing practices and benefit designs can thwart. *See* 45 C.F.R. §§ 147.104(e), 155.120(c)(1)(ii), 155.220(j)(2)(i), 156.200(e), & 156.1230(b)(2); *see also* PPACA; Establishment of Exchanges and Qualified Health Plans, 77 Fed. Reg. 18,310, 18,319, 18,415 (March 27, 2012); PPACA; Health Insurance Market Rules, 78 Fed. Reg. 13,406, 13,417 (Feb. 27, 2013); PPACA; Exchange and Insurance Market Standards for 2015 and Beyond, 79 Fed. Reg. 30,240, 30,261 (May 27, 2014); PPACA; HHS Notice of Benefit and Payment Parameters for 2018, 81 Fed. Reg. 94,058, 94,064, 94,152 (Dec. 22, 2016).

155. The Revised Rule eliminates the prohibitions on gender identity and sexual orientation discrimination in these regulations. *See* 85 Fed. Reg. at 37, 219-21, 37,247-48 (to be codified at 45 C.F.R. §§ 147.104(e), 155.120(c)(1)(ii), 155.220(j)(2)(i), 156.200(e), & 156.1230(b)(2)).

156. HHS offers no legal, policy, or cost-benefit analysis for amending these regulations, including the effects they have had during the years they have been in place or the costs and benefits of amending them.

157. HHS's erroneous analysis of discrimination on the basis of sex under longstanding civil rights laws provides no justification for amending these regulations, which were promulgated to advance the goals of other statutory provisions.

158. HHS's amendment of these unrelated regulations to eliminate protections for LGBTQ people is arbitrary and capricious and without legal support.

XII. The Revised Rule's Cost-Benefit Analysis Is Arbitrary and Capricious

159. The Revised Rule fails to address adequately the direct and indirect costs that repeal of protections for LGBTQ people will have on patients, providers, insurers, and the overall health care system.

160. These costs take many forms, none of which the Revised Rule considers. First, out-of-pocket costs for necessary medical procedures will shift from insurers to patients and providers. Under the 2016 Final Rule, most insurers covered these services, but under the Revised Rule, insurers can deny coverage on the basis that these are cosmetic procedures, rather than medically necessary to alleviate gender dysphoria. Thus, many patients may forgo this necessary medical care due to the high cost of these procedures or cover the cost themselves. Providers also would lose out on the revenue from these procedures when patients cannot afford them.

161. Second, insurers' increased transgender exclusions and transgender patients' increased fear of discrimination by health care providers empowered by the Revised Rule will lead to transgender patients delaying or declining to seek care.[15] As such, transgender patients may develop comorbid conditions such as depression, anxiety, drug abuse, and other stress-related conditions. Treating these increased comorbid conditions will increase costs to patients, insurers, providers, and the health system overall.

[15] *See* Lambda Legal, *When Health Care Isn't Caring: Lambda Legal's Survey on Discrimination Against LGBT People and People Living with HIV* at 12 (2010), https://perma.cc/9SEG-JD2K; *see also* S.E. James *et al.*, Nat'l Ctr. for Transgender Equality, *The Report of the 2015 U.S. Transgender Survey* at 98 (2016), https://perma.cc/9S9L-VJ9C.

162. Third, patients' delays or failures to obtain treatment will increase the direct cost of treating physical medical conditions and is a patient safety issue that can lead to poor patient outcomes. LGBTQ patients who fear discrimination may delay, or never receive, preventative care such as cancer screenings. Without regular screenings, LGBTQ patients will develop more advanced cancers and other health conditions. Because the cost of treating more advanced diseases far outweighs the cost of preventative care, the Revised Rule will increase costs to patients, insurers, providers, and the overall health care system.

163. The Revised Rule does not consider these costs associated with inviting discrimination against LGBTQ patients, and in particular those who are transgender. Ignoring such substantial costs makes the Revised Rule's cost-benefit analysis seriously flawed and arbitrary and capricious.

164. Indeed, the Revised Rule specifically admits HHS did not take the costs or harms to transgender patients into account, stating: "the Department also lacks the data necessary to estimate the number of individuals who currently benefit from covered entities' policies governing discrimination on the basis of gender identity who would no longer receive those benefits after publication of this rule." 85 Fed. Reg. at 37,225.

165. The costs of prohibiting sex-based discrimination against transgender people in health insurance coverage is minimal compared to the costs associated with inviting such discrimination. The 2016 Final Rule acknowledged this fact, stating that prohibiting discrimination against transgender consumers in health insurance "will have de minimis impact on the overall cost of care and on health insurance premiums." 81 Fed. Reg. at 31,456-57. Moreover, studies have found that providing coverage of transition-related care is extremely cost-effective and reduces costs in the long term. For example, a 2013 survey of employers

found that providing transition-related health care benefits has "zero or very low costs" and utilization rates of approximately 1 per 10,000 to 20,000 employees.[16] Another study found that the cost of providing coverage for treatment of gender dysphoria was about $0.016 per member per month. It also concluded that this small cost could reduce other costly health risks like depression and drug abuse.[17] Numerous other studies confirm these conclusions.[18]

166. The Revised Rule also fails to include in its cost-benefit analysis the costs associated with (1) eliminating gender identity nondiscrimination protections in the CMS regulations promulgated under different statutes, and (2) adopting the broad religious exemptions from Title IX and unrelated statutes. The costs of these changes include those associated with the increased discrimination that will result from the Revised Rule. Failing to consider these costs also makes the Revised Rule arbitrary and capricious.

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[16] Jody L. Herman, *Cost and Benefits of Providing Transition-Related Health Care Coverage in Employee Health Benefits Plans,* The Williams Institute of the UCLA School of Law (Sept. 2013), https://perma.cc/D8J5-FACP.

[17] 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. INTERN. MED. 394, 398 (Oct. 2015), https://perma.cc/74EW-LZPY.

[18] *See* Declaration of Raymond Edwin Mabus, Jr., former Secretary of the Navy, in Support of Plaintiff's Motion for Preliminary Injunction ¶ 41, *Doe* v. *Trump*, No. 1:17-cv-1597-CKK (Aug. 31, 2017), ECF No. 13-9, https://perma.cc/8ZU8-8NGE (concluding costs associated with providing health care to transgender service members was considered by a former Secretary of the Navy to be "budget dust, hardly even a rounding error"); Padula, *et al.*, *Societal Implications of Health Insurance Coverage for Medically Necessary Services in the U.S. Transgender Population: A Cost-Effectiveness Analysis* at 398, https://perma.cc/74EW-LZPY (calculating the costs would be fewer than two pennies per month for every person with health insurance coverage in the United States); Cal. Dep't of Ins., Economic Impact Assessment: Gender Nondiscrimination in Health Insurance (Reg. File No. REG-2011-00023) (Apr. 13, 2012), https://perma.cc/QJ34-RVNQ (finding that costs of providing health care did not increase materially when employers adopted policies that prohibited discrimination against transgender individuals).

XIII. The Revised Rule Betrays Discriminatory Animus Against LGBTQ People

167. HHS's discriminatory animus in promulgating the Revised Rule is evident, as the promulgation of the Revised Rule is just the latest step in its multi-step erasure of LGBTQ people from health care-related nondiscrimination protections.

168. Defendant Severino has a history of anti-LGBTQ sentiments, advocacy, and comments. For example, in 2016, before he became Director of OCR, defendant Severino decried the 2016 Final Rule because it ran counter to some people's "moral, and religious beliefs about biology" and because, in his opinion, the 2016 Final Rule "create[d] special privileges, new protected classes, or new rights to particular procedures."[19]

169. In 2016, defendant Severino also denounced the Department of Justice's enforcement of Title IX's sex discrimination protections as they applied to transgender people as "using government power to coerce everyone, including children, into pledging allegiance to a radical new gender ideology."[20]

170. That same year, defendant Severino also stated that he believes transgender military personnel serving openly "dishonors" the service of other service members.[21] In addition, he referred to a transgender male student involved in a Title IX lawsuit as a "teen biological girl."[22]

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[19] Ryan Anderson & Roger Severino, *Proposed Obamacare Gender Identity Mandate Threatens Freedom of Conscience and the Independence of Physicians*, The Heritage Foundation (Jan. 8, 2016), https://perma.cc/5XKG-S79Z.

[20] Roger Severino, *DOJ's Lawsuit Against North Carolina Is Abuse of Power*, The Daily Signal (May 9, 2016), https://perma.cc/3FFM-KFMB.

[21] Roger Severino, *Pentagon's Radical New Transgender Policy Defies Common Sense*, CNSNews (July 1, 2016), https://perma.cc/VK37-5FP7.

[22] Roger Severino & Jim DeMint, *Court Should Reject Obama's Radical Social Experiment, The Heritage Foundation* (Dec. 14, 2016), https://perma.cc/N6K8-HQY5.

171. In 2018, it was reported that HHS's OCR was considering defining sex as "a person's status as male or female based on immutable biological traits identifiable by and before birth," a definition that is contrary to the legal, medical, and scientific understanding of sex.[23]

172. And in 2019, HHS issued a Notification of Nonenforcement of Health and Human Services Grants Regulation, in which it stated that it would no longer enforce regulations that prohibit discrimination based on sex, sexual orientation, or gender identity in grant programs that HHS funds. 84 Fed. Reg. 63,809 (Nov. 19, 2019).

173. With defendant Severino now Director of OCR, defendants seek to eviscerate the nondiscrimination protections Severino denounced.

174. For example, HHS asserts that it considered adding gender identity and sexual orientation discrimination to a definition of "sex" or discrimination "on the basis of sex" under Title IX, but concluded doing so was "inappropriate to do so in light of the ordinary public meaning of discrimination on the basis of sex under Title IX" and because "[a]s a policy matter," state and local entities "are better equipped to address with sensitivity issues of gender dysphoria, sexual orientation, and any competing privacy interests, especially when young children or intimate settings are involved." 85 Fed. Reg. at 37,222. Not only has the Supreme Court rejected HHS's position on the definition of "sex" under Title VII, but the notion that health care protections for LGBTQ people are at odds with "young children" is as offensive as it is telling.

175. As another example, although HHS declares that its position on the meaning of sex discrimination "will not bar covered entities from choosing to grant protections on the basis

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[23] Erica L. Green, Katie Benner & Robert Pear, '*Transgender' Could Be Defined Out of Existence Under Trump Administration*, N.Y. Times (Oct. 21, 2018), https://perma.cc/YQR6-YN2F.

of sexual orientation and gender identity that do not conflict with any other Federal law," 85 Fed. Reg. at 37,222, HHS also states that a covered entity's refusal to make distinctions on the basis of sex "could in some cases violate personal privacy interests and so create a hostile environment under Title IX." 85 Fed. Reg. at 37,184. This assertion and the cases cited have nothing to do with Section 1557 and what facilities should be available to a patient in a health care setting.

176. HHS also fails to acknowledge that no cognizable legal claim exists based on having to share a restroom or other single-sex facility with a transgender person. HHS's suggestion to the contrary, *see* 85 Fed. Reg. at 37,190-91, is inconsistent with the rule of law and not a "reasonable" analysis. It serves only to heighten alarm among LGBTQ people and embolden those who attack them with frivolous assertions.

177. The Revised Rule reflects HHS's animosity toward LGBTQ people.

XIV. The Revised Rule Creates Immediate and Irreparable Harms

178. The Revised Rule cannot change the law and the courts will determine the meaning of Section 1557. However, HHS's rules have a substantial effect on health care providers and institutions, as well as on the public. The Revised Rule will result in increased discrimination against LGBTQ people, including those with LEP, by health care providers and health insurers. This increased discrimination will directly and irreparably injure plaintiffs, their members, their patients, and the individuals whom they serve.

A. The Revised Rule Will Increase LGBTQ Discrimination by Health Care Providers and Staff and Cause Irreparable Harm to Plaintiffs and the Patients and Individuals They Serve

179. Discrimination delays or denies necessary health care. It also discourages LGBTQ people from seeking care and from fully disclosing personal information that health care providers need for proper diagnosis and treatment.

180. The Revised Rule sends a message to the health care industry and the LGBTQ community that federal law permits discrimination against LGBTQ patients.

181. Indeed, in its Notice of Proposed Rulemaking, HHS acknowledged the 2016 Final Rule "likely induced many covered entities to conform their policies and operations to reflect gender identity as protected classes [sic] under Title IX." 84 Fed. Reg. at 27,876. And in the Revised Rule, HHS acknowledges that some covered entities may revert to the policies and practices they had in place before the 2016 Final Rule. 85 Fed. Reg. at 37,225. OCR also estimates that 60% of the increase in its anticipated long-term caseload of claims of discrimination are attributable to discrimination claims based on the 2016 Rule's definition of sex discrimination with respect to gender identity and sex stereotyping, though OCR has not enforced such claims. 85 Fed. Reg. at 37,235.

182. HHS tries to minimize the harm the Revised Rule will create, repeatedly claiming that because a federal district court enjoined enforcement of claims based on the definition of sex discrimination in the 2016 Final Rule in December 2016 and later vacated those provisions, any harm would not be the result of the Revised Rule, which merely is maintaining the status quo. *See, e.g.*, 85 Fed. Reg. at 37,181-82, 37,192, 37,199, & 37,238.

183. HHS's position is disingenuous at best. HHS has issued a Revised Rule attempting to legislate that claims of discrimination based on LGBTQ status are not "cognizable" under Section 1557. 85 Fed. Reg. at 37,225.

184. Without complete protection from discrimination based on their sex, including discrimination based on their sexual orientation, gender identity, transgender status, or failure to conform to sex stereotypes, LGBTQ people will be discouraged from seeking the health care they need.

185. The Revised Rule also will discourage LGBTQ people from fully disclosing personal information related to their sexuality and gender that health care providers need for proper diagnosis.

186. The Revised Rule will harm plaintiffs, their patients, and the LGBTQ people whom they serve in multiple ways.

1. Harm to Patients and Individuals Whom Plaintiffs Serve

187. LGBTQ individuals and especially transgender and gender-nonconforming people already face particularly acute barriers to care and health disparities that will be compounded by the Revised Rule. A majority of LGBTQ patients fear going to health care providers because of past experiences of anti-LGBTQ bias in health care settings. Many LGBTQ patients report negative experiences, including hostility, discrimination, and denials of care, when they disclose to health care providers their sexual orientation, history of sexual conduct, gender identity, transgender status, or history of gender-affirming medical treatment, and related medical histories.

188. For example, multiple LGBTQ patients at Whitman-Walker have previously been refused medical care, including routine care unrelated to gender dysphoria, by providers outside of Whitman-Walker simply because they are LGBTQ. In one instance, a radiological technician refused to perform an ultrasound for testicular cancer on a transgender patient. In another, a health care worker at a dialysis clinic confronted a Whitman-Walker patient with end-stage renal disease and objected to being involved in the patient's care because of hostility to his sexual orientation. In another, after a Whitman-Walker patient—a transgender teenager—was hospitalized in a local hospital following a suicide attempt, the staff would only address or refer to the young person with pronouns inconsistent with their gender identity, exacerbating the teenager's acutely fragile state of mind. Local hospitals and surgeons have refused to perform

transition-related surgeries on Whitman-Walker transgender patients, even when they routinely perform the very same procedures on non-transgender patients, including in situations when the patient's insurance would have covered the procedure or when the patient was able to pay for the procedure. Many local primary-care physicians unaffiliated with Whitman-Walker have refused to prescribe hormone therapy for transgender patients. And multiple Whitman-Walker patients have been denied prescriptions by pharmacists. Behavioral-health providers at Whitman-Walker report that the vast majority of transgender patients—as many as four out of five—report instances of mistreatment or discrimination by health care providers, hospitals, clinics, doctors' offices, or other facilities outside of Whitman-Walker.

189. Patients of the LA LGBT Center report similar experiences of discrimination by other providers. One transgender patient, who developed profuse bleeding after surgery, was denied treatment at an emergency room and arrived at the LA LGBT Center in distress three days later, having lost a significant amount of blood. Another patient required extensive surgery to repair damage caused by a prior silicone breast-augmentation procedure. But she was turned down by an academic plastic-surgery center in Los Angeles because the surgeon said her health problems were caused by her own poor decision-making and she therefore would not be considered for treatment. By the time she was able to identify a surgeon who was willing to treat her, with the assistance of a physician at the LA LGBT Center, years had passed and her condition had become life-threatening. For patients at the LA LGBT Center, the ability to receive gender-affirming medical care can mean the difference between life and death.

190. In many geographic regions, a majority of LGBTQ people lack a provider whom they consider to be their personal doctor. As a result, when they seek health care services, they will encounter a health care provider with whom they do not have a relationship. This makes

them especially vulnerable to discriminatory treatment from providers who are not LGBTQ-affirming. For some medical specialties, there are only a handful of health care providers in the region who have the expertise necessary to treat a patient for a particular condition, so a denial of care from even one provider could make it practically impossible for an LGBTQ patient to receive any care at all.

191. In a recent study, nearly one in five LGBTQ people, including 31% of transgender people, said that if they were turned away from a hospital, it would be very difficult or impossible to get the health care they need elsewhere.[24] The rate was substantially higher for LGBTQ people living in non-metropolitan areas, with 41% reporting that it would be very difficult or impossible to find an alternative provider. Even when they are able to get access to care, many LGBTQ individuals report that health care professionals have used harsh language toward them, refused to touch them, used excessive precaution, or blamed the individuals for their health status.[25]

192. Consequently, LGBTQ patients are disproportionately likely to delay preventative screenings and necessary medical treatment and therefore to end up with more acute health problems and outcomes, raising concerns about patient safety. Research has identified pervasive health disparities for LGBTQ people with respect to cancer, HIV, obesity, mental health, tobacco use, and more. In other words, LGBTQ people, who are disproportionately likely to need a wide range of routine medical care, already have reason to fear, and often do fear, negative consequences of "coming out" to health care providers about their sexual orientation, history of

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[24] *See* Mirza & Rooney, *Discrimination Prevents LGBT People From Accessing Health Care*, https://perma.cc/ZG7E-7WK8.

[25] *Id.*

sexual conduct, gender identity, transgender status, history of gender-affirming medical treatment, and related medical histories.

193. The Revised Rule will exacerbate the acute health disparities LGBTQ people already face. The Revised Rule sends the message that discrimination on the basis of gender identity and sex stereotyping is permissible under federal law, which will increase the number of LGBTQ people who will be denied care.

194. The Revised Rule also encourages LGBTQ people to remain closeted to the extent possible when seeking medical care. But remaining closeted to a health care provider may result in significant adverse health consequences. For instance, a patient who conceals or fails to disclose a same-sex sexual history may not be screened for HIV or other relevant infections or cancers, or may not be prescribed preventative medications such as Pre-Exposure Prophylaxis or PrEP, which is extremely effective at preventing HIV transmission. Patients who fail fully to disclose their gender identity and sex assigned at birth may not undergo medically indicated tests or screenings (such as tests for cervical or breast cancer for some transgender men, or testicular or prostate cancer for some transgender women). The barriers to care are particularly high for transgender people. Nearly one-quarter of transgender people report delaying or avoiding medical care when sick or injured, at least partially because of fear of discrimination by and disrespect from health care providers.[26]

195. Patients remaining closeted to health care providers also results in increased costs to the health care system. For example, when a patient is closeted, medical providers may not order medically necessary tests or screenings, which has downstream effects such as

[26] *See* Mirza & Rooney, *Discrimination Prevents LGBT People From Accessing Health Care*, https://perma.cc/ZG7E-7WK8.

exacerbating a patient's distress and increasing costs to providers and the health care system as a whole for delayed treatment.

196. The Revised Rule will result in increased discrimination against LGBTQ people in the provision of health care and cause harm to the health of LGBTQ people and to public health generally.

2. Harm to Private Health Care Provider Plaintiffs, LGBTQ-Services Plaintiffs, and Health Professional Association Plaintiffs

197. The Revised Rule, which fosters discrimination against LGBTQ people in the provision of health care, frustrates plaintiffs' core missions of providing and advocating for affirming, high-quality care to all LGBTQ people and protecting against discrimination on the basis of LGBTQ status in the delivery of health care and services to patients.

198. In addition, because more LGBTQ patients will delay seeking health care, they will come to Whitman-Walker and the LA LGBT Center, the private health care provider plaintiffs who serve many LGBTQ patients, and members of the health professional association plaintiffs – GLMA and AGLP – with more acute conditions, diseases that are more advanced at diagnosis, less responsive to treatment, or no longer treatable. This delay will strain the resources of providers and increase costs for providers and patients and the health care system in general.

199. The discriminatory experiences LGBTQ patients have with other health care providers erode patients' trust in health care providers overall and thus also challenges the ability of plaintiffs to treat their patients effectively and provide appropriate services and referrals. To provide proper medical care and services to the LGBTQ community, plaintiffs rely on frank and complete communication with their patients and the individuals who seek their services. Plaintiffs need patients and individuals seeking services to fully disclose all aspects of their

health history, sexual history, and gender identity to provide appropriate care for the patients' health. Without full disclosure, plaintiffs are not able to treat adequately their patients. For instance, plaintiffs need to know patients' sexual history to know whether to test them for HIV or other infections or cancers. And plaintiffs need to be aware of patients' gender identity and sex assigned at birth to order proper screenings and tests – like cervical or breast cancer for some transgender men, or testicular or prostate cancer for some transgender women. The Revised Rule endangers the provider-patient relationship and will harm plaintiffs and their patients by discouraging full disclosure. This also means that medical and health care providers bear increased risk of malpractice when patients do not feel comfortable to fully disclose all aspects of their health history, sexual history, and gender identity.

200. The Revised Rule's effect of increasing discrimination by other providers will lead to increased demand for providers, entities, and individuals who serve the LGBTQ community, like Whitman-Walker, LA LGBT Center, the TransLatin@ Coalition (and its affiliated organizations like FLAS and Arianna's Center), Bradbury-Sullivan Center, and the members of GLMA and AGLP. This increased demand will place a strain on these plaintiffs' resources, leaving them unable to fulfill their organizational missions, spend sufficient time on each patient or individual seeking services, and provide care and services to all individuals. It also will harm LGBTQ people through increased wait times and delays of care that may worsen conditions.

201. In addition, Whitman-Walker, LA LGBT Center, the TransLatin@ Coalition (and some of its affiliated organizations like FLAS and Arianna's Center), and Bradbury-Sullivan Center, as well as the members of GLMA and AGLP and the individual provider plaintiffs, all refer patients to other health care providers. The Revised Rule will harm the ability of these

plaintiffs to refer LGBTQ patients to other providers because they will not know whether these providers will discriminate against their patients and/or refuse to treat their patients under the Revised Rule's personal religious or moral belief exemptions. Thus, these plaintiffs will be required to redirect their staff and resources from providing their own services to assisting patrons in determining who among the health care providers in the region will serve LGBTQ patients in a nondiscriminatory manner.

202. The Revised Rule also will burden the private health care provider and LGBTQ-services plaintiffs by precluding them from carrying out their organizational missions of providing affirming, non-discriminatory care to all LGBTQ patients based on the religious views of a single employee. The sweeping religious exemptions in the Revised Rule encourage individual employees to believe their discriminatory beliefs can prevail over their duties to patients – and to their fellow employees – posing barriers to patient care and creating burdens for the organizations. The private health care provider and LGBTQ-services plaintiffs may be forced to institute costly workarounds and duplicative staff to accommodate the religious views of a single employee, which also may result in unfairly burdening non-objecting employees. These increased costs also may result in a reduction of services and closure of programs, thus frustrating plaintiffs' institutional missions and core functions of providing comprehensive health care and other services to LGBTQ people.

3. Additional Harm to GLMA, AGLP, and Their Members

203. The Revised Rule also will create additional harms to the health professional association plaintiffs GLMA and AGLP, their members, the LGBTQ patients whose interests they represent, and the patients whom their members treat.

204. GLMA works with professional accreditation bodies, such as the Joint Commission, and health-professional associations, on standards, guidelines, and policies that

address LGBTQ health and protect individual patient health and public health in general. The Revised Rule prevents GLMA from achieving its goals with professional accreditation bodies by preventing such bodies from holding health care providers accountable for discrimination against LGBTQ people.

205. For a health care organization to participate in and receive federal payment from Medicare or Medicaid programs, the organization must obtain a certification of compliance with health and safety requirements. That certification is achieved based on a survey conducted either by a state agency on behalf of the federal government, or by a federally recognized national accrediting organization, like the Joint Commission. Accreditation surveys include requirements that health care organizations not discriminate on the basis of sex, sexual orientation, or gender identity in providing services or in employment. The Revised Rule presents a direct conflict with nondiscrimination standards the Joint Commission has adopted and all the major health-professional associations stating that health care providers should not discriminate in providing care for patients and clients because of sexual orientation or gender identity.

206. The Revised Rule invites health care organizations who discriminate against LGBTQ people to become accredited. The Revised Rule conflicts with GLMA's mission of achieving and enforcing accreditation standards relating to nondiscrimination.

207. Members of GLMA and AGLP also will be harmed by the Revised Rule because some members are employed by health care organizations that may rely on the religious and moral exemptions in the Revised Rule to deny care or discriminate against LGBTQ patients. The Revised Rule encourages religiously-affiliated health care employers to discriminate against employees who are GLMA or AGLP members for adhering to and enforcing their medical and

ethical obligations to treat all patients in a nondiscriminatory manner, including providing all medically-necessary care that is in LGBTQ patients' best interests.

208. In addition, the Revised Rule invites harassment and discriminatory treatment of GLMA and AGLP members in the workforce by fellow employees. The Revised Rule sends a message that discrimination against LGBTQ health care providers and their LGBTQ patients is permissible. GLMA and AGLP members and their LGBTQ patients are stigmatized and demeaned by this message that LGBTQ people are not deserving of legal protections in the health care context. The Revised Rule thus frustrates GLMA's and AGLP's missions of achieving and enforcing safe workspaces for LGBTQ health professionals and non-discriminatory health care services for their LGBTQ patients.

4. Additional Harm to the TransLatin@ Coalition, Its Members, and the Individuals it Serves

209. The Revised Rule also will harm the TransLatin@ Coalition, its members, its affiliated organizations, and the individuals whom the Coalition serves in that the harms the Revised Rule will exact on LGBTQ people, particularly those who are transgender, will be exacerbated for those with LEP. The Revised Rule's elimination of notice and tagline requirements will make it more difficult for LGBTQ people with LEP to be aware of their rights, which language services and aids are available, how to access such services, and how to handle discrimination and complaints. The health care system was already difficult to navigate for LEP individuals, and the Revised Rule serves to exacerbate those difficulties and undermines access to health care, health insurance, and legal redress. The Revised Rule will harm the TransLatin@ Coalition's mission and members by making it more difficult to access health care and by decreasing protections from discrimination.

210. The Revised Rule's elimination of the unitary standard also harms the TransLatin@ Coalition, its members, and individuals whom it serves by making it more difficult to bring claims of intersectional discrimination. Rather than being able to assert claims under a unitary standard, intersectional discrimination claims will be subject to different standards, enforcement mechanisms, and remedies based on which identities are at issue.

B. The Revised Rule Will Result in Increased Discrimination by Health Plans, Particularly Against Persons Seeking Gender-Affirming Care

211. Many private and public plans resist coverage of medically necessary procedures, whether through blanket exclusions of "sex change" or "sex transition" procedures, or through denials of coverage of specific procedures. Many plans that do not contain blanket exclusions still exclude many essential types of surgeries related to gender transition, such as facial or chest surgery.

212. Many insurers also deny coverage of other specific treatments needed to complete an individual's transition on the grounds that the procedure is "cosmetic" – either by relying on general plan language excluding cosmetic procedures or concluding that a procedure is not medically necessary. Examples of procedures that are categorically excluded as "cosmetic" in many plans and by many utilization reviewers include:

a. Surgeries of the head and face, such as hair transplant, scalp advancement, brow reduction, lip reduction or augmentation, rhinoplasty, cheek and chin contouring, jawline modification, blepheroplasty, and other facial feminization techniques for transgender women;

b. Laser hair removal and electrolysis, on the face and elsewhere on the body;

c. Surgeries involving the neck, such as cartilage reduction (modification of the Adam's Apple) and vocal feminization surgery;

d. Breast augmentation and reduction;

e. Other body contouring procedures, such as waist reduction, hip/buttocks implants, fat transfer, pectoral implants; and

f. Lessons/training to modify the vocal range.

213. Relying on its definition of "on the basis of sex" to include gender identity and to forbid discrimination against transgender individuals, the 2016 Final Rule helped persuade Medicaid administrators, insurance company personnel, and employee health plan sponsors to eliminate outdated exclusions and to agree to cover procedures when supported by evidence of medical necessity. Following its promulgation, the 2016 Final Rule led to a decrease in discriminatory policies and practices.[27] A recent study of 37 states in the federal marketplace showed that 97% of plans analyzed did not contain blanket exclusions of transition-related care in 2019.[28]

214. By eliminating the 2016 Final Rule's definition of "on the basis of sex" and the explicit prohibitions on "categorical coverage exclusion[s] or limitation[s] for all health services related to gender transition" and denials, limitations, or restrictions "for specific health services related to gender transition if such denial, limitation, or restriction results in discrimination against a transgender individual," 81 Fed. Reg. at 31,472 (formerly codified at 45 C.F.R. § 92.207(b)(4)-(5)), the Revised Rule invites reversal of much of this progress, leading to a

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[27] Gruberg & Bewkes, *The ACA's LGBTQ Nondiscrimination Regulations Prove Crucial*, https://perma.cc/CTP2-UMEJ.

[28] Out2Enroll, *Summary of Findings: 2020 Marketplace Plan Compliance with Section 1557*, https://perma.cc/WU25-C9BN. This is consistent with summaries from 2017, 2018, and 2019.

reduction in coverage and access to medically necessary health care for transgender and gender nonconforming patients.

215. In addition, the Revised Rule's narrow interpretation of what constitutes a covered entity similarly will result in a reduction in coverage and access to medically necessary health care for transgender and gender nonconforming patients.

216. Increased discrimination by health insurance plans will harm plaintiffs and the patients and individuals whom they serve. Plaintiffs that provide health care services will face increased costs because many private and public plans will refuse to cover medically necessary procedures based on the Revised Rule's elimination of protections against gender identity discrimination. Plaintiffs, in turn, will be forced to either cover the costs of these medically necessary procedures, or turn away LGBTQ patients who need these services but cannot afford to pay for them out of pocket. Likewise, patients may forgo necessary medical care due to the high cost of these procedures or cover the cost themselves.

C. The Revised Rule Will Result in Increased Discrimination towards Patients with Limited English Proficiency

217. Language access protections are required to prevent discrimination based on national origin. These services are important because ineffective communication between health care providers and LEP patients for the purposes of diagnosis, treatment options, proper use of medication, obtaining informed consent, and insurance coverage can result in adverse health consequences or death.

218. The Revised Rule eliminates the requirement that covered entities take reasonable steps to provide meaningful access to "*each individual* with LEP eligible to be served or likely to be encountered" and replaces it with a general reference to "LEP individuals." *See, e.g.*, 85 Fed.

Reg. at 37,245. However, focusing on LEP individuals in general as opposed to each individual will result in some individuals not receiving the services they need for meaningful access.

219. In addition, the Revised Rule eliminates the existing requirement that non-discrimination notices include the availability of language assistance services and taglines in the top 15 languages spoken by LEP individuals in a state. HHS "acknowledges the potential of reduced awareness of the availability of language services by LEP individuals by the changes made in this rule, or downstream effects on malpractice claims due to less awareness," 85 Fed. Reg. at 37,235, yet HHS dismissed these negative effects claiming enforcement of Section 1557 will diminish them.

220. The Revised Rule will harm LEP patients, including members of the TransLatin@ Coalition and those the Coalition and its affiliated organizations (like FLAS and Arianna's Center) serve, as well as the LEP patients private health care provider plaintiffs serve, by diminishing or eliminating meaningful access to health care because they will not be aware of their rights or the programs or services available to them.

221. The weakening of protections for LEP individuals will result not only in poorer health outcomes for LEP individuals, but also in increased costs and burdens for plaintiffs. As a result of the Revised Rule, private health care and individual provider plaintiffs will face increased burdens due to fewer clients being aware of their language access rights and the likelihood that more people will turn to them for help in their language, rather than other covered health care providers.

222. For example, the weakening of protections for LEP individuals will harm LEP patients of private health care providers who get care elsewhere and who private health care providers need to refer outside their organizations for specialty care, as they will no longer

benefit from the notices, taglines, and additional language access provisions that are critical to ensure meaningful access to care.

223. The weakening of protections also will burden private health care and individual provider plaintiffs, as well as members of health professional association plaintiffs, because patients will come to them sicker due to inadequate care elsewhere, and more people may come to them because their LEP services will remain robust.

224. In addition, the weakening of protections for LEP individuals will harm private health care providers and individual provider plaintiffs, as well as members of health professional association plaintiffs, as it will place them at an increased risk for malpractice claims linked to inadequate language access.

FIRST CLAIM FOR RELIEF
Violation of Administrative Procedure Act, 5 U.S.C. § 706(2)(A)
Arbitrary and Capricious

225. Plaintiffs repeat and incorporate by reference each allegation of the prior paragraphs as if fully set forth herein.

226. Defendants are subject to the Administrative Procedure Act ("APA"), 5 U.S.C. § 551 *et seq*.

227. The APA provides that courts must "hold unlawful and set aside agency action" that is "arbitrary, capricious, [or] an abuse of discretion." 5 U.S.C. § 706(2)(A).

228. The Revised Rule is arbitrary and capricious because defendants' justifications for repealing critical anti-discrimination protections run counter to the evidence before the agency and disregard material facts and evidence, defendants fail to supply a reasoned explanation for their policy change from the 2016 Final Rule to the Revised Rule, defendants have failed to consider important aspects of the problem, including the Revised Rule's interference with

current law, and defendants failed to account properly for the costs and benefits of the Revised Rule.

229. The Revised Rule relies primarily on a single ruling and the federal government's litigation position in the *Bostock* case and related litigation to justify HHS's rejection of long-standing authority that has defined discrimination on the basis of sex in a variety of federal civil rights laws to include discrimination against individuals who are LGBTQ. The Supreme Court now has rejected HHS's position.

230. The Revised Rule also eliminates, contrary to statutory authority, the unitary legal standard for enforcement of violations of Section 1557, replacing it with a fractured approach that will complicate and make it more difficult to bring discrimination claims under Section 1557, particularly claims of intersectional discrimination.

231. The Revised Rule's elimination of the explicit recognition of private rights of action and the availability of compensatory damages under Section 1557 also will confuse the public and mislead many individuals into not asserting their legal rights.

232. In addition, contrary to the statutory language of Section 1557, the Revised Rule imports broad and sweeping exemptions for discrimination based on personal religious or moral belief from both the named statutes in Section 1557 and other statutes, like the Religious Freedom Restoration Act (42 U.S.C. § 2000bb *et seq.*), which Section 1557 does not reference. These exemptions invite individual health care providers, health care entities (hospitals, clinics etc.), and insurers across the country to opt out of treating patients, including many transgender patients, if they believe doing so would compromise their faith. Defendants' attempt to create new religious exemptions in Section 1557 is contrary to law and endangers patients' health in the name of advancing the religious beliefs of those who are entrusted with caring for them – a result

sharply at odds with HHS's stated mission, which is to "enhance and protect the health and well-being of all Americans" and to "provid[e] for effective health and human services." It also adversely affects health care providers that serve and treat the LGBTQ community because (1) individual health care employees may decline to serve patients based on religious objections, and (2) their ability to refer patients to other providers will be impaired, as the Revised Rule invites those other providers to discriminate against their LGBTQ patients.

233. The Revised Rule also arbitrarily limits the scope of Section 1557, cutting back on the entities subject to the statute, contrary to the plain language of Section 1557.

234. Defendants also have failed to provide a sufficient explanation for the decision to eliminate the references to sexual orientation and gender identity discrimination in unrelated regulations promulgated under different statutes. Neither the evidence before the agency nor the weight of the legal authority supports the elimination of these protections.

235. Defendants also have failed to provide a sufficient explanation for the decision to eliminate protections against discrimination on the basis of association. Neither the evidence before the agency nor the weight of the legal authority supports the elimination of these protections.

236. The Revised Rule also is arbitrary and capricious in that it eliminates the requirement of notice of nondiscrimination requirements and access to language protections without adequate justification, undermining the ACA's charge to ensure individuals have access to health care and health insurance.

237. The Revised Rule fails to consider important regulatory costs, including significant direct or indirect health costs to plaintiffs, their patients, and public health and safety.

238. The Revised Rule therefore is arbitrary, capricious, [or] an abuse of discretion" in violation of the APA. 5 U.S.C. § 706(2)(A).

239. Defendants' violations cause ongoing harm to plaintiffs, their patients, the individuals they serve, and their members.

SECOND CLAIM FOR RELIEF
Violation of Administrative Procedure Act, 5 U.S.C. § 706(2)(A)
Not in Accordance with Law

240. Plaintiffs repeat and incorporate by reference each allegation of the prior paragraphs as if fully set forth herein.

241. Under the APA, a court must "hold unlawful and set aside agency action" that is "not in accordance with law." 5 U.S.C. § 706(2)(A).

242. The Revised Rule is not in accordance with law because it conflicts with the Supreme Court's ruling in *Bostock* that discrimination on the basis of a person's sexual orientation or transgender status is discrimination on the basis of sex under Title VII, and rejects the well-established understanding of "sex" under longstanding civil rights laws as including such discrimination.

243. The Revised Rule's elimination of protections based on sexual orientation and gender identity in unrelated regulations promulgated under different statutes likewise conflicts with controlling legal authority regarding the meaning of "sex."

244. The Revised Rule's elimination of protections against discrimination on the basis of association contravenes existing case law and the underlying statutes and therefore is , not in accordance with law.

245. The Revised Rule conflicts with the statutory language and purpose of Section 1557 by failing to make the enforcement mechanisms provided by Title VI, Title IX, the Age

Discrimination Act, and the Rehabilitation Act available in the case of discrimination against a person based on any characteristic protected by these statutes.

246. The Revised Rule also conflicts with the statutory language of Section 1557 by importing broad and sweeping exemptions based on personal religious or moral belief from the identified statutes in Section 1557 and other statutes, including the Religious Freedom Restoration Act (42 U.S.C. § 2000bb *et seq.*), which Section 1557 does not reference.

247. In addition, the Revised Rule conflicts with the statutory language of Section 1557 by limiting the entities covered under Section 1557.

248. The Revised Rule violates Section 1554 of the ACA, which explicitly prohibits the Secretary of HHS from promulgating any regulation that "creates any unreasonable barriers to the ability of individuals to obtain appropriate medical care" or "impedes timely access to health care services." 42 U.S.C. § 18114. The Revised Rule creates unreasonable barriers and impedes timely access to health care by reversing protections against discrimination of historically marginalized communities and eliminating access to language provisions.

249. The Revised Rule therefore is "not in accordance with law" as required by the APA. 5 U.S.C. § 706(2)(A).

250. Defendants' violations cause ongoing harm to plaintiffs, their patients, the individuals they serve, and their members.

THIRD CLAIM FOR RELIEF
Violation of Administrative Procedure Act, 5 U.S.C. § 706(2)(C)
Exceeds Statutory Authority

251. Plaintiffs repeat and incorporate by reference each allegation of the prior paragraphs as if fully set forth herein.

252. Under the APA, a court must "hold unlawful and set aside agency action" that is "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right." 5 U.S.C. § 706(2)(C).

253. Federal agencies do not have the power to act unless Congress confers the power upon them. Defendants were not given the power to alter Section 1557's statutory terms, but that is precisely what the Revised Rule attempts to do. The Revised Rule unduly limits the explicit nondiscrimination protections against sex discrimination set forth in Section 1557 by purporting to preclude claims of discrimination based on an individual's LGBTQ status. It also places health care services for LGBTQ people, gender nonconforming people, and other consumers at risk without congressional authorization to make these changes.

254. The Revised Rule's elimination of a unitary legal standard to address violations of Section 1557 and limitation on the entities covered under Section 1557 likewise is contrary to the language and intent of Section 1557 and exceeds HHS's authority.

255. The Revised Rule also amends a series of unrelated regulations to conform with the Revised Rule. The Revised Rule erases not only existing protections for LGBTQ people in the 2016 Final Rule, but eliminates such protections in other regulations, which were promulgated pursuant to the authority granted by several different statutes, including Section 1321(a) and the provisions of the ACA, Social Security Act, and other statutory authority, not Section 1557.

256. The Revised Rule also eliminates notice requirements and access to language protections, undermining the ACA's central purpose to ensure individuals have access to health care and health insurance.

257. The Revised Rule therefore is "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right" in violation of the APA. 5 U.S.C. § 706(2)(C).

258. Defendants' violations cause ongoing harm to plaintiffs, their patients, the individuals they serve, and their members.

FOURTH CLAIM FOR RELIEF
Violation of Administrative Procedure Act, 5 U.S.C. § 706(2)(B) and U.S. Constitution, Fifth Amendment, Equal Protection Component

259. Plaintiffs repeat and incorporate by reference each allegation of the prior paragraphs as if fully set forth herein.

260. Under the APA, a court must "hold unlawful and set aside agency action" that is "contrary to constitutional right, power, privilege, or immunity." 5 U.S.C. § 706(2)(B).

261. The Fifth Amendment's Due Process Clause provides that no person shall be deprived of life, liberty, or property without due process of law.

262. The Due Process Clause includes within it a prohibition against the denial of equal protection of the laws by the federal government, its agencies, or its officials or employees.

263. The purpose and effect of the Revised Rule are to discriminate against plaintiffs, their patients, the individuals they serve, and their members based on their sex, gender identity, transgender status, gender nonconformity, and exercise of their fundamental rights, including the rights to bodily integrity and autonomous medical decision-making, and the rights to live and express oneself consistent with one's gender identity.

264. The Revised Rule also is intended to have and will have a disproportionate impact on LGBTQ people. The Revised Rule places an impermissible special burden on these individuals.

265. LGBTQ people have suffered a long history of discrimination and continue to suffer that discrimination. They are part of discrete and insular groups and lack the power to protect their rights through the political process.

266. Transgender people have a gender identity that differs from the sex assigned to them at birth. A person's gender identity is a core, defining trait fundamental to a person's sense of self and personhood.

267. Requiring a person to abandon their gender identity as a condition to equal treatment violates the Equal Protection Clause.

268. Discrimination on the basis of sex, including on the basis of gender identity, transgender status, sexual orientation, and failure to conform to sex stereotypes, is presumptively unconstitutional and subject to heightened scrutiny.

269. Similarly, discrimination based on the exercise of a fundamental right is presumptively unconstitutional and is subject to strict scrutiny.

270. The Revised Rule lacks a rational or legitimate justification, let alone the important or compelling one that is constitutionally required. The Revised Rule also lacks adequate tailoring under any standard of review.

271. Defendants' encouragement of discrimination against LGBTQ people deprives LGBTQ people of their right to equal dignity and stigmatizes them as second-class citizens.

272. The Revised Rule therefore violates the Equal Protection Clause of the Fifth Amendment of the U.S. Constitution and must be set aside under the APA and the Fifth Amendment.

273. Defendants' violations cause ongoing harm to plaintiffs, their patients, the individuals they serve, and their members.

FIFTH CLAIM FOR RELIEF
Violation of Administrative Procedure Act, 5 U.S.C. § 706(2)(B)
and U.S. Constitution, Fifth Amendment, Substantive Due Process

274. Plaintiffs repeat and incorporate by reference each allegation of the prior paragraphs as if fully set forth herein.

275. Under the APA, a court must "hold unlawful and set aside agency action" that is "contrary to constitutional right, power, privilege, or immunity." 5 U.S.C. § 706(2)(B).

276. The Fifth Amendment's Due Process Clause protects individuals' substantive rights to be free to make certain decisions central to privacy, bodily autonomy, integrity, self-definition, intimacy, and personhood without unjustified governmental intrusion. Those decisions include the right to transition-related medical treatment, as well as the right to live openly and express oneself consistent with one's gender identity.

277. By encouraging health care providers and insurers to interfere with and unduly burden patients' access to medically necessary health care, the Revised Rule violates the rights of plaintiffs to privacy, liberty, dignity, and autonomy as guaranteed by the Fifth Amendment.

278. A person's gender identity and ability to live and express oneself consistent with one's gender identity without unwarranted governmental interference is a core aspect of each person's autonomy, dignity, self-definition, and personhood. By encouraging health care providers and insurers to deny or otherwise interfere with individuals' access to gender-affirming medical care, including surgical procedures, hormone therapy, and other medically necessary care, and by interfering with the ability of transgender and gender-nonconforming individuals to live and express themselves in accordance with their gender identities, the Revised Rule infringes on patients' interests in privacy, liberty, dignity, and autonomy protected by the Fifth Amendment.

279. There is no legitimate interest supporting the Revised Rule's infringement on patients' fundamental rights, let alone an interest that can survive the elevated scrutiny required to justify infringement of these fundamental rights.

280. The Revised Rule therefore violates the Due Process Clause of the Fifth Amendment of the U.S. Constitution and must be set aside under the APA and the Fifth Amendment.

281. Defendants' violations cause ongoing harm to plaintiffs, their patients, the individuals they serve, and their members.

SIXTH CLAIM FOR RELIEF
Violation of Administrative Procedure Act, 5 U.S.C. § 706(2)(B)
and U.S. Constitution, First Amendment, Free Speech

282. Plaintiffs repeat and incorporate by reference each allegation of the prior paragraphs as if fully set forth herein.

283. Under the APA, a court must "hold unlawful and set aside agency action" that is "contrary to constitutional right, power, privilege, or immunity." 5 U.S.C. § 706(2)(B).

284. The Free Speech Clause of the First Amendment to the United States Constitution declares: "Congress shall make no law . . . abridging the freedom of speech." U.S. Const. amend. I. The Free Speech Clause prohibits the government from "chilling" a person's right to free expression.

285. A person's disclosure of their transgender or gender nonconforming status, speech or expression that discloses gender identity, and a person's gendered speech and expressive conduct all receive constitutional protection under the First Amendment.

286. The Revised Rule has the purpose and effect of chilling constitutionally protected First Amendment activity. As a result of the Revised Rule, an increased number of LGBTQ

people will remain closeted in health care settings and to doctors, nurses, and other healthcare providers and will decline to disclose their sexual orientation, transgender status, or gender identity.

287. Further, an increased number of LGBTQ people will decline to engage in gendered speech and expression, including by declining to disclose related medical histories—even when that self-censorship impedes the ability of their health care providers to provide appropriate treatment and results in negative health consequences to the patients and to public health.

288. The Revised Rule will chill a patient of ordinary firmness from making such disclosures.

289. The Revised Rule violates the Free Speech Clause of the First Amendment because it impermissibly burdens the exercise of patients' constitutionally protected speech, expression and expressive conduct based on the content and viewpoint of patients' speech.

290. In addition, the Revised Rule is overbroad because it will chill protected First Amendment activity.

SEVENTH CLAIM FOR RELIEF
Violation of Administrative Procedure Act, 5 U.S.C. § 706(2)(B) and U.S. Constitution, First Amendment, Establishment Clause

291. Plaintiffs repeat and incorporate by reference each allegation of the prior paragraphs as if fully set forth herein.

292. Under the APA, a court must "hold unlawful and set aside agency action" that is "contrary to constitutional right, power, privilege, or immunity." 5 U.S.C. § 706(2)(B).

293. The Establishment Clause of the First Amendment to the United States Constitution declares: "Congress shall make no law respecting an establishment of religion."

U.S. Const. amend. I. The Establishment Clause prohibits the government from favoring one religion over another, or religion over nonreligion.

294. The Establishment Clause permits the government to provide religious accommodations or exemptions from generally applicable laws only if, among other requirements, the accommodation (1) lifts a substantial, government-imposed burden on the exercise of religion, and (2) does not shift substantial costs or burdens onto a discrete class of third parties, without regard for the third parties' interests. In other words, the government may "accommodate" religion in accordance with the Free Exercise Clause, but it may not "promote" religion.

295. The Revised Rule violates the Establishment Clause by creating expansive religious exemptions for health care providers, plans, and employees at the expense of third parties – namely, plaintiffs, other providers, and most importantly the patients and the individuals whom plaintiffs serve. It invites health care providers, including insurance companies, hospitals, doctors, and nurses, to deny LGBTQ patients necessary medical treatment based on their religious beliefs.

296. The effect of the Revised Rule will be that patients who seek care at odds with the religious beliefs of a health care provider or employee of a health care provider may be delayed in receiving care (including emergency care) or denied care altogether.

297. The Revised Rule also will burden plaintiffs by precluding them from carrying out their organizational missions based solely on the religious views of a single employee.

298. In addition, plaintiffs will be harmed because their ability to refer LGBTQ patients to other providers will be affected in that they will not know whether these providers will discriminate against their patients and/or refuse to treat their patients under the Revised

Rule's personal religious or moral belief exemptions. Plaintiffs thus will be required to redirect their staff and resources from providing their own services to assisting patrons in determining who among the health care providers in the region will serve LGBTQ patients in a nondiscriminatory manner.

299. The Revised Rule violates the Establishment Clause because it:

(a) has the primary purpose and effect of favoring, preferring, and endorsing certain religious beliefs and certain religious denominations over others and over nonreligion;

(b) has the primary purpose and effect of preferring the religious beliefs of some people and institutions over the lives, health, and other rights and interests of third parties;

(c) impermissibly entangles government with religion;

(d) makes plaintiffs, their patients, and other third parties bear the costs and harms of objecting employees' religious beliefs or religious exercise; and

(e) imposes on plaintiffs a requirement to accommodate employees' religious objections without taking constitutionally required account of the actual burdens (if any) on the objectors or the effects on or harms to plaintiffs, their patients, or the greater public health.

300. Those who are denied coverage will suffer the stigma of government-sanctioned discrimination. They also will be forced to either endure significant psychological burdens or, if they can afford it, pay for treatment out-of-pocket. The Revised Rule favors religion at the expense of LGBTQ patients without regard for LGBTQ patients' interests. The Revised Rule contains no provision for balancing or accounting for a patient's right to care. Instead, it applies

categorically to deny patients the right to medical treatment based on a provider's religious or moral beliefs.

301. The Revised Rule therefore violates the Establishment Clause of the First Amendment of the U.S. Constitution and must be set aside under the APA and the Establishment Clause.

302. Defendants' violations cause ongoing harm to plaintiffs, their patients, the individuals they serve, and their members.

EIGHTH CLAIM FOR RELIEF
Equitable Relief to Preserve Remedy

303. Plaintiffs repeat and incorporate by reference each allegation of the prior paragraphs as if fully set forth herein.

304. The Revised Rule will become effective on August 18, 2020 unless it is enjoined. Plaintiffs are entitled to a full, fair, and meaningful process to adjudicate the lawfulness of the Revised Rule before being required to implement its far-reaching and harmful requirements.

305. Plaintiffs will suffer irreparable injury by implementation of the Revised Rule, which would erode hard-won trust between LGBTQ people and their health care providers, stigmatize and traumatize patients, interfere with medical procedures and operations, and result in delays and denials of care leading to physical harm and even death. Preliminary and permanent injunctive relief is needed to ensure that plaintiffs' injuries are fully remedied.

306. Injunctive relief also is needed to prevent the immediate harm resulting from the Revised Rule. Patients need assurance that they will receive complete, accurate information and timely and responsive medical care in an environment that protects their constitutional rights and does not expose them to stigma and harm. This Court should step in to protect plaintiffs' institutions, their patients, the individuals they serve, and their members, in addition to the

foremost principle guiding medical providers in responding to those in need of assistance and care – first, do no harm.

307. Accordingly, to ensure that plaintiffs receive meaningful relief should they prevail in this action, the Court should preliminarily and permanently enjoin defendants from implementing the Revised Rule.

REQUEST FOR RELIEF

Wherefore, plaintiffs pray that the Court grant the following relief:

A. Declare that the Revised Rule is unlawful and unconstitutional through a declaratory judgment under 28 U.S.C. § 2201(a) and 5 U.S.C. § 706(a);

B. Set aside and vacate the Revised Rule;

C. Preliminarily and permanently enjoin the implementation and enforcement of the Revised Rule;

D. Award reasonable attorneys' fees, costs, and expenses; and

E. Award any other further and additional relief the Court deems just and proper.

Dated: June 22, 2020

Respectfully submitted,

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** Motion for admission pro hac vice pending.*

*** Application for admission to U.S. District Court for the District of Columbia forthcoming.*

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EXHIBIT 1

AUTHENTICATED U.S. GOVERNMENT INFORMATION GPO

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Part IV

Department of Health and Human Services

Office of the Secretary

45 CFR Part 92

Nondiscrimination in Health Programs and Activities; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

45 CFR Part 92

RIN 0945–AA02

Nondiscrimination in Health Programs and Activities

AGENCY: Office for Civil Rights (OCR), Office of the Secretary, HHS.

ACTION: Final rule.

SUMMARY: This final rule implements 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. The final rule clarifies and codifies existing nondiscrimination requirements and sets forth new standards to implement Section 1557, particularly with respect to the prohibition of discrimination on the basis of sex in health programs other than those provided by educational institutions and the prohibition of various forms of discrimination in health programs administered by the Department of Health and Human Services (HHS or the Department) and entities established under Title I of the ACA. In addition, the Secretary is authorized to prescribe the Department's governance, conduct, and performance of its business, including, here, how HHS will apply the standards of Section 1557 to HHS-administered health programs and activities.

DATES: *Effective Date:* This rule is effective July 18, 2016.

Applicability Dates: The provisions of this rule are generally applicable on the date the rule is effective, except to the extent that provisions of this rule require changes to health insurance or group health plan benefit design (including covered benefits, benefits limitations or restrictions, and cost-sharing mechanisms, such as coinsurance, copayments, and deductibles), such provisions, as they apply to health insurance or group health plan benefit design, have an applicability date of the first day of the first plan year (in the individual market, policy year) beginning on or after January 1, 2017.

FOR FURTHER INFORMATION CONTACT: Eileen Hanrahan at (800) 368–1019 or (800) 537–7697 (TDD).

SUPPLEMENTARY INFORMATION:

Electronic Access

This **Federal Register** document is also available from the **Federal Register** online database through *Federal Digital System (FDsys),* a service of the U.S. Government Printing Office. This database can be accessed via the Internet at *http://www.gpo.gov/fdsys.*

I. Background

Section 1557 of the ACA provides that an individual shall not, on the grounds prohibited under Title VI of the Civil Rights Act of 1964 (Title VI), 42 U.S.C. 2000d *et seq.* (race, color, national origin), Title IX of the Education Amendments of 1972 (Title IX), 20 U.S.C. 1681 *et seq.* (sex), the Age Discrimination Act of 1975 (Age Act), 42 U.S.C. 6101 *et seq.* (age), or Section 504 of the Rehabilitation Act of 1973 (Section 504), 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 Title I of the Act or its amendments. Section 1557 states that the enforcement mechanisms provided for and available under Title VI, Title IX, Section 504, or the Age Act shall apply for purposes of addressing violations of Section 1557.

Section 1557(c) of the ACA authorizes the Secretary of the Department to promulgate regulations to implement the nondiscrimination requirements of Section 1557. In addition, the Secretary is authorized to prescribe regulations for the Department's governance, conduct, and performance of its business, including how HHS applies the standards of Section 1557 to HHS-administered health programs and activities.[1]

A. Regulatory History

On August 1, 2013, the Office for Civil Rights of the Department (OCR) published a Request for Information (RFI) in the **Federal Register** to solicit information on issues arising under Section 1557. OCR received 402 comments; one-quarter (99) were from organizational commenters, with the remainder from individuals.

On September 8, 2015, OCR issued a proposed rule, ''Nondiscrimination in Health Programs and Activities,'' in the **Federal Register**, and invited comment on the proposed rule by all interested parties.[2] The comment period ended on November 9, 2015. In total, we received approximately 24,875 comments on the proposed rule. 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 organizations, and organizations serving lesbian, gay, bisexual, or transgender (LGBT) 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 organizations. Of the total comments, 23,344 comments were from individuals. The great majority of those comments were letters from individuals that were part of mass mail campaigns organized by civil rights/advocacy groups.

B. Overview of the Final Rule

This final rule adopts the same structure and framework as the proposed rule: 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.

OCR has made some changes to the proposed rule's provisions, based on the comments we received. Among the significant changes are the following.

Section 92.4 now provides a definition of the term ''national origin.''

OCR decided against including a blanket religious exemption in the final rule; however, the final rule includes a provision noting that insofar as application of any requirement under the rule would violate applicable Federal statutory protections for religious freedom and conscience, such application would not be required.

OCR has modified the notice requirement in § 92.8 to exclude publications and significant communications that are small in size from the requirement to post all of the content specified in § 92.8; instead, covered entities will be required to post only a shorter nondiscrimination statement in such communications and publications, along with a limited number of taglines. OCR also is translating a sample nondiscrimination statement that covered entities may use in fulfilling this obligation. It will be available by the effective date of this rule.

In addition, with respect to the obligation in § 92.8 to post taglines in at least the top 15 languages spoken nationally by persons with limited English proficiency, OCR has replaced the national threshold with a threshold

[1] 5 U.S.C. 301.

[2] 80 FR 54172 (Sept. 8, 2015).

requiring taglines in at least the top 15 languages spoken by limited English proficient populations statewide.

OCR has changed § 92.101 to provide that sex-specific health programs or activities are allowable only where the covered entity can demonstrate an exceedingly persuasive justification, *i.e.,* that the sex-specific program is substantially related to the achievement of an important health-related or scientific objective.

OCR has changed § 92.201, addressing the obligation to take reasonable steps to provide meaningful access. That section now requires the Director to 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 to take into account all other relevant factors, including whether the entity has developed and implemented an effective language access plan, appropriate to its particular circumstances. The final rule deletes the specific list of illustrative factors set out in the proposed rule.

Also, OCR has changed § 92.203, addressing accessibility of buildings and facilities for individuals with disabilities, to require covered entities that were covered by the 2010 Americans with Disabilities Act (ADA) Standards for Accessible Design prior to the effective date of this final rule to comply with those standards for new construction or alterations by the effective date of the final rule. The final rule also narrows § 92.203's safe harbor for building and facility accessibility so that compliance with the Uniform Federal Accessibility Standards (UFAS) will be deemed compliance with this part only if construction or alteration was commenced before the effective date of the final rule and the facility or part of the facility was not covered by standards under the ADA. As nearly all covered entities under the final rule are already covered by the ADA standards, these changes impose a de minimis cost.

Section 92.301 has been changed to clarify that compensatory damages for violations of Section 1557 are available in administrative and judicial actions to the extent they are available under the authorities referenced in Section 1557. Finally, we have added a severability clause to § 92.2, to indicate our intention that the rule be construed to give the maximum effect permitted by law to each provision.

In responding to the comments it received on the proposed rule, OCR has provided a thorough explanation of each of these changes in the preamble. OCR has also clarified some of the nondiscrimination requirements of Section 1557 and made some technical changes to the rule's provisions. In addition, we have added some definitions to proposed § 92.4, as summarized in the preamble to this final rule.

II. Provisions of the Proposed Rule and Analysis and Responses to Public Comments

A. General Comments

OCR received a large number of comments asking that we categorically declare in the final rule that certain actions are or are not discriminatory. For example, some commenters asked that OCR state that a modification to add medically necessary care, or a prohibition on exclusions of medically necessary services, is never a fundamental alteration to a health plan. Similarly, other commenters asked that OCR include a statement in the final rule that an issuer's refusal to cover core services commonly needed by individuals with intellectual disabilities is discrimination on the basis of disability. Still other commenters asked that OCR state that limiting health care and gender transition services to transgender individuals over the age of 18 is discriminatory. Other commenters asked that OCR state that it is discriminatory to require individuals with psychiatric disabilities to see a mental health professional in order to continue receiving treatment for other conditions.

Many of these same commenters asked that OCR supplement the final rule with in-depth explanations and analyses of examples of discrimination. For example, several commenters asked that OCR add an example of discrimination in research trials. Similarly, many other commenters asked that OCR add an example of what they considered to be disability discrimination in health insurance practices, such as higher reimbursement rates for care in segregated settings.

OCR appreciates the commenters' desire for further information on the application of the rule to specific circumstances. OCR's intent in promulgating this rule is to provide consumers and covered entities with a set of standards that will help them understand and comply with the requirements of Section 1557. Covered entities should bear in mind the purposes of the ACA and Section 1557—to expand access to care and coverage and eliminate barriers to access—in interpreting requirements of the final rule. But we neither address every scenario that might arise in the application of these standards nor state that certain practices as a matter of law are ''always'' or ''never'' permissible. The determination of whether a certain practice is discriminatory typically requires a nuanced analysis that is fact-dependent. Nonetheless, OCR has included in the preamble a number of examples of issues and circumstances that may raise compliance concerns under the final rule.

OCR also received several comments, primarily from representatives of the insurance industry, recommending that where specific Centers for Medicare & Medicaid Services (CMS) or State requirements apply to covered entities, OCR should either (1) harmonize all standards with existing CMS rules, or (2) allow issuers to be deemed compliant with Section 1557 if they are compliant with existing Federal or State law. For example, some commenters requested that compliance with CMS regulations that pertain to qualified health plans or insurance benefit design, such as prescription drug formularies designed by a pharmacy and therapeutics committee, be deemed compliance with the final rule on Section 1557. These commenters were concerned that CMS or a State might approve a plan that OCR might later find discriminatory. The commenters sought clarification on how OCR will handle cases involving health plans regulated by multiple authorities, and suggested that a ''deeming'' approach would reduce confusion and avoid duplication of costs and administrative effort. Other commenters asked that compliance with language access standards promulgated by CMS or the States be deemed compliance with the final rule; those comments are discussed in more detail in the preamble at § 92.201.

OCR recognizes the efficiencies inherent in harmonizing regulations to which covered entities are subject under various laws. Indeed, entities covered under Section 1557 are likely also subject to a host of other laws and regulations, including CMS regulations, the Genetic Information Nondiscrimination Act of 2008,[3] the Family and Medical Leave Act, the ADA, Title VII of the Civil Rights Act of 1964, and State laws. OCR will coordinate as appropriate with other Federal agencies to avoid inconsistency and duplication in enforcement efforts.

That said, OCR declines to adopt a deeming approach whereby compliance with another set of laws or regulations automatically constitutes compliance with Section 1557. As to State laws, it

[3] Public Law 110–233, 122 Stat. 881 (2008).

is inappropriate to define requirements under Federal law based on what could be the varying, and potentially changing, requirements of different States' approaches. As to other Federal laws, OCR will give consideration to an entity's compliance with the requirements of other Federal laws where those requirements overlap with Section 1557. In such cases, OCR will work closely with covered entities where compliance with this final rule requires additional steps. But in the final analysis, OCR must, in its capacity as the lead enforcement agency for Section 1557, maintain the discretion to evaluate an entity's compliance with the standards set by the final rule. This is consistent with the approach taken by other agencies to civil rights obligations, in which compliance with one set of requirements, adopted under different laws or for different purposes, is not considered automatic compliance with civil rights obligations.

Subpart A—General Provisions

Purpose and Effective Date (§ 92.1)

In § 92.1, we proposed that the purpose of this part is to implement Section 1557 of the ACA, which prohibits discrimination in certain health programs and activities on the grounds prohibited under Title VI, Title IX, the Age Act, and Section 504, which together prohibit discrimination on the basis of race, color, national origin, sex, age, or disability.

We also proposed that the effective date of the Section 1557 implementing regulation shall be 60 days after the publication of the final rule in the **Federal Register**.

The comments and our responses regarding the proposed effective date are set forth below.

Comment: Some commenters asserted that 60 days after publication of the final rule did not allow sufficient time for entities to come into compliance with Section 1557 and requested that the effective date be one year after publication of the final rule. Similarly, one commenter stated that State agencies covered by Section 1557 need at least 150 days to come into compliance with Section 1557. The commenter stated that State agencies need additional time to assess the impacts, align nondiscrimination requirements from multiple Federal agencies, and make the required policy, operational, and system changes.

Response: OCR does not believe that extending the effective date beyond 60 days is warranted, except with regard to specific provisions for which there is a later applicability date, as set forth below. Most of the requirements of Section 1557 are not new to covered entities, and 60 days should be sufficient to come into compliance with any new 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 § 92.1 with one modification. We recognize that some covered entities will have to make changes to their health insurance coverage or other health coverage to bring that coverage into compliance with this final rule. We are sensitive to the difficulties that making changes in the middle of a plan year could pose for some covered entities and are committed to working with covered entities to ensure that they can comply with the final rule without causing excessive disruption for the current plan year. Consequently, to the extent that provisions of this rule require changes to health insurance or group health plan benefit design (including covered benefits, benefits limitations or restrictions, and cost-sharing mechanisms, such as coinsurance, copayments, and deductibles), such provisions, as they apply to health insurance or group health plan benefit design, have an applicability date of the first day of the first plan year (in the individual market, policy year) beginning on or after January 1, 2017.

Application (§ 92.2)

Section 92.2 of the proposed rule stated that Section 1557 applies to all health programs and activities, any part of which receives Federal financial assistance from any Federal agency. It also stated that Section 1557 applies to all programs and activities that are administered by an Executive Agency or any entity established under Title I of the ACA.

In paragraph (a), we proposed to apply the proposed rule, except as otherwise provided in § 92.2, to: (1) All health programs and activities, any part of which receives Federal financial assistance administered by HHS; (2) health programs and activities administered by the Department, including the Federally-facilitated Marketplaces; and (3) health programs and activities administered by entities established under Title I of the ACA, including the State-based Marketplaces.

In paragraph (b), we proposed limitations to the application of the final rule. We proposed the adoption of the existing limitations and exceptions that already, under the statutes referenced in Section 1557, govern the health programs and activities subject to Section 1557. We noted that these limitations and exceptions are found in the Age Act and in the regulations implementing the Age Act, Section 504, and Title VI, which apply to all programs and activities that receive Federal financial assistance.

In paragraph (b)(1), we proposed to incorporate the exclusions found in the Age Act, such that the provisions of the proposed rule would not apply to any age distinction contained in that part of a Federal, State, or local statute or ordinance adopted by an elected, general purpose legislative body which provides any benefits or assistance to persons based on age, establishes criteria for participation in age-related terms, or describes intended beneficiaries to target groups in age-related terms.[4] We requested comment on whether the exemptions found in Title IX and its implementing regulation should be incorporated into the final rule. We noted that unlike the Age Act, Section 504, and Title VI, which apply to all programs and activities that receive Federal financial assistance (including health programs and activities), Title IX applies only in the context of education programs and not to the majority of the health programs and activities subject to the proposed rule. In addition, we noted that many of Title IX's limitations and exceptions do not readily apply in a context that is grounded in health care, rather than education.

We invited comment on whether the regulation should include any specific exemptions for health service providers, health plans, or other covered entities with respect to requirements of the proposed rule related to sex discrimination. We stated that we wanted to ensure that the proposed rule had the proper scope and appropriately protected sincerely held religious beliefs to the extent that those beliefs may conflict with provisions of the proposed regulation. We noted that certain protections already exist with respect to religious beliefs, particularly with respect to the provision of certain health-related services; for example, we noted that the proposed rule would not displace the protections afforded by provider conscience laws,[5] the Religious Freedom Restoration Act (RFRA),[6] provisions in the ACA related to abortion services,[7] or regulations issued

[4] *See* 42 U.S.C. 6103(b).

[5] *See, e.g.,* 42 U.S.C. 300a–7; 42 U.S.C. 238n; Consolidated and Further Continuing Appropriations Act 2015, Public Law 114–53, Div. G, § 507(d) (Dec. 16, 2015).

[6] 42 U.S.C. 2000bb–1.

[7] *See, e.g.,* 42 U.S.C. 18023.

under the ACA related to preventive health services.[8] We invited comment on the extent to which these existing protections provide sufficient safeguards for any religious concerns in applying Section 1557.

We noted that a fundamental purpose of the ACA is to ensure that health services are available broadly on a nondiscriminatory basis to individuals throughout the country. Thus, we requested comment on any health care consequences that would ensue were the regulation to provide additional exemptions.

We also requested comment on the scope of additional exemptions, if any, that should be included and the processes for claiming them, including whether those processes should track those used under Title IX, at 45 CFR 86.12.

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

Comment: Some commenters recommended that the final rule apply not only to health programs and activities receiving Federal financial assistance from the Department, but to health programs and activities receiving Federal financial assistance from other Departments. The commenters noted that in enacting Section 1557, Congress delegated rulemaking authority to the Department; they therefore maintained that the Department has the authority to promulgate rules that apply to other Departments. Commenters further noted that the Department has greater expertise in the application of civil rights laws to health programs and activities than do other Departments, and further urged that HHS regulations applicable to health programs and activities receiving Federal financial assistance from other Departments would be afforded deference under *Chevron U.S.A.* v. *NRDC, Inc.*[9]

In the alternative, commenters recommended that we collaborate with other Departments to effectuate the provisions of the final rule and ensure that other Departments enter into delegation agreements or Memoranda of Understanding that grant HHS interpretation and enforcement authority over health programs funded and administered by other Departments or that commit other Departments to move quickly to engage in their own rulemaking on Section 1557.

Response: While the rule recognizes that Section 1557 itself applies to health programs and activities receiving Federal financial assistance from other Departments, we decline to extend the scope of the rule to health programs and activities receiving Federal financial assistance from other Departments. Drafting a rule applicable to health programs and activities assisted by other Departments would pose numerous challenges, one of which is that the Department lacks the information and expertise necessary to apply the rule to those programs without further engagement and collaboration with those Departments. We agree that expeditious implementation of Section 1557 by other Departments is desirable, and hope that the Department's final rule will inform enforcement of Section 1557 by other Departments with respect to their federally assisted health programs and activities. To this end, the OCR Director sent a memorandum encouraging coordination of enforcement responsibilities under Section 1557 to all Federal agencies in November 2015.

Comment: Commenters recommended that the final rule apply not just to programs administered by HHS, but also to programs administered by other Departments.

Response: We decline to make the rule applicable to programs administered by other Departments. We will, however, continue to work with other Departments that administer health programs and activities to help those Departments ensure that their programs are nondiscriminatory.

Comment: Many commenters responded to the proposed rule's request for comment on whether the rule should include a religious exemption for health care providers, health plans, or other covered entities with respect to the requirements of the rule related to sex discrimination, or whether existing protections, including RFRA, ACA regulations for preventive health services, and Federal provider conscience laws provide sufficient safeguards for religious concerns.

Most of the organizations that commented on this issue, including professional medical associations and civil rights organizations, and the overwhelming majority of individual commenters, many of whom identified themselves as religious, opposed any religious exemption on the basis that it would potentially allow for discrimination on the bases prohibited by Section 1557 or for the denial of health services to women. Several religious organizations also opposed a religious exemption, asserting that RFRA, the Federal provider conscience statutes, and State RFRA statutes, which many States have enacted, provide sufficiently strong protections for religious providers and institutions. Many commenters said that mergers of religiously-affiliated hospitals with other hospitals have deepened concerns that would be raised by providing a religious exemption, as the mergers may leave individuals in many communities with fewer health care options offering the full range of women's health services. Many commenters also pointed to the language in the majority opinion in the Supreme Court's decision in *Hobby Lobby* v. *Burwell* that RFRA is not a shield that permits discrimination ''cloaked as religious practice to escape legal sanction.''[10]

Some religious organizations that submitted comments strongly supported a religious exemption, arguing that faith-based health care providers and employers would be substantially burdened if required to provide or refer for, or purchase insurance covering, particular services such as gender transition services. Supporters of an exemption recommended that Section 1557 incorporate the religious exemption in Title IX, which exempts educational institutions controlled by religious organizations from the prohibition of sex discrimination if the application would be inconsistent with the religious tenets of the organization.[11] None of the commenters supporting a religious exemption asserted that there would be a religious basis for generally refusing to treat LGBT individuals for a medical condition, for example, refusing to treat a broken bone or cancer; rather, commenters asserted that the rule should exempt faith-based providers from providing particular services, such as services related to gender transition, that are inconsistent with their religious beliefs.

Response: As noted in the preamble to the proposed rule, certain protections already exist in Federal law with respect to religious beliefs, particularly with regard to the provision of certain health-related services. For example, we noted that the proposed rule would not displace the protections afforded by provider conscience laws,[12] RFRA,[13] provisions in the ACA related to abortion services,[14] or regulations issued under the ACA related to preventive health services.[15] Nothing in

[8] *See* 45 CFR 147.131.

[9] 467 U.S. 837 (1984).

[10] 132 S. Ct. 2751, 2783 (2014).

[11] 20 U.S.C. 1681(a)(3).

[12] *See, e.g.,* 42 U.S.C. 300a–7; 42 U.S.C. 238n; Consolidated and Further Continuing Appropriations Act 2015, Pub. L. 114–53, Div. G, § 507(d) (Dec. 16, 2015).

[13] 42 U.S.C. 2000bb–1.

[14] *See, e.g.,* 42 U.S.C. 18023.

[15] *See* 45 CFR 147.131.

this final rule displaces those protections.

Although some commenters urged us also to incorporate Title IX's blanket religious exemption into this final rule, we believe that applying the protections in the laws identified above offers the best and most appropriate approach for resolving any conflicts between religious beliefs and Section 1557 requirements. With regard to abortion, for example, specific ACA provisions concerning abortion will continue to control, including, but not limited to, provisions that bar qualified health plans offered through a Marketplace℠ [16] from discriminating against an individual health care provider or health care facility because of its unwillingness to provide, pay for, provide coverage of, or refer for abortions,[17] and provisions that state that nothing in the ACA shall be construed to require a qualified health plan to provide coverage of abortion as an essential health benefit.[18]

In other cases, application of RFRA is the proper means to evaluate any religious concerns about the application of Section 1557 requirements. The RFRA analysis evaluates whether a legal requirement substantially burdens the exercise of religion; if so, the question becomes whether the legal requirement furthers a compelling interest and is the least restrictive means to further that interest.

We believe that the government has a compelling interest in ensuring that individuals have nondiscriminatory access to health care and health coverage and, under RFRA, would assess whether a particular application of Section 1557 substantially burdened a covered entity's exercise of religion and, if so, whether there were less restrictive alternatives available. Claims under RFRA are individualized and fact specific and we would make these determinations on a case-by-case basis, based on a thorough analysis and relying on the extensive case law interpreting RFRA standards.

We decline to adopt commenters' suggestion that we import Title IX's blanket religious exemption [19] into Section 1557. Section 1557 itself contains no religious exemption. In addition, Title IX and its exemption are limited in scope to educational institutions, and there are significant differences between the educational and health care contexts that warrant different approaches.

First, students or parents selecting religious educational institutions typically do so as a matter of choice; a student can attend public school (if K–12) or choose a different college. In the health care context, by contrast, individuals may have limited or no choice of providers, particularly in rural areas or where hospitals have merged with or are run by religious institutions. Moreover, the choice of providers may be even further circumscribed in emergency circumstances.

Second, a blanket religious exemption could result in a denial or delay in the provision of health care to individuals and in discouraging individuals from seeking necessary care, with serious and, in some cases, life threatening results. Thus, it is appropriate to adopt a more nuanced approach in the health care context, rather than the blanket religious exemption applied for educational institutions under Title IX.

Based on the foregoing, we have included a provision in this final regulation making clear that where application of this regulation would violate applicable Federal statutory protections for religious freedom and conscience, that application will not be required. The Department also retains the discretion to provide other accommodations or exemptions where permitted by Federal law and supported by sound public policy.

Comment: One commenter suggested that we clarify that the regulation applies only to a covered entity's health operations ''in the United States.''

Response: This regulation applies only to individuals who are subjected to discrimination, at least in part, in the United States and to the provision or administration of health-related services or health-related insurance coverage in the United States, consistent with the four statutes referenced in Section 1557.[20]

Consistent with the Department's Title VI regulation,[21] OCR interprets ''United States'' to include the U.S. territories. The definition of ''recipient'' of Federal financial assistance in the civil rights laws referenced in Section 1557 does not contain geographic limitations, and includes, in addition to States and political subdivisions, other ''public or private agenc[ies], institution[s], or organization[s].'' [22] Thus, health programs and activities of the U.S. Territories, and those provided or administered in the U.S. Territories, are covered by the final rule.[23]

Comment: One commenter requested that we clarify that expatriate health plans, plan sponsors of self-funded expatriate health plans, and issuers of fully-insured expatriate health plans are exempt from Section 1557 pursuant to the Expatriate Health Coverage Clarification Act of 2014 (EHCCA),[24] which provides generally that provisions of the ACA do not apply to expatriate health plans, employer plan sponsors of expatriate health plans, or expatriate health insurance issuers. The commenter noted that the EHCCA does not include any exceptions or special rules pertaining to Section 1557; thus, the commenter asserted, applying Section 1557 to expatriate health plans would be contrary to Congressional intent and would competitively disadvantage American health issuers in the global marketplace, resulting in consumers choosing offshore options and American issuers moving their plans offshore to compete.

Response: Section 3(a) [25] of the EHCCA specifies that the provisions of (including any amendment made by) the ACA and Title I and subtitle B of Title II of the Health Care and Education Reconciliation Act of 2010 shall not apply with respect to expatriate health plans; employers with respect to such plans, solely in their capacity as plan sponsors for such plans; or expatriate health insurance issuers with respect to coverage offered by such issuers under such plans, subject to the exceptions and special rules enumerated in Sections 3(B) and 3(C) of the EHCCA. Section 1557 is contained in Title I of the ACA; thus, pursuant to the EHCCA, Section 1557 does not apply with respect to expatriate health plans, expatriate health insurance issuers, or employer plan sponsors of expatriate plans, as defined in the EHCCA.

Comment: Tribes and tribal organizations submitted comments recommending that we make a number of changes throughout the rule and preamble to address the application of the rule to tribes and tribal health programs. Commenters objected to the characterization of 45 CFR 80.3(d), the exception in the Title VI regulation for

[16] Health Insurance Marketplace℠ and Marketplace℠ are service marks of the U.S. Department of Health and Human Services.

[17] 42 U.S.C. 18023(b)(4).

[18] 42 U.S.C. 18023(b)(1)(A).

[19] 42 U.S.C. 18116(a).

[20] 20 U.S.C. 1681(a); 29 U.S.C. 794(a); 42 U.S.C. 2000d; 42 U.S.C. 6102.

[21] 45 CFR 80.13(e).

[22] 45 CFR 80.13(i) (Title VI); 84.3(f) (Section 504); 86.2(i) (Title IX); 90.4 (Age Act).

[23] OCR notes that in contrast to Section 1557, which does not refer to the United States or to ''states,'' other ACA provisions refer to ''states'' and the Department has interpreted the meaning of ''state'' in the context of those statutory requirements. See 45 CFR 144.103.

[24] Consolidated and Further Continuing Appropriations Act, 2015, Public Law 113–235, Div. M, § 3 (codified at 42 U.S.C. 18014).

[25] 42 U.S.C. 18014(f).

Indian health programs and other programs limited by Federal law to individuals of a particular race, color, or national origin, that has been incorporated into the Section 1557 rule, and recommended that we refer to 45 CFR 80.3(d) throughout and describe it rather than simply cite to it. Commenters asked us to exempt tribes and tribal health programs from § 92.207 and § 92.208 and make clear that tribal governments and health programs can limit insurance to their members. Commenters asserted that Purchased/Referred Care [26] programs should be permitted to limit coverage and be held harmless for discrimination on the basis of disability, age, or sex. One commenter recommended several additional changes to the rule to address its application to tribes, including excluding tribes and tribal health programs from the definitions of ''covered entity'' and ''health program or activity,'' and excluding assistance to tribes and tribal health programs from the definition of ''Federal financial assistance,'' along with other changes intended to achieve this purpose. Commenters stated that the changes proposed were necessary to reflect the full scope of protections in Federal law for tribal classifications and tribal sovereignty.

Response: 45 CFR 80.3(d) is not an exemption from coverage; it provides an exception to application of the prohibitions on race, color, and national origin discrimination when programs are authorized by Federal law to be restricted to a particular race, color, or national origin. The final rule incorporates that exception, and OCR will fully apply it, as well as other exemptions or defenses that may exist under Federal law. OCR intends to address any restrictions on application of the law to tribes in the context of individual complaints.

Comment: One tribal organization commented that tribal consultation on development of the rule was insufficient.

Response: We engaged in tribal consultation on the rule and, during that consultation, encouraged tribes and tribal organizations to submit comments on the proposed rule. Many did so. We believe that tribal consultation was sufficient.

Comment: One tribal organization stated that the reference to Indian Health Services (IHS) programs in the preamble was misleading, as some IHS programs are administered directly by tribes.

Response: We agree that the reference to IHS programs as an example of a federally administered program may be confusing, given that some IHS programs are administered directly by tribes. We have therefore changed the reference to ''IHS programs'' to ''IHS programs administered by IHS.''

Finally, we have added a severability clause to § 92.2, to indicate our intention that the rule be construed to give the maximum effect permitted by law to each provision. The rule provides that if a provision is held to be unenforceable in one set of circumstances, it should be construed to give maximum effect to the provision as applied to other persons or circumstances. Similarly, if a provision is held to be invalid or unenforceable, that provision should be severable from, and have no impact on the application of, the remainder of the rule. This provision is consistent with our interpretation of the Department's regulations implementing Title VI, Title IX, Section 504, and the Age Act.

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 two modifications. We are adding § 92.2(b)(2), which clarifies that if an application of Section 1557 requirements or this part would violate applicable Federal statutory protections for religious freedom and conscience, application of Section 1557 is not required. In addition, we have added § 92.2(c), containing a severability clause.

Relationship to Other Laws (§ 92.3)

In § 92.3 of the proposed rule, we proposed an explanation of the relationship of the rule to existing laws. Paragraph (a) proposed that Section 1557 is not intended 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. Consistent with the statute, paragraph (b) proposed that nothing in this part shall be interpreted to invalidate or limit the existing rights, remedies, procedures, or legal standards available to individuals aggrieved under other Federal civil rights laws or to supersede State or local laws that provide greater or equal protection against discrimination on the basis of race, color, national origin, sex, age, or disability. OCR explained that this intent is derived from Section 1557(b) of the ACA. In addition to the statutes that are cited directly in Section 1557(b), the proposed rule cited the Architectural Barriers Act of 1968,[27] the Americans with Disabilities Act of 1990 (ADA),[28] and Section 508 of the Rehabilitation Act of 1973 (Section 508).[29] We noted that these laws establish additional Federal civil rights protections for individuals with disabilities, and covered entities must be mindful that the obligations imposed by those laws apply to them independent of the application of Section 1557.

Summary of Regulatory Changes

OCR did not receive any comments on this provision. Therefore, for the reasons set forth in the proposed rule, we are finalizing the provisions as proposed in § 92.3 without modification.

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.

Disability. We proposed that the definition of ''disability'' be the same as the definition of this term in the Rehabilitation Act,[30] which incorporates the definition of disability in the ADA, as construed by the ADA Amendments Act of 2008.[31] In addition, we proposed to use the term ''disability'' in place of the term ''handicap,'' which is used in some previous civil rights statutes and regulations. We provided that when we cross-reference other regulatory provisions, regulatory language that uses the term ''handicap'' shall mean ''disability.'' We noted that this change in terminology does not reflect a change in the substance of the definition.

Comment: OCR received many comments related to the definition of disability. Several commenters asked OCR to provide additional guidance regarding the meaning of terms used within the definition of disability, including ''physical or mental impairment,'' ''major life activities,'' and ''substantially limits.'' Other commenters asked OCR to include the term ''chronic conditions'' in the definition of disability or to add

[26] Funds under the Purchased/Referred Care program (formerly the Contract Health Services program) are used to supplement and complement other health care resources available to eligible American Indians and Alaska Natives. *See https://www.ihs.gov/newsroom/index.cfm/factsheets/purchasedreferredcare* (last updated Jan. 2015).

[27] 42 U.S.C. 4151–4157 (2012).

[28] 42 U.S.C. 12101 *et seq.* (codified as amended by the Americans with Disabilities Amendments Act of 2008, Public Law 110–325, 122 Stat. 3553 (2008)).

[29] 29 U.S.C. 794d.

[30] 29 U.S.C. 705(9)(B).

[31] Public Law 110–325, 122 Stat. 3553, § 4 (Sept. 25, 2008) (codified at 42 U.S.C. 12102).

regulatory language to the definition of disability that creates a rebuttable presumption of disability for serious and chronic conditions. Still other commenters urged that OCR clarify that the definitions of disability and qualified individual with a disability are broad.

Response: As noted in the proposed rule, the definition of ''disability'' is the same as the definition of this term in the Rehabilitation Act, which incorporates the definition of disability in the ADA, as construed by the ADA Amendments Act of 2008. Thus, the proposed rule incorporates the definition of ''major life activities'' and the construction of all of the terms and standards in the definition of ''disability'' set forth in the ADA Amendments Act. We believe this definition is appropriate and that OCR's intent, consistent with the ADA Amendments Act, to broadly interpret the term ''disability'' is clear. Whether a chronic condition is a disability will depend on whether it falls within the definition of disability in the final rule.

Comment: A few commenters asked for a definition of the term ''reasonable modification.'' Other commenters asked for a definition of ''accessibility,'' especially as that term pertains to electronic and information technology. Both sets of commenters suggested that adding definitions to the final rule would provide greater clarity to covered entities.

Response: OCR believes that defining the terms ''reasonable modification'' and ''accessibility'' in this rule is unnecessary, given the meaning that these terms have acquired in the long history of enforcement of Section 504 and the ADA in the courts and administratively. We intend to interpret both terms consistent with the way that we have interpreted these terms in our enforcement of Section 504 and the ADA and so decline to add these definitions to 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 ''disability'' as proposed without modification.

Electronic and information technology. We proposed to define ''electronic and information technology'' to be consistent with 36 CFR 1194.4, the regulation implementing Section 508.

Comment: A few commenters recommended that OCR amend the definition of ''electronic and information technology'' to state that ''electronic and information technology includes hardware, software, integrated technologies or related licenses, intellectual property, upgrades, or packaged solutions sold as services that are designed for or support the use by health care entities or patients for the electronic creation, maintenance, access, or exchange of health information.'' These commenters asserted that this definition, which is based on the definition of ''health information technology'' in the Health Information Technology for Economic and Clinical Health (HITECH) Act of 2009,[32] is preferable to the definition OCR proposed, which is based on the regulations implementing Section 508 that were promulgated in 2000. According to these commenters, the Section 508 definition is outdated and unduly narrow.

Response: As OCR stated in the Notice of Proposed Rulemaking, the definition of ''electronic and information technology'' is based on 36 CFR 1194.4, the regulation implementing Section 508. OCR believes that a definition of ''electronic and information technology'' that is consistent with the regulations implementing Section 508 will reduce the possibility of confusing or conflicting standards for covered entities. Moreover, the definition used in the HITECH Act was created for use in another context and is narrower in some respects than would be appropriate for Section 1557. However, OCR also shares the commenters' concern that the current definition found at 36 CFR 1194.4 is outdated and unduly narrow. Accordingly, OCR notes the recent Access Board proposal to replace the term ''electronic and information technology'' with an updated term and definition.

Specifically, on February 27, 2015, the Access Board proposed to revise and update its standards for electronic and information technology developed, procured, maintained, or used by Federal agencies covered by Section 508.[33] As part of these proposed revisions and updates, the Access Board announced that it intends to replace the term ''electronic and information technology'' in 36 CFR 1194.4 with the term ''information and communication technology'' and revise the definition significantly to make it broader and more compatible with modern technology.[34] OCR believes that the changes proposed by the Access Board will address the commenters' concerns. Therefore, and in order to maintain consistency with Section 508 while also addressing commenters' concerns that the definition proposed by OCR is outdated and unduly narrow, OCR has decided to change the definition of ''electronic and information technology'' in this rule so that it means the same as ''electronic and information technology'' as defined at 36 CFR 1194.4 or any term that replaces ''electronic and information technology'' at 36 CFR 1194.4. By citing to the regulation, OCR's definition will update with the Access Board's finalized rule.

Summary of Regulatory Changes

For the reasons set forth above and considering the comments received, we have changed the definition of ''electronic and information technology'' as proposed in § 92.4 to state that it means the same as ''electronic and information technology,'' or any term that replaces it at 36 CFR 1194.4.

Employee health benefit program. We proposed that the term ''employee health benefit program'' means (1) health benefits coverage or health insurance provided to employees and/or their dependents established, operated, sponsored or administered by, for, or on behalf of one or more employers, whether provided or administered by entities including but not limited to a health insurance issuer, group health plan (as defined in the Employee Retirement Income Security Act of 1974 (ERISA), at 29 U.S.C. 1191b(a)), a third party administrator, or an employer; (2) an employer-provided or -sponsored wellness program; (3) an employer-provided health clinic; or (4) long term care coverage or insurance provided or administered by an employer, group health plan, third party administrator, or health insurance issuer for a covered entity's employees.

Comment: One commenter requested that OCR clarify that wellness programs that are separate from the employee health benefit plan are still an ''employee health benefit program.''

Response: We agree that wellness programs separate from an employee health benefit plan fall within the definition of an employee health benefit program. For example, an employer providing a gift card to each employee who receives a flu shot would be a wellness program within the meaning of the regulation, regardless of whether the wellness program is part of the employer's group health plan. We believe that the definition of ''employee health benefit program'' in the

[32] 42 U.S.C. 300jj(5).

[33] Architectural and Transportation Barriers Compliance Board, Information and Communication Technology (ICT) Standards and Guidelines. 80 FR 10880 (proposed Feb. 27, 2015) (to be codified at 36 FR pt. 1194).

[34] *See* 80 FR at 10905.

regulation makes this clear and thus are not adopting any revisions.

Comment: Some commenters requested that the definition of ''employee health benefit program'' specifically include excepted benefits, as defined for purposes of section 2791(c) of the Public Health Service Act (codified at 42 U.S.C. 300gg–91(c)), such as limited scope vision and dental insurance, disease-specific insurance and fixed-indemnity plans.

Response: We do not believe it is necessary to include an exhaustive list of types of benefits that would be included as an ''employee health benefit program.'' The definition is broad enough to encompass any health benefit coverage or health insurance provided by an employer to its employees. Excepted benefits are further discussed infra under § 92.207.[35]

Summary of Regulatory Changes

For the reasons set forth in the proposed rule and considering the comments received, we are finalizing this definition as proposed in § 92.4 with minor technical revisions for clarity and for consistency with other parts of the final rule. We are making minor technical corrections to correct the ERISA citation to read ''29 U.S.C. 1191b(a)(1)''; to clarify that the term ''sponsored wellness program'' is an ''employer-sponsored'' wellness program; to add ''coverage'' to the term ''health insurance''; and to clarify that long term care coverage or insurance is provided or administered ''for the benefit of an employer's employees.''

Federal financial assistance. We proposed that the term ''Federal financial assistance'' includes grants, loans, and other types of assistance in accordance with the definition of ''Federal financial assistance'' in the regulations implementing Section 504 [36] and the Age Act,[37] and also specifically includes subsidies and contracts of insurance, in accordance with the statutory language of Section 1557. We also proposed that, consistent with OCR's enforcement of other civil rights authorities, the definition of Federal financial assistance does not include Medicare Part B.

An additional clause was added to the proposed regulatory provision, modeled on the definition of ''Federal financial assistance'' in the regulation implementing Title IX, which clarifies that in the educational context, Federal financial assistance includes wages, loans, grants, scholarships and other monies that are given to any entity for payment to or on behalf of students who are admitted to that entity or that are given directly to these students for payment to that entity.[38] In the proposed rule, we noted that in the health care context, Federal funds are provided to or on behalf of eligible individuals for premium tax credits and advance payments of premium tax credits and cost sharing reductions to ensure the affordability of health insurance coverage purchased through the Health Insurance Marketplaces. Thus, we noted that an issuer participating in any Health Insurance Marketplace℠ is receiving Federal financial assistance when advance payments of premium tax credits and/or cost sharing reductions are provided to or on behalf of any of the issuer's enrollees. We noted that a health care provider that contracts with such an issuer does not become a recipient of Federal financial assistance by virtue of the contract, but would be a recipient if the provider otherwise receives Federal financial assistance.

Comment: Many commenters objected to the statement in the preamble to the proposed rule that, consistent with OCR's enforcement of other civil rights authorities, the definition of Federal financial assistance does not include Medicare Part B. These commenters urged us to reverse this position, asserting that the historical rationale for the Department's position that Medicare Part B payments are not Federal financial assistance is inapplicable to Section 1557, which explicitly covers ''contracts of insurance,'' and inconsistent with the current Medicare Part B payment scheme, in which providers are paid directly by the Medicare program instead of receiving payment from consumers who are then reimbursed by the Medicare program.

Response: OCR notes commenters' concerns, but does not believe that this rule is the appropriate vehicle to modify the Department's position.

Comment: We received many comments proposing that OCR revise the statement that a health care provider that contracts with an issuer does not become a recipient of Federal financial assistance by virtue of the contract. Commenters proposed that such a provider should become a recipient, and thus be covered by Section 1557, by virtue of the contract. The commenters expressed concern that under OCR's interpretation, such contractors would not be covered by the nondiscrimination requirements of Section 1557, thereby weakening the rule's effect.

Response: We do not believe the law supports the commenters' proposed across-the-board revision. Under the regulations implementing the statutes cited in Section 1557 and incorporated into this final rule, a recipient of Federal financial assistance is an entity to which Federal financial assistance is extended directly or through another recipient, including any successor, assignee, or transferee of a recipient. To determine whether an entity is a recipient of such assistance, courts look to the entity that Congress intended to assist or subsidize with those funds.[39] In this context, the contractor that is providing health services is not the intended recipient of a premium tax credit or cost-sharing reduction that an issuer receives and is therefore not covered under Section 1557 by virtue of the contract.

That said, there are numerous ways in which health services providers are recipients in their own right, whether the Federal financial assistance they receive comes through certain Medicare payments, Medicaid payments, or other funds from the Department. Therefore, instead of falling outside of Section 1557's purview, many health care providers will be subject to Section 1557 irrespective of their relationship to issuers receiving Federal financial assistance.

Moreover, nothing in the rule authorizes qualified health plan issuers or other issuers that are covered entities to contract away their own nondiscrimination obligations. Issuers must ensure that enrollees have equal access to health services provided by their coverage without discrimination on the basis of a prohibited criterion. Thus, even if individual providers do not independently receive Federal financial assistance, an issuer maintains a duty to ensure compliance with civil rights laws with respect to the treatment of its enrollees who use its networks.

Comment: One comment inquired whether the rule applies to programs in which the Department is an employer or when the Department offers benefits to Department employees.

Response: The Department is not covered as a federally assisted program, although the Department is covered by the rule as an administrator of health programs and activities. As to programs for Department employees, HHS is covered by employment discrimination laws, including Section 504 and Title VII, protecting Federal employees.

[35] *See infra* discussion of excepted benefits under § 92.207.

[36] 45 CFR 84.3(h).

[37] 45 CFR 91.4.

[38] *See* 45 CFR 86.2(g)(1)(ii).

[39] *United States Dep't of Transport.* v. *Paralyzed Veterans of Amer.,* 477 U.S. 597, 604–06 (1986).

Comment: One commenter raised concerns over the applicability of the rule to doctors in solo medical practice, to doctors who practice in many settings, and to medical students receiving student loans. The commenter suggested that the health program or activity—not the solo practitioner as an individual—be required to comply with the rule, and requested that we clarify how a doctor can determine whether she is covered by the rule as she moves between practice settings. The commenter also expressed concern that a disproportionate number of younger doctors would be required to comply with the rule as recipients of Federal financial assistance in the form of student loans.

Response: We have not modified the final rule in response to these comments; however, we offer the following for clarification.

Section 1557 applies to a recipient of Federal financial assistance, whether a hospital, clinic, medical practice, or individual physician. Where, for example, a doctor is an employee of a hospital and the hospital receives Federal financial assistance, the hospital's program is the relevant health program or activity and it is the hospital that will be held accountable for discrimination under Section 1557. Where, similarly, a doctor contracts as an individual to provide health services at a free neighborhood clinic that receives Federal financial assistance, the clinic is the recipient of Federal financial assistance and liable for discrimination; the doctor is simply a contractor who is assisting the clinic in performing clinic services.

When a doctor has a private medical practice that receives Federal financial assistance, and the doctor, through her practice, works as an attending physician at a hospital, it is the medical practice that is providing the services at the hospital, and thus the practice that is liable for the discrimination.[40] Moreover, a solo medical practice (whether incorporated or not) that receives Federal financial assistance is a covered health program or activity.[41]

This approach is consistent with longstanding interpretations of civil rights law and the definition of a ''recipient'' of Federal financial assistance in the regulations implementing Section 504, Title VI, Title IX and the Age Act.

[40] The hospital may also be responsible for discrimination by the doctor's practice that occurs at the hospital.

[41] The rule defines a ''recipient'' of Federal financial assistance to include an individual. See § 92.4.

Finally, regarding receipt of student loan payments as Federal financial assistance, we clarify that the educational institution—not the student—is the recipient of the Federal financial assistance in that circumstance. Although the money is paid directly to the student, the university or other educational institution is the intended recipient. This is consistent with longstanding regulations implementing civil rights laws.

We made two clarifying changes to the definition of Federal financial assistance. In the proposed rule, we defined Federal financial assistance in subsection (1) as any type of arrangement in which the Federal government ''provides or makes available'' assistance. In subsection (2), we explained that Federal financial assistance ''provided or administered by the Department'' includes tax credits and other subsidies under Title I of the ACA and other funds providing health insurance coverage. Because our intention was to explain further the meaning of (1) as it applies to the Department in (2), we have changed (2) to use the same terms used in (1). Thus, (2) now refers to Federal financial assistance ''provided or made available'' by the Department.

In addition, in the proposed rule, subsection (2) provided that ''Federal financial assistance provided or administered by the Department includes all tax credits under Title I of the ACA,'' as well as other funds extended by the Department for providing health coverage. Because the Department plays a role in administering tax credits under Title I of ACA but does not have primary responsibility for administering that credit, and to ensure that tax credits under Title I of the ACA are understood to be included within the definition, we have modified this subsection to state that Federal financial assistance the Department provides or makes available includes Federal financial assistance that the Department plays a role in providing or administering.

Summary of Regulatory Changes

For the reasons set forth in the proposed rule and considering the comments received, we are finalizing this definition as proposed in § 92.4 with two modifications. The language of Subsection (2) of the definition has been modified to state that Federal financial assistance the Department provides or makes available includes Federal financial assistance that the Department plays a role in providing or administering.

Gender identity. We proposed that the term ''gender identity'' means an individual's internal sense of gender, which may be different from an individual's sex assigned at birth. We noted that the way an individual expresses gender identity is frequently called ''gender expression,'' and may or may not conform to stereotypes associated with a particular gender. We also noted in the proposed rule that gender may be expressed through, for example, dress, grooming, mannerisms, speech patterns, and social interactions. For purposes of this part, we proposed that an individual has a transgender identity when the individual's gender identity is different from the sex assigned to that person at birth; an individual with a transgender identity is referred to in this part as a transgender individual. In the proposed rule, we noted that the approach taken in the proposed definition is consistent with the approach taken by the Federal government in similar matters.[42]

Comment: Several commenters suggested that we revise the definition of ''gender identity'' to reference non-binary identities in order to avoid ambiguity regarding application of the rule to individuals with non-binary gender identities. Some commenters noted that explicitly referencing non-binary identities in this definition would be important to avoid any doubt or misinterpretation given that gender has often been assumed to be binary, thus ignoring or marginalizing individuals with non-binary gender identities.

Response: OCR has made a slight change to the definition of ''gender identity'' to insert the clause ''which may be male, female, neither, or a combination of male and female.'' The insertion of this clause helps clarify that those individuals with non-binary gender identities are protected under the rule.

Comment: Some commenters suggested that, consistent with previous court and Federal agencies' interpretations, OCR add ''gender expression'' to the definition of ''gender identity'' in order to make explicit our

[42] *See, e.g.,* U.S. Office of Personnel Management, Guidance Regarding the Employment of Transgender Individuals in the Federal Workplace (May 27, 2011), *https://www.opm.gov/policy-data-oversight/diversity-and-inclusion/reference-materials/gender-identity-Guidance/;* U.S. Office of Personnel Management, U.S. Equal Employment Opportunity Commission, U.S. Office of Special Counsel, U.S. Merit Systems Protection Board. Addressing Sexual Orientation and Gender Identity Discrimination in Federal Civilian Employment: A Guide to Employment Rights, Protections, and Responsibilities, p. 2 (June 2015), *http://www.opm.gov/LGBTGuide.*

intention to protect individuals on this basis.

Response: In the proposed and final rules' definition of gender identity, we explain that the way an individual expresses gender identity is frequently called ''gender expression.'' OCR is clarifying that throughout this final rule, we interpret references to the term ''gender identity'' as encompassing ''gender expression'' and ''transgender status.'' This position is consistent with the position taken by courts and Federal agencies.[43] These bases of discrimination are protected under the rule.

Summary of Regulatory Changes

For the reasons set forth in the proposed rule and considering the comments received, we are finalizing the definition as proposed in § 92.4 with three modifications. The first sentence of the definition of gender identity has been revised to reference the application of the rule to individuals with non-binary gender identities. OCR also made a technical edit to the last sentence to delete reference to the term ''transgender identity.'' Finally, for clarity and consistency within the final rule, OCR has made a technical revision to the definition of gender identity to clarify that a transgender individual is an individual whose gender identity is different from the sex assigned to that person at birth.

Health program or activity. We proposed that the term ''health program or activity'' means the provision or administration of health-related services or health-related insurance coverage and the provision of assistance in obtaining health-related services or health-related insurance coverage. We also proposed that, similar to the approach of the Civil Rights Restoration Act of 1987 (CRRA) [44] and except as specifically set forth otherwise in this part,[45] the term further includes all of the operations of an entity principally engaged in providing or administering health services or health insurance coverage, such as a hospital, health clinic, community health center, group health plan, health insurance issuer, physician's practice, nursing facility, or residential or community-based treatment facility. We proposed that OCR interpret ''principally engaged'' in a manner consistent with civil rights laws that use this term.

In the proposed rule, OCR stated that we intended the plural ''health programs or activities'' used in this part to have the same meaning as the term ''health program or activity'' in the singular. Similarly, we noted that the proposed part's use of ''health programs and activities,'' a variation of ''health program or activity,'' does not reflect a change in the substance of the definition of ''health program or activity.''

We proposed to interpret ''health programs and activities'' to include programs such as health education and health research programs. Because Federal civil rights laws already prohibit discrimination on the basis of race, color, national origin, disability, or age in all health research programs and activities that receive Federal financial assistance and prohibit discrimination on the basis of sex in all health research programs conducted by colleges and universities, we determined that the application of Section 1557 to health research should impose limited additional burden on covered entities.

However, OCR recognized that health research is conducted to answer scientific questions and improve health through the advancement of knowledge; it is not designed to result in direct health benefits to participants. We also recognized that research projects are often limited in scope for many reasons, such as the principal investigator's scientific interest, funding limitations, recruitment requirements, and other nondiscriminatory considerations. Thus, we noted 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.[46] OCR noted that we do not intend for inclusion of health research within the definition of health program or activity to alter the fundamental manner in which research projects are designed, conducted, or funded; nor did OCR propose to systematically review health research protocols.

We invited comment on programs and activities that should be considered health programs or activities.

Comment: We received comments requesting that we enumerate additional examples of a health program or activity, including but not limited to the Children's Health Insurance Program, all of the operations of Medicare, and student health plans.

Response: We agree that the Children's Health Insurance Program and other health programs operated by State and local governments are covered by the rule. We also agree that student health plans are a health program or activity covered by the rule, and note that all student health plans are covered by Title IX, as well as the other civil rights laws cited in Section 1557, if the institution receives Federal financial assistance.

Although the definition does not and could not specifically identify all health programs and activities covered by the rule (for example, we do not specifically mention programs that provide physical and/or behavioral health services, although they are health programs), we are adding the Children's Health Insurance Program and the Basic Health Program as additional examples, given their significance.

We decline to include ''all the operations of Medicare'' in the definition of health program or activity. While we agree that all parts of the Medicare program are a health program or activity, not all operations in the Medicare program constitute Federal financial assistance; as discussed above, Medicare Part B is excluded from the definition of Federal financial assistance under this rule and other HHS civil rights authorities.[47] Thus, we believe the proposed language could create confusion in determining the scope of the final rule.

Comment: Some commenters noted that OCR did not propose to define the term ''health'' in ''health program and activity,'' and recommended that OCR use the definition of ''health'' adopted by the World Health Organization, which includes an individual's or population's physical, mental, or social well-being.[48]

Response: OCR declines to add a definition of ''health,'' but interprets ''health'' to include physical and mental well-being.

Comment: Several commenters recommended that the rule apply only to the specific health program for which the entity receives Federal financial assistance, such as health insurance coverage sold through the Marketplace℠, and not to other

[43] *See Rumble* v. *Fairview Heath Servs.,* Civ. No. 14–cv–2037, 2015 WL 1197415, at *10 (D. Minn. Mar. 16, 2015) (Section 1557); *Schroer* v. *Billington,* 577 F. Supp.2d 293, 303 (D.D.C. 2008)(Title VII); *Macy* v. *Holder,* EEOC Appeal No. 0120120821, Agency No. ATF–2011–00751, 2012 WL 1435995, at *7 (Apr. 20, 2012), *http://www.eeoc.gov/decisions/0120120821%20Macy%20v%20DOJ%20ATF.txt* (Title VII).

[44] Public Law 100–259, 102 Stat. 28 (1988).

[45] Employee health benefits programs are discussed elsewhere in rule. *See infra* discussion of § 92.208.

[46] We note that it is not permissible for clinical researchers to consider ''cost'' of accommodating participants with disabilities as a reason to exclude them from participation.

[47] Medicare Parts A, C, and D all constitute Federal financial assistance. See *www.hhs.gov/civil-rights/for-individuals/faqs/what-qualifies-as-federal-financial-assistance/301/indeix.html*.

[48] *See http://www.who.int/about/definition/en/print.html.*(last visited Mar. 11, 2016).

products and services provided outside the Marketplace℠ by issuers participating in the Marketplace℠. These commenters stated that applying the rule to operations or products that are not the direct recipients of Federal financial assistance conflicts with the plain meaning of Section 1557.

Response: Section 1557 prohibits discrimination under ''any health program or activity, any part of which is receiving Federal financial assistance. . . .'' By applying the prohibition if ''any part'' of the health program or activity receives Federal financial assistance, the law provides that the term ''health program or activity'' must be interpreted in a manner that uniformly covers all of the operations of any entity that receives Federal financial assistance and that is principally engaged in health services, health insurance coverage, or other health coverage, even if only part of the health program or activity receives such assistance. This interpretation serves the central purposes of the ACA, and effectuates Congressional intent, by ensuring that entities principally engaged in health services, health insurance coverage, or other health coverage do not discriminate in any of their programs and activities, thereby enhancing access to services and coverage.

This approach is consistent with the approach Congress adopted in the CRRA, which amended the four civil rights laws referenced in Section 1557 and defines ''program or activity'' to mean ''all of the operations of . . . an entire corporation, partnership, or other private organization, or an entire sole proprietorship . . . which is principally engaged in the business of providing,'' among other things, a range of social and health services. The CRRA establishes that the entire program or activity is required to comply with the prohibitions on discrimination if any part of the program or activity receives Federal financial assistance. The CRRA has been consistently applied since its enactment in 1988, and we believe that Congress adopted a similar approach with respect to the scope of health programs and activities covered by Section 1557. If any part of a health care entity receives Federal financial assistance, then all of its programs and activities are subject to the discrimination prohibition.

Summary of Regulatory Changes

For the reasons set forth in the proposed rule and considering the comments received, we are modifying the definition as proposed in § 92.4 to include the Children's Health Insurance Program and the Basic Health Program as additional examples of a health program or activity.

Individual with limited English proficiency. We proposed that the term ''individual with limited English proficiency'' codify the Department's longstanding definition reflected in guidance interpreting Title VI's prohibition of national origin discrimination, entitled Guidance to Federal Financial Assistance Recipients Regarding Title VI Prohibition Against National Origin Discrimination Affecting Limited English Proficient Persons [49] (HHS LEP Guidance). Under the proposed definition, an individual whose primary language for communication is not English is considered an individual with limited English proficiency if the individual has a limited ability to read, write, speak or understand English. Accordingly, we proposed that an individual whose primary language for communication is not English, even if he or she has some ability to speak English, is an individual with limited English proficiency if the individual has a limited ability to read, write, speak or understand English.

Commenters addressing this definition overwhelmingly supported its codification from the HHS LEP Guidance to regulatory text. We did not receive suggested revisions to the wording of this definition.

Summary of Regulatory Changes

For the reasons set forth in the proposed rule and considering the comments received, we are finalizing this definition as proposed in § 92.4, without modification.

Language assistance services. OCR proposed that the term ''language assistance services'' identify types of well-established methods or services used to communicate with individuals with limited English proficiency, including (1) oral language assistance; (2) written translation of documents and Web sites; and (3) taglines. We noted that a covered entity has flexibility to provide language assistance services in-house or through commercially available options. We declined to offer an exhaustive list of available methods. However, we proposed that paragraph (1) identify the following as available methods to communicate orally with individuals with limited English proficiency: Oral interpretation (in-person or remotely) [50] and direct communication through the use of bilingual or multilingual staff competent to communicate directly, in non-English languages using any necessary specialized vocabulary, with individuals with limited English proficiency.

We did not receive suggested revisions to the wording of this definition. Comments we received on the specific types of language assistance services mentioned in the definition are addressed in the relevant portions of the preamble to § 92.4 for those respective terms.

For clarity and consistency within the final rule, we are replacing several phrases in this definition with other terms to conform to changes made in other provisions of the final rule. First, in paragraph (1) regarding oral language assistance, we are adding the words ''for an individual with limited English proficiency'' after ''qualified interpreter'' because § 92.4 now defines ''qualified interpreter for an individual with limited English proficiency'' separately from a ''qualified interpreter for an individual with a disability.'' Also, because § 92.4 defines ''qualified bilingual/multilingual staff,'' we are replacing ''bilingual or multilingual staff competent to communicate, in non-English languages using any necessary specialized vocabulary'' with ''the use of qualified bilingual/multilingual staff to communicate.'' In paragraph (2) regarding written translation, we are replacing the reference to written translation of ''documents and Web sites'' to ''written content in paper or electronic form.'' Finally, because § 92.4 defines ''qualified translator,'' we are adding ''performed by a qualified translator'' after ''written translation.''

Summary of Regulatory Changes

For the reasons set forth in the proposed rule and considering the comments received, we are finalizing the definition as proposed in § 92.4 with technical revisions, as described in the preceding paragraph, to ensure consistency with other provisions of the final rule.

[49] 68 FR 47311, 47313 (Aug. 8, 2003).

[50] We use the terms ''oral interpretation'' and ''written translation'' for clarity. The term ''interpretation'' used without the preceding descriptor of ''oral'' refers to the communication of information orally and the term ''translation'' used without the preceding descriptor of ''written'' refers to the communication of information in writing. *See, e.g.*, U.S. Dep't of Justice, Commonly Asked Questions and Answers Regarding Limited English Proficient (LEP) Individuals, *http://www.lep.gov/faqs/faqs.html#OneQ11* (last visited Mar. 15, 2016) (differentiating between interpreters and translators in FAQ 11); Interpreters and Translators, U.S. Dep't of Labor, Bureau of Labor Statistics, Occupational Outlook Handbook, 2014–15, *http://www.bls.gov/ooh/media-and-communication/interpreters-andtranslators.htm* (explaining that interpreters convert information in a spoken language and translators convert information in written language).

National origin. The proposed rule did not define the term ''national origin.''

Comment: A few commenters recommended defining ''race, color, or national origin'' to include ''language'' and ''immigration status.'' Commenters asserted that ''language'' should be included to capture the application of national origin discrimination to individuals with limited English proficiency. As to immigration status, some commenters requested clarification that immigrants, and particularly non-U.S. citizens, are protected from discrimination on the basis of race, color, national origin, sex, age, or disability under Section 1557 and this part.

Response: In response to comments, we are providing further clarification on the scope of ''national origin''; we determine it unnecessary to define ''race'' or ''color.'' Thus, this final rule defines ''national origin'' consistent with the well-established definition of the term that the Equal Employment Opportunity Commission (EEOC) uses in its interpretation of Title VII of the Civil Rights Act of 1964.[51] This definition clarifies that national origin includes not only an individual's place of origin, but also his or her ancestor's place of origin, which reflects our intent that individuals born in the United States but who have an ancestry outside the United States are protected. This definition also clarifies that national origin includes an individual's manifestation of the physical, cultural, or linguistic characteristics of a national origin group.[52]

By contrast, we decline to include the term ''immigration status'' in the definition of ''national origin.'' An individual's national origin is not the same as her citizenship or immigration status, and neither Title VI nor Section 1557 explicitly protects individuals against discrimination on the basis of citizenship or immigration status. However, as under Title VI, Section 1557 and this part protect individuals present in the United States, whether lawfully or not, who are subject to discrimination based on race, color, national origin, sex, age, or disability. Moreover, OCR considers an immigrant or noncitizen to state a cognizable national origin discrimination claim under Title VI,[53] Section 1557, and this part when the claim alleges that a covered entity's use of a facially neutral policy or practice related to citizenship or immigration status has a disparate impact on individuals of a particular national origin group.

Summary of Regulatory Changes

For the reasons set forth above and considering the comments received, we are defining the term ''national origin'' in § 92.4 to include an individual's manifestation of the physical, cultural, or linguistic characteristics of a national origin group as well as an individual's or her ancestor's place of origin.

On the basis of sex. We proposed that the term ''on the basis of sex'' includes, but is not limited to, discrimination on the basis of pregnancy, false pregnancy, termination of pregnancy, or recovery therefrom, childbirth or related medical conditions, sex stereotyping, and gender identity.

We noted that Section 1557 extends the grounds for discrimination found in the nondiscrimination laws cited in the statute (*i.e.,* race, color, national origin, sex, age, or disability) to certain health programs and activities. We noted that the HHS Title IX regulation explicitly includes discrimination on the basis of pregnancy as a form of discrimination on the basis of sex, and we proposed that the definition in this section mirror that regulation.[54]

We noted that the proposed inclusion of sex stereotyping reflects the Supreme Court's holding in *Price Waterhouse* v. *Hopkins,*[55] and that discrimination based on stereotypical notions of appropriate behavior, appearance or mannerisms for each gender constitutes sex discrimination.

We proposed that discrimination on the basis of sex further includes discrimination on the basis of gender identity. We noted that like other Federal agencies,[56] HHS has previously interpreted sex discrimination to include discrimination on the basis of gender identity.[57] We also noted that courts, including in the context of Section 1557, have recognized that sex discrimination includes discrimination based on gender identity.[58] Thus, we proposed to adopt formally this well-

[51] 29 CFR 1606.1 (defining ''national origin discrimination'').

[52] In addition, courts have adopted this principle. *See, e.g., Bennun* v. *Rutgers State Univ.,* 941 F.2d 154, 173 (3d Cir. 1991), *cert. denied,* 502 U.S. 1066 (1992) *(*stating that an individual's birth in a foreign country where another culture predominates, immersion in that country's ways of life, and speaking the native language in one's home, are sufficient to identify the individual as part of a national origin group); *Fragante* v. *City and County of Honolulu,* 888 F.2d 591, 595–96 (9th Cir. 1989), *cert. denied,* 494 U.S. 1081 (1990) (stating that accent and national origin are inextricably intertwined in many cases); *Gutierrez* v. *Mun. Court of Southeast Jud. Dist., Los Angeles Cnty.,* 838 F.2d 1031, 1039 (9th Cir. 1988 *vac'd and rem,* 490 U.S. 1016 (1989)(stating that ''[b]ecause language and accents are identifying characteristics, ''rules which have a negative effect on bilinguals, individuals with accents, or non-English speakers, may be mere pretexts for intentional national origin discrimination''). A member of a religious group states a cognizable national origin discrimination claim under Title VI and Section 1557 and this part when that discrimination is based on a religious group's shared ancestry or its physical, cultural, and linguistic characteristics rather than its members' religious practice. *See* Letter from Thomas Perez, Assistant Attorney Gen., Civil Rights Div., U.S. Dep't of Justice to Russlynn Ali, Assistant Sec'y for Civil Rights, Office for Civil Rights, U.S. Dep't of Educ. Re: Title VI and Coverage of Religiously Identifiable Groups, at 2 (Sept. 8, 2010), *https://www.justice.gov/sites/default/files/crt/legacy/2011/05/04/090810_AAG_Perez_Letter_to_Ed_OCR_Title%20VI_and_Religiously_Identifiable_Groups.pdf.*

[53] *See* Voluntary Resolution Agreement between U.S. Dep't of Health & Human Servs., Office for Civil Rights and Ariz. Health Care Cost Containment System & the Ariz. Dep't of Econ. Sec., OCR Transaction Nos. 10–117078 & 10–117875 (2015), *http://www.hhs.gov/sites/default/files/ocr/civilrights/activities/agreements/Arizona/vra.pdf* [hereinafter HHS OCR VRA with AZ Agencies] (resolving cognizable complaints of national origin discrimination under Title VI following implementation of a State law requiring State employees, in the administration of public benefits programs, to report ''discovered violations of federal immigration law'' to U.S. Immigration and Customs Enforcement).

[54] *See* 45 CFR 86.40(b) (prohibiting discrimination on the basis of ''pregnancy, childbirth, false pregnancy, termination of pregnancy or recovery therefrom'').

[55] 490 U.S. 228, 250–51 (1989).

[56] *See* 5 CFR 300.102(c), 300.103(c), 300.103(c), 315.806(d), 335.103(b)(1), 537.105(d), 900.603(e) (U.S. Office of Personnel Management regulations providing that discrimination on the basis of sex includes discrimination on the basis of gender identity); Directive 2014–02, U.S. Dep't of Labor, Office of Fed. Contract Compliance Programs, § 5 (Aug. 19, 2014), *http://www.dol.gov/ofccp/regs/compliance/directives/dir2014_02.html;* Statement of Interest of the United States, *Jamal* v. *SAKS & Co.,* No. 4:14–CV–2782 (S.D. Tex. Jan. 26, 2015) *https://www.justice.gov/sites/default/files/crt/legacy/2015/02/27/jamalsoi.pdf;* Statement of Interest of the United States, *Tooley* v. *Van Buren Pub. Sch.,* No. 2:14–cv–13466–AC–DRG (E.D. Mich. Feb. 24, 2015) *https://www.justice.gov/sites/default/files/crt/legacy/2015/02/27/tooleysoi.pdf;* Memo from Eric Holder, Att'y Gen., to U.S. Att'ys & Heads of Dep't Components (Dec. 18, 2014), *https://www.justice.gov/opa/pr/attorney-general-holder-directs-department-include-gender-identity-under-sex-discrimination;* U.S. Dep't of Educ., Questions and Answers on Title IX and Sexual Violence, p. B–2, *http://www2.ed.gov/about/offices/list/ocr/docs/qa-201404-title-ix.pdf; Macy,* 2012 WL 1435995, at *11.

[57] *See* Letter from Leon Rodriguez, Director, U.S. Dep't of Health & Human Servs., Office for Civil Rights, to Maya Rupert, Federal Policy Director, National Center for Lesbian Rights (Jul. 12, 2012), *https://www.nachc.com/client/OCRLetterJuly2012.pdf.*

[58] *See, e.g., Rumble* v. *Fairview Heath Servs.,* Civ. No. 14–cv–2037, 2015 WL 1197415, at *10 (D. Minn. Mar. 16, 2015) (Section 1557) (order denying motion to dismiss); *Barnes* v. *City of Cincinnati,* 401 F.3d 729, 737 (6th Cir.), *cert. denied,* 546 U.S. 1003 (2005)(Title VII); *Smith* v. *City of Salem, Ohio,* 378 F.3d 566, 575 (6th Cir. 2004) (Title VII); *Schroer* v. *Billington,* 577 F.Supp.2d 293, 304 (D.D.C. 2008) (Title VII). *But see Johnston* v. *Univ. of Pittsburgh,* 97 F.Supp.3d 657, 671 (W.D. Pa. 2015) (appeal docketed, No. 1502922) (3d Cir. Apr. 24, 2015) (holding that an individual treated in accordance with sex assigned at birth has not been discriminated against on the basis of sex under Title IX).

accepted interpretation of discrimination ''on the basis of sex.''

OCR stated that as a matter of policy, we also support banning discrimination in health programs and activities on the basis of sexual orientation. We noted that current law is mixed on whether existing Federal nondiscrimination laws prohibit discrimination on the basis of sexual orientation as a part of their prohibitions on sex discrimination. However, we further noted that a recent U.S. EEOC decision, *Baldwin* v. *Department of Transportation,*[59] concluded that Title VII's prohibition of discrimination ''on the basis of sex'' includes sexual orientation discrimination because discrimination on the basis of sexual orientation necessarily involves sex-based considerations.

We proposed that the final rule reflect the current state of nondiscrimination law, and we sought comment on the best way of ensuring that this rule includes the most robust set of protections supported by the courts on an ongoing basis.

Comment: Several commenters commended OCR's inclusion of discrimination not only on the basis of pregnancy, but also on the basis of pregnancy-related procedures or conditions in the definition of ''on the basis of sex'' and noted that such a position is consistent with existing civil rights statutes. Other commenters noted concern that the inclusion of the phrase ''termination of pregnancy'' in the definition of ''on the basis of sex'' will be interpreted as requiring the provision or coverage of, or referral for, pregnancy termination, and urged OCR to state explicitly that neither Section 1557 nor the regulation imposes such a requirement.

Response: The definition of ''on the basis of sex'' established by this rule is based upon existing regulation and previous Federal agencies' and courts' interpretations that discrimination on the basis of sex includes discrimination on the basis of pregnancy, childbirth, false pregnancy, termination of pregnancy or recovery therefrom.

Additionally, the final rule balances an individual's right to access health programs and activities free from discrimination with protections for religious beliefs and practices. As we explained in the preamble to the proposed rule and have reiterated here, this rule does not displace existing protections afforded by, for example, Federal provider conscience laws and RFRA. Again, with respect to concerns about potential conflicts between provisions of the final rule and individuals' or organizations' sincerely held religious beliefs, we refer to the discussion at § 92.2 in this preamble. With respect to abortion, moreover, nothing in Section 1557 displaces the ACA provisions regarding abortion, including but not limited to the provision that no qualified health plan offered through a Marketplace may discriminate against an individual health care provider or health care facility because of its unwillingness to provide, pay for, provide coverage of, or refer for abortions;[60] provisions that state that nothing in the ACA shall be construed to require a qualified health plan to provide coverage of abortion as an essential health benefit;[61] and the provision permitting States to prohibit abortion coverage in qualified health plans and restricting the use of Federal funding for abortion services.[62]

Comment: A significant number of commenters commended our inclusion of gender identity and sex stereotyping in the definition of ''on the basis of sex'' and noted that the inclusion is consistent with a growing body of legal precedent. Some commenters suggested OCR add transgender status and gender expression in the definition of ''on the basis of sex'' in order to make explicit our intention to protect individuals on these bases, consistent with previous court and Federal agency interpretations.

Conversely, a few commenters opined that the inclusion of gender identity discrimination as a form of discrimination on the basis of sex was based on erroneous interpretations of Title IX legislative history because Congressional intent to ban sex discrimination was based only on the biological classifications of males and females, not gender identity. A few commenters thought that OCR's reliance on previously adopted Federal agencies' interpretations was weak and unpersuasive and that the reliance on cases arising under Federal civil rights laws other than Title IX was misplaced, further pointing to a few recent court decisions under Title IX that rejected claims that discrimination on the basis of sex includes discrimination on the basis of gender identity.

A few commenters also suggested that the inclusion of ''gender identity'' as a prohibited basis of discrimination on the basis of sex may infringe upon individual patients' constitutional right to privacy by requiring those patients to participate in sex-specific programs or activities with a ''non-biological'' male or female and additionally contravenes employees' and faith-based organizations' religious beliefs by forcing them to participate in services affirming gender identity in violation of their religious convictions.

Response: The definition of ''on the basis of sex'' established by this rule is based upon existing regulation and previous Federal agencies' and courts' interpretations that discrimination on the basis of sex includes discrimination on the basis of gender identity and sex stereotyping. While OCR appreciates the commenters' request that we add transgender status and gender expression to the definition of ''on the basis of sex,'' we do not believe that it is necessary to add these terms to the definition. As previously stated, we encompass these bases in the definition of ''gender identity''; thus, references to ''gender identity'' include ''gender expression'' and ''transgender status.'' Because the definition of ''on the basis of sex'' includes gender identity, further reference to transgender status or gender expression here is superfluous.

OCR also believes that its inclusion of gender identity is well grounded in the law and disagrees with those commenters who argued to the contrary. As the Supreme Court made clear in *Price Waterhouse* v. *Hopkins,* in prohibiting sex discrimination, Congress intended to strike at the entire spectrum of discrimination against men and women resulting from sex stereotypes.[63] Courts after *Price Waterhouse* interpret Title VII's protections against discrimination on the basis of sex as encompassing not only ''sex,'' or biological differences between the sexes, but also ''gender'' and its manifestations.[64] In essence, *Price Waterhouse* thus rejects the reasoning, and vitiates the precedential value, of earlier Federal appellate court decisions that limited Title VII's coverage of ''sex'' to the anatomical and biological characteristics of sex. Moreover, courts frequently look to case law interpreting other civil rights provisions, including Title VII, for guidance in interpreting Title IX.[65]

OCR's approach accords with well-accepted legal interpretations adopted by other Federal agencies and courts.

[59] U.S. Equal Employment Opportunity Comm'n Appeal No. 0120133080, Agency No. 2012–24738–FAA–03 (July 15, 2015), *http://www.eeoc.gov/decisions/0120133080.txt.*

[60] 42 U.S.C. 18023(b)(4).

[61] 42 U.S.C. 18023(b)(1)(A).

[62] 42 U.S.C. 18023.

[63] 490 U.S. at 251 (citations omitted).

[64] *See, e.g., Smith* v. *City of Salem, Ohio,* 378 F.3d. 566, 573–74 (6th Cir. 2004).

[65] *See, e.g., Wolfe* v. *Fayetteville, Ark. Sch. Dist.,* 648 F.3d 860, 864 n.4 (8th Cir. 2011); *Weinstock* v. *Columbia Univ.,* 224 F.3d 33, 42 n.1 (2d Cir. 2000), *cert. denied,* 540 U.S. 811 (2003).

For example, Title IX Guidance issued by the U.S. Department of Education generally requires recipients of federal financial assistance to treat transgender students consistent with their gender identity.[66] The Fourth Circuit reversed a lower court decision dismissing the Title IX sex discrimination claim of a transgender student prohibited from using the school bathroom consistent with his gender identity, holding that the Department of Education's interpretation of its regulation was not plainly erroneous, and thus was entitled to controlling weight.[67]

The fact that there may be circumstances in which it is permissible to make sex-based distinctions is not a license to exclude individuals from health programs and activities for which they are otherwise eligible simply because their gender identity does not align with other aspects of their sex, or with the sex assigned to them at birth. The Department has a responsibility to ensure that health programs and activities of covered entities are carried out free from such discrimination.

To the extent that privacy considerations may be relevant in an anti-discrimination analysis, OCR will consider these interests in the context of individual complaints. We note, however, that at least one court has rejected a claim that an individual's legal right to privacy is violated simply by permitting another person access to a sex-specific program or facility that corresponds to their gender identity.[68] With respect to concerns about potential conflicts between provisions of the final rule and individuals' or organizations' sincerely held religious beliefs, we refer to the discussion at § 92.2 in this preamble.

Comment: A few commenters recommended that OCR clarify that the prohibition on sex discrimination extends to discrimination on the basis of the presence of atypical sex characteristics and intersex traits (*i.e.,* people born with variations in sex characteristics, including in chromosomal, reproductive, or anatomical sex characteristics that do not fit the typical characteristics of binary females or males). At least one commenter noted that this clarification is necessary because intersex people may face discrimination when medical providers or insurance companies follow policies which deem certain medical procedures available to only one sex, thereby excluding intersex people who may be registered under another sex.

Response: We agree with the commenters that the prohibition on sex discrimination extends to discrimination on the basis of intersex traits or atypical sex characteristics. OCR intends to apply its definition of ''on the basis of sex'' to discrimination on these bases.

Comment: Many commenters requested that OCR explicitly state in the rule that Section 1557's prohibition of discrimination on the basis of sex includes discrimination on the basis of sexual orientation. Other commenters asserted that Section 1557 did not intend to protect against sexual orientation discrimination and that OCR does not have authority to include this basis because no Federal appellate court has interpreted Title IX's or Title VII's ban on sex discrimination to protect same-sex relationships or conduct.

Response: As we noted in the preamble to the proposed rule, we support a prohibition on discrimination based on sexual orientation as a matter of policy. We believe that it is critical to meeting the goals of Section 1557 and, more broadly, the ACA, to ensure equal access to health care and health coverage. Indeed, these policy goals are reflected in the increasing number of actions taken by Federal agencies to ensure that lesbian, gay, and bisexual individuals are protected from discrimination. For example, CMS regulations bar discrimination on the basis of sexual orientation by Health Insurance Marketplaces and issuers offering qualified health plans;[69] Medicare regulations prohibit the restriction of visitation rights in hospitals based on sexual orientation (or gender identity);[70] and the Social Security Administration is now processing Medicare enrollments for same-sex spouses.[71] Court decisions have, moreover, repeatedly made clear that individuals and couples deserve equal rights regardless of their sexual orientation.[72]

The preamble to the proposed rule stated our policy position and noted that ''[t]he final rule should reflect the current state of nondiscrimination law, including with respect to prohibited bases of discrimination'' while seeking comment on the issue. While the preamble observed that no Federal appellate court has concluded to date ''that Title IX's prohibition of discrimination 'on the basis of sex'—or Federal laws prohibiting sex discrimination more generally—prohibits sexual orientation discrimination,'' it also noted recent court decisions that have prohibited discrimination in cases involving allegations of discrimination relating to an individual's sexual orientation on the grounds that such discrimination is discrimination on the basis of sex stereotyping.

Price Waterhouse v. *Hopkins*[73] is the foundational decision that underlies these legal developments. Though *Price Waterhouse* did not involve an allegation of discrimination based on an individual's sexual orientation, the Supreme Court recognized in that case that unlawful sex discrimination occurs where an individual is treated differently based on his or her failure to conform to gender-based stereotypes about how men or women should present themselves or behave. The Department of Justice has therefore taken the position that a well-pled complaint alleging discrimination against a gay employee because of his failure to conform to sex stereotypes states a viable sex discrimination claim under Title VII.[74] When a covered entity discriminates against an individual based on his or her sexual orientation, the entity may well rely on stereotypical notions or expectations of how members of a certain sex should act or behave. These stereotypes are precisely the type of gender-based assumptions prohibited by *Price Waterhouse.*[75]

[66] U.S. Dep't of Education, Office for Civil Rights, Questions and Answers in Title IX and Single Sex Elementary and Secondary Classes and Extra-Curricular Activities, (2014), *http://www2.ed.gov/about/offices/list/ocr/docs/faqs-title-ix-single-sex-201412.pdf.*

[67] *.G. ex rel. Grimm* v. *Gloucester Cty. Sch. Bd.,* No. 15–2056, 2016 WL 1567467 at * 6 (4th Cir. 2016).

[68] *See e.g., Crosby* v. *Reynolds,* 763 F. Supp. 666 (D. Me. 1991) (requiring female prisoner to share a cell with a transgender woman violated no clearly established constitutional right); *cf. Cruzan* v. *Special Sch. Dist., #1,* 294 F.3d 981 (8th Cir. 2002) (per curiam) (teacher's assertion that her personal privacy was invaded when school permitted a transgender woman to use women's restroom was not cognizable under employment discrimination law).

[69] 45 CFR 155.120(c)(1)(ii); 156.200(e).

[70] 42 CFR 482.13(h)(3).

[71] *http://www.medicare.gov/sign-up-change-plans/same-sex-marriage.html* (last visited Mar. 11, 2016).

[72] For example, in 1996, the Supreme Court struck down an amendment to the Colorado constitution that prohibited the State government from providing any legal protections to gay, lesbian, and bisexual individuals. *Romer* v. *Evans,* 517 U.S. 620 (1996). And, just last year, the Supreme Court ruled in *Obergefell* v. *Hodges,* 135 S. Ct. 2584 (2015), that states may not prohibit same-sex couples from marrying and must recognize the validity of same-sex couples' marriages.

[73] 490 U.S. 228 (1989).

[74] *See* Def.'s Renewed Mot. to Dismiss at 18–19, *Terveer* v. *Billington,* No. 1:12–cv–1290, ECF No. 27 (D.D.C. Mar. 21, 2013).

[75] *See, e.g., Deneffe* v. *SkyWest, Inc.,* No. 14–cv–00348, 2015 WL 2265373, at * (D. Colo. May 11, 2015); *Terveer* v. *Billington,* 34 F. Supp. 3d 100, 116 (D.D.C. 2014); *Boutillier* v. *Hartford Pub. Schs.,*

Continued

Based on this understanding, some courts have recognized in the wake of *Price Waterhouse* that discrimination ''because of sex'' includes discrimination based on sex stereotypes about sexual attraction and sexual behavior [76] or about deviations from ''heterosexually defined gender norms.'' [77] For example, a recent district court decision in the Ninth Circuit held that the distinction between discrimination based on gender stereotyping and discrimination based on sexual orientation is artificial, and claims based on sexual orientation are covered by Title VII and Title IX, not as an independent category of claims separate from sex and gender stereotyping, but as sex or gender discrimination.[78]

In addition, in *Baldwin* v. *Department of Transportation* the EEOC concluded that Title VII's prohibition of discrimination ''because of sex'' includes sexual orientation discrimination because discrimination on the basis of sexual orientation necessarily involves sex-based considerations.[79] The EEOC relied on several theories to reach this conclusion: A plain reading of the term ''sex'' in the statutory language, an associational theory of discrimination based on ''sex,'' and the gender stereotype theory announced in *Price Waterhouse.*

For all of these reasons, OCR concludes that Section 1557's prohibition of discrimination on the basis of sex includes, at a minimum, sex discrimination related to an individual's sexual orientation where the evidence establishes that the discrimination is based on gender stereotypes. Accordingly, OCR will evaluate complaints alleging sex discrimination related to an individual's sexual orientation to determine whether they can be addressed under Section 1557.

OCR has decided not to resolve in this rule whether discrimination on the basis of an individual's sexual orientation status alone is a form of sex discrimination under Section 1557. We anticipate that the law will continue to evolve on this issue, and we will continue to monitor legal developments in this area. We will enforce Section 1557 in light of those developments and will consider issuing further guidance on this subject as appropriate.

Summary of Regulatory Changes

For the reasons set forth in the proposed rule and considering the comments received, we are finalizing this definition as proposed in § 92.4 without modification.

Qualified bilingual/multilingual staff. In the proposed rule, we proposed to define ''language assistance services'' to include, as a type of oral language assistance, the use of staff members who are ''competent to communicate, in non-English languages using any necessary specialized vocabulary, directly with individuals with limited English proficiency.'' [80] The proposed rule did not define the term ''qualified bilingual/multilingual staff.''

Comment: Some commenters observed that as an alternative to providing oral interpretation, many covered entities rely on staff members to serve individuals with limited English proficiency in their respective primary languages. According to these commenters, covered entities mistakenly assume that staff members who possess a rudimentary familiarity with at least one non-English language are competent to provide oral language assistance for the covered entity's health program or activity. Commenters asked us to require covered entities to assess the proficiency of staff members who communicate directly with individuals with limited English proficiency in their respective primary languages.

Response: In response to commenters' observations, we have defined the term ''qualified bilingual/multilingual staff'' in § 92.4 to clarify the knowledge, skills, and abilities that a staff member must demonstrate for a covered entity to designate that staff member to provide effective oral language assistance.[81] Specifically, qualified bilingual/multilingual staff must demonstrate to the covered entity that they are proficient in English and at least one other spoken language, including any necessary specialized vocabulary, terminology and phraseology, and are able to effectively, accurately, and impartially communicate directly with individuals with limited English proficiency in their primary language. An individual who meets the definition of ''qualified bilingual/multilingual staff'' does not necessarily qualify to interpret or translate for individuals with limited English proficiency within the meaning of this rule.

Summary of Regulatory Changes

For the reasons set forth above and considering the comments received, we are defining the term ''qualified bilingual/multilingual staff'' in § 92.4 to clarify that such an individual must be proficient in speaking and understanding both spoken English and at least one other spoken language, including any necessary specialized vocabulary, terminology and phraseology, and must be able to effectively, accurately, and impartially communicate directly with individuals with limited English proficiency in their primary languages.

Qualified interpreter. We proposed that the term ''qualified interpreter'' means an individual who has the characteristics and skills necessary to interpret for an individual with a disability, for an individual with limited English proficiency, or for both. In the proposed rule, the language in paragraph (1), applicable for interpreting for an individual with a disability, is the same as language in the regulations implementing Titles II and III of the ADA, at 28 CFR 35.104 and 36.104, respectively. The language in paragraph (2) of the proposed rule, applicable for interpreting for an individual with limited English proficiency, reflects a synthesis of the attributes, described in the Department's LEP Guidance, that are necessary for an individual to interpret competently and effectively under the circumstances and thus to provide the effective oral language assistance services required under the law.[82] We noted that the fact

2014 WL 4794527 at *2 (D. Conn. 2014); *Koren* v. *The Ohio Bell Tel. Co.,* 894 F. Supp.2d 1032, 1037–38 (N.D. Ohio. 2012); *Heller* v. *Columbia Edgewater Country Club,* 195 F. Supp.2d 1212, 1224, *adopted,* 195 F. Supp.2d 1216 (D. Or. 2002); *Centola* v. *Potter*, 183 F. Supp.2d 403, 410 (D. Mass. 2002).

[76] *See Videckis and White* v. *Pepperdine Univ.,* No. 15–00298, 2015 WL 8916764 (C.D. Cal. Dec. 15, 2015) (denying motion to dismiss).

[77] *Isaacs* v. *Felder,* No. 2:13 cv 693, 2015 WL 6560655, at * 9 (M.D. Ala. Oct. 29, 2015) (internal quotation marks omitted).

[78] *Videckis,* 2015 WL 8916764. Prior circuit court decisions have drawn such distinctions. *See, e.g., Dawson* v. *Bumble & Bumble,* 398 F.3d 211, 218 (2d Cir. 2005); *Vickers* v. *Fairfield Med. Ctr.,* 453 F.3d 757, 763 (6th Cir. 2006).

[79] U.S. Equal Employment Opportunity Comm'n Appeal No. 0120133080, Agency No. 2012–24738–FAA–03 (July 15, 2015), *http://www.eeoc.gov/decisions/0120133080.txt* (finding that sexual orientation is inseparable from and inescapably linked to sex and thus that an allegation of discrimination based on sexual orientation is necessarily an allegation of sex discrimination).

[80] *See* 80 FR at 54176, 54216.

[81] *See* HHS LEP Guidance, *supra* note 49, 68 FR at 47317 (stating that the covered entity may provide oral language assistance through bilingual staff members that are ''competent to communicate directly with [limited English proficient] persons in their language'').

[82] *See* HHS LEP Guidance, 68 FR at 47311, 47316 (explaining that an individual's proficiency in another language, knowledge of specialized terminology, and adherence to interpreter ethics are considerations in determining competency to interpret); *id.* at 47317–18, 47323 (discussing why family members, friends, and ad hoc interpreters may not be competent to interpret); The language is also consistent with the approach we have taken in our Title VI enforcement efforts. *See, e.g.,* Voluntary Resolution Agreement between U.S. Dep't of Health & Human Servs., Office for Civil Rights and Mee Memorial Hosp., OCR Transaction

that an individual has above average familiarity with speaking or understanding a language other than English does not suffice to make that individual a qualified interpreter for an individual with limited English proficiency.

We proposed that the definition of ''qualified interpreter'' includes criteria regarding interpreter ethics, including maintaining client confidentiality. As we stated in the proposed rule, bilingual or multilingual staff members may not possess competence in the skill of interpreting nor have knowledge of generally accepted principles of interpreter ethics. A qualified bilingual/multilingual nurse who is competent to communicate in Spanish directly with Spanish-speaking individuals may not be a qualified interpreter for an individual with limited English proficiency if serving as an interpreter would pose a conflict of interest with the nurse's treatment of the patient.

Comment: A few commenters suggested that OCR amend the definition of qualified interpreter to require interpreters to be licensed by State law in the State where the entity is providing services. Other commenters suggested that OCR require interpreters to be certified by a national nonprofit certification organization.

Response: We recognize the commenters' concerns regarding licensure and certification, but we decline to accept these recommendations. Although OCR considers licensure and certification as evidence that an interpreter is qualified, licensure and certification are neither necessary nor sufficient evidence of qualification for the following reasons.[83] First, OCR does not wish to unduly narrow the pool of qualified interpreters available to a covered entity by requiring certification or licensure; many interpreters who are currently unlicensed and uncertified are competent to translate at a level that would meet the requirements of Section 1557 and this part.

Second, there are several organizations, both for-profit and non-profit, that offer certification programs for interpreters. Even if the credentialing standards developed by those organizations currently satisfy Section 1557 requirements, the organizations' standards are subject to change and there is no assurance that such standards would consistently meet the standards of Section 1557. In addition, other national credentialing organizations could be established whose standards failed to meet the requirements of the law. Similar issues with respect to new and changing standards could also arise in the State licensing context.

Third, there are factors unrelated to credentials that could cause OCR to determine that an interpreter is unqualified. For example, if an interpreter has not practiced in a long time or is late to appointments, the interpreter might be unqualified regardless of the interpreter's State or non-profit credentials. For all of these reasons, we decline to amend the definition of qualified interpreter in the ways these commenters proposed.

Comment: We received many comments in support of the proposed rule's inclusion of a definition of ''qualified interpreter.'' Some commenters, however, requested that we define a qualified interpreter who interprets for individuals with limited English proficiency separately from a qualified interpreter who interprets for individuals with disabilities, noting that there are significant differences between the provision of oral interpretation services in these two contexts. Other commenters suggested broadening the lexicon an interpreter must possess to be a qualified interpreter for a particular covered entity's health program. Specifically, commenters suggested that an interpreter's required knowledge and abilities to be ''qualified'' should include not only knowledge of any necessary specialized vocabulary but also knowledge of terminology and phraseology.

Response: We have modified § 92.4 to provide separate definitions of ''qualified interpreter for an individual with limited English proficiency'' [84] and ''qualified interpreter for an individual with a disability.'' We agree that it is important to account for the qualifications necessary for interpreting for each set of individuals. In addition, we added the words ''terminology'' and ''phraseology'' in both definitions to align the final rule's description of the requisite knowledge, skills, and abilities an interpreter must possess with those recognized within the field.

Summary of Regulatory Changes

For the reasons set forth above and considering the comments received, we no longer define ''qualified interpreter'' as one term. We are using the content from proposed paragraphs (1), (1)(i), and (2) to create a separate definition for ''qualified interpreter for an individual with a disability'' and similarly use the content from proposed paragraphs (1) and (1)(ii) to create a separate definition for ''qualified interpreter for an individual with limited English proficiency.'' For both definitions, we added ''terminology and phraseology'' to the lexicon a qualified interpreter in both contexts must possess.

Qualified translator. The proposed rule did not use or define the term ''qualified translator.''

Comment: We received a significant number of comments recommending that the proposed rule define ''qualified translator.'' Commenters explained that bilingual individuals do not necessarily possess the skill of translating or the knowledge of specialized terminology to be able to translate written documents from English to another language. Similarly, a qualified interpreter for an individual with limited English proficiency may not possess the knowledge, skills, and abilities to translate, as the skill of interpreting is different from the skill of translating.[85]

Response: In response to commenters' recommendations, we are adding the term ''qualified translator'' to the final rule. The final rule defines qualified translator as someone who translates effectively, accurately, and impartially; adheres to generally accepted translator ethics principles; and is proficient in both written English and at least one other written non-English language, including any necessary specialized vocabulary, terminology and phraseology. We agree with commenters that even if an individual meets the definition of ''qualified bilingual/multilingual staff'' or ''qualified interpreter for an individual with

Nos. 12–143846, 13–1551016 & 13–153378, pt. II.J. (2014) [hereinafter HHS OCR VRA with Mee Memorial Hospital], *http://www.hhs.gov/ocr/civilrights/activities/agreements/mee.html* (defining qualified interpreter); Voluntary Resolution Agreement between U.S. Dep't of Health & Human Servs., Office for Civil Rights and Montgomery County Dep't of Soc. Servs., OCR Transaction No. 08–79992, pts. II.E (defining qualifications of an ''interpreter'' under the agreement), IV.H (requiring timely, competent language assistance); & IV.L (identifying interpreter standards) [hereinafter HHS OCR VRA with Montgomery County DSS], *http://www.hhs.gov/civil-rights/for-providers/compliance-enforcement/examples/limited-english-proficiency/MCDSS-resolution-agreement/index.html.*

[83] *See* HHS LEP Guidance, 68 FR at 47316 (''Competency to interpret, however, does not necessarily mean formal certification as an interpreter, although certification is helpful.'').

[84] We note that this final rule uses the terms ''qualified interpreter for an individual with limited English proficiency'' interchangeably with ''qualified interpreter for the individual with limited English proficiency'' and ''qualified interpreter to an individual with limited English proficiency.'' The preposition and article used within the phrase do not represent a change in meaning.

[85] *See* HHS LEP Guidance, *supra* note 49, 68 FR at 47316; Int'l Medical Interpreters Assoc., Guide on Medical Translation 4 (Jan. 2009), *http://www.imiaweb.org/uploads/pages/438.pdf.*

limited English proficiency'' under this rule, that individual does not necessarily possess the knowledge, skills, or abilities to translate written content in paper or electronic form used in a covered entity's health programs or activities.

Summary of Regulatory Changes

For the reasons set forth above and considering the comments received, we are defining the term ''qualified translator'' in § 92.4 to set out the competencies an individual must have to translate written content in paper or electronic form in the covered entity's health programs or activities.

Sex stereotypes. We proposed that the term ''sex stereotypes'' refers to stereotypical notions of masculinity or femininity, including expectations of how individuals represent or communicate their gender to others, such as behavior, clothing, hairstyles, activities, voice, mannerisms, or body characteristics. We noted that these stereotypes can include expectations that gender can only be constructed within two distinct opposite and disconnected forms (masculinity and femininity), and that gender cannot be constructed outside of this gender construct.

Comment: Commenters suggested that OCR revise the definition of ''sex stereotypes'' because, while accurate in describing the types of assumptions that may motivate discrimination against non-binary individuals, the definition is cumbersome and may not be readily understood by persons not familiar with the issue. Several commenters expressed concern that the proposed language might be interpreted as limiting sex discrimination based on sex stereotyping to only include discrimination based on gender identity. Commenters suggested affirming in the final rule that any form of sex discrimination on the basis of sex stereotypes constitutes sex discrimination, whether or not it also constitutes discrimination on the basis of gender identity. Some commenters requested that OCR provide examples illustrating discrimination based on sex stereotypes that can form the basis of prohibited sex discrimination.

Several commenters suggested that OCR clarify the definition of ''sex stereotypes'' to address the relationship between sex stereotypes and sexual orientation. In this regard, commenters suggested that OCR revise the definition of ''sex stereotypes'' to add that ''sex-stereotypes also include gendered expectations related to the appropriate roles of men and women, such as the expectation that women are primary caregivers, and aspects of an individual's sexual orientation, such as the sex of an individual's sexual or romantic partners.''

Response: We have added a reference in the regulatory text to make clear that sex stereotypes include gendered expectations related to the appropriate roles of a certain sex.[86] With regard to sexual orientation, we refer commenters to the discussion in the preamble addressing the definition of ''on the basis of sex.''[87]

Comment: Some commenters stated that the proposed definition of sex stereotypes is unprecedented in its breadth with no legal authority to support the proposition that individuals who claim to identify with non-binary genders constitute a protected class under Title IX or any other Federal law. Commenters suggested that it is impossible for an individual to have a non-binary gender identity.

Response: OCR has adopted the approach taken by the Federal government and numerous courts in similar matters—that sex stereotypes encompass not only stereotypes concerning the biological differences between the sexes, but also include stereotypes concerning gender norms.[88] As stated in the preamble to the proposed rule and clarified in the final rule, OCR recognizes that sex stereotypes can include the expectation that individuals consistently identify with only one of two genders (male or female), and that they act in conformity with the gender-related expressions stereotypically associated with that gender. Sex stereotypes can also include a belief that gender can only be binary and thus that individuals cannot have a gender identity other than male or female. OCR recognizes that an individual's gender identity involves the interrelationship between an individual's biology, gender, internal sense of self and gender expression related to that perception; thus, the gender identity spectrum includes an array of possible gender identities beyond male and female.

Summary of Regulatory Changes

For the reasons set forth in the proposed rule and considering the comments received, we are finalizing the definition as proposed in § 92.4 with the following modifications: We have clarified that sex stereotypes can be based on expectations about gender roles.

Taglines. In the proposed rule, we defined taglines as short statements written in non-English languages to alert individuals with limited English proficiency to the availability of language assistance services, free of charge, and how the services can be obtained.[89] We did not receive comments with suggested revisions to the wording of this definition.

Summary of Regulatory Changes

For the reasons set forth in the proposed rule and considering the comments received, we are finalizing this definition as proposed in § 92.4 without modification.

Assurances Required (§ 92.5)

In § 92.5, we proposed that each entity applying for Federal financial assistance, each issuer seeking certification to participate in a Health Insurance Marketplace SM, and each state seeking approval to operate a State-based Marketplace SM be required to submit an assurance that its health programs and activities will be operated in compliance with Section 1557. We noted that the regulations implementing Title VI, Title IX, Section 504, and the Age Act all require similar assurances. We modeled the assurance, duration of obligation, and covenants language on the Section 504 regulation.[90] We also proposed to revise the Assurance of Compliance HHS–690 Form to include all civil rights laws, including Section 1557, with which covered entities must comply.

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

Comment: Several commenters recommended that OCR require covered entities to collect data on race, ethnicity, language, sex, gender, gender identity, sexual orientation, disability, and age. These commenters suggested that covered entities should be required to assess the populations they serve so that the covered entities can better plan how to meet the needs of those populations.

[86] *See, e.g., Chadwick* v. *Wellpoint,* Inc., 561 F.3d 38, 45 (1st Cir. 2009) (adverse employment action based on assumption that women are responsible for family caregiving and will perform their jobs less well as a result of caregiving responsibilities is discrimination based on sexual stereotypes in violation of Title VII). *See also Glenn* v. *Brumby,* 663 F.3d 1312 (11th Cir. 2011) (''These instances of discrimination against plaintiffs because they fail to act according to socially prescribed gender roles constitute discrimination under Title VII according to the rationale of *Price Waterhouse.''*).

[87] *See* discussion § 92.4, *supra.*

[88] *See Price Waterhouse,* 490 U.S. at 251; *Smith,* 378 F.3d. at 573 (citations omitted).

[89] The HHS LEP Guidance, *supra* note 49, 68 FR at 47320, describes the practice of tagging non-English statements on the front of common documents, such as ''brochures, booklets, and in outreach and recruitment information'' informing individuals with limited English proficiency of the availability of language assistance services.

[90] 45 CFR 84.5.

The commenters also urged that OCR require annual submission of the data to OCR and develop standards to address training on data collection, privacy protections, safeguarding, voluntary reporting by patients, and supporting analyses based on multiple variables.

Response: OCR agrees that data collection is an important tool that can help covered entities to better serve their communities, and encourages covered entities to regularly evaluate the impact of the services they provide on different populations. However, OCR declines to require data collection as part of the assurances required under Section 1557. The Department collects data pursuant to Section 4302 of the ACA, and OCR has access to these data. In addition, OCR has the authority to require covered entities to collect data and to provide OCR access to information under §§ 92.302 and 92.303 of this part,[91] and will exercise this authority as needed and appropriate under particular circumstances in the future. With respect to recipients and State-based Marketplaces, §§ 92.302(a) and 92.302(b) incorporate the procedural provisions in the Title VI and the Age Act implementing regulations regarding enforcement actions under this part. Pursuant to these procedural provisions, when a recipient or State-based Marketplace SM fails to provide OCR with requested information in a timely, complete, and accurate manner, OCR may find noncompliance with Section 1557 and initiate appropriate enforcement procedures, including beginning the process for fund suspension or termination and taking other action authorized by law. OCR has inserted a new subsection (c) to § 92.302 to clarify that it has that it has this authority, and the text that was previously found at § 92.302(c) has been moved to the new § 92.302(d).

Summary of Regulatory Changes

For the reasons set forth in the proposed rule and considering the comments received, we are finalizing the provisions proposed in § 92.5 without modification.

[91] Section 92.302 incorporates provisions of the Title VI implementing regulation with respect to enforcement actions concerning discrimination on the basis of race, color, national origin, sex, age, or disability. Those provisions authorize OCR to collect reports from recipients as necessary to determine compliance. Section 92.303 incorporates provisions in the Section 504 implementing regulation with respect to discrimination on the basis of prohibited criteria in health programs or activities administered by the Department. Those provisions authorize OCR to initiate actions as necessary to ensure compliance.

Remedial Action and Voluntary Action (§ 92.6)

In § 92.6, we proposed provisions addressing remedial action and voluntary action by covered entities. In paragraph (a), we proposed that a recipient or State-based Marketplace SM that has been found to have discriminated on any of the bases prohibited by Section 1557 be required to take remedial action as required by the Director to overcome the effects of that discrimination. We proposed that similar to recipients and State-based Marketplaces, the Department, including the Federally-facilitated Marketplaces, is also obligated to address discrimination, but is subject to a different remedial process than recipients and State-based Marketplaces. In paragraph (b), we proposed to permit but not require all covered entities to take voluntary action in the absence of a finding of discrimination to overcome the effects of conditions that result or resulted in limited participation by persons based on race, color, national origin, sex, age, or disability. The provisions at §§ 92.6(a) and (b) are modeled after the Title VI, Title IX, Section 504, and Age Act regulations.

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

Comment: One commenter requested that OCR specifically list the remedial actions available to OCR as well as the circumstances under which such remedial actions will be taken.

Response: In the discussion of enforcement mechanisms and procedures in the preamble to the proposed rule, OCR identified the range of enforcement tools available to OCR. However, it would not be feasible to specify the circumstances in which specific remedial actions would be taken. OCR evaluates each situation on a case-by-case basis and may use different remedial actions in different cases. In all cases, OCR attempts to achieve compliance and, in our experience, this approach has been successful.

Comment: One commenter requested clarification of the word ''control'' in the part of the regulation that states that where a recipient exercises ''control'' over a recipient that has discriminated, the Director may require both entities to take remedial action. Another commenter suggested that OCR only pursue remedial action against the entity actually found to have discriminated against an individual and not against the controlling entity.

Response: OCR declines to further define the word ''control'' as used in the regulation. This term has appeared in civil rights regulations enforced by OCR for many years, and its meaning has been established over time. OCR also declines to limit its authority to pursue remedial action with respect to an entity that exercises control over an entity that has discriminated. This too is longstanding authority under OCR's other authorities, and in OCR's experience, controlling entities that are recipients often play an important role in securing appropriate action to remedy discrimination.

Comment: One commenter suggested that there be limitations on the uses of remedial action. Specifically, the commenter stated that OCR should require remedial action only on behalf of individuals who either (1) applied to participate but were unable to participate due to alleged discrimination; or (2) had been participants and were subject to alleged discrimination. The commenter asserted that without such limitations, covered entities could be unfairly exposed to claims by individuals who would not have been participants notwithstanding any alleged discrimination.

Response: OCR does not believe that limiting the availability of remedial action as suggested is appropriate. It would not be consistent with Section 1557's and OCR's commitment to eliminating discrimination in all parts of a program or activity and remedying discrimination, where necessary, with respect to harmed individuals.

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 of Responsible Employee and Adoption of Grievance Procedures (§ 92.7)

In § 92.7, we proposed requirements for each covered entity that employs 15 or more persons to designate a responsible employee to coordinate the entity's compliance with the rule and adopt a grievance procedure. Many entities covered by Section 1557 and this part are already required to designate a compliance coordinator and have a written process in place for handling grievances with respect to disability discrimination in all programs and activities or sex discrimination in education programs or activities.[92]

[92] Under Section 504, a recipient of Federal financial assistance with 15 or more employees must designate at least one individual to coordinate the covered entity's compliance with Section 504's

Continued

In paragraph (a), we proposed that a covered entity that employs 15 or more persons be required to designate at least one employee to coordinate compliance with the requirements of the rule. We noted that a covered entity that has already designated a responsible employee pursuant to the regulations implementing Section 504 or Title IX may use that individual to coordinate its efforts to comply with Section 1557.

In paragraph (b), we proposed that a covered entity that employs 15 or more persons be required to adopt a grievance procedure that incorporates appropriate due process standards and allows for the prompt and equitable resolution of complaints concerning actions prohibited by Section 1557 and this part. We noted that a covered entity that already has a grievance procedure addressing claims of disability discrimination that meets the standards established under the Section 504 regulation may use that procedure to address disability claims under Section 1557. In addition, we noted that covered entities may use that procedure to address all other Section 1557 claims, provided that the entity modifies the procedure to apply to race, color, national origin, sex, and age discrimination claims.

We proposed that for the Department, including Federally-facilitated Marketplaces, OCR will be deemed the responsible employee. In addition, we proposed that OCR's procedures for addressing complaints of discrimination on the grounds protected under Section 1557 will be deemed grievance procedures for the Department, including for the Federally-facilitated Marketplaces.

In the proposed rule, OCR invited comment on whether all covered entities, not only those that employ 15 or more persons, should be required to designate responsible employees and establish grievance procedures.

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

Comment: Some commenters opposed inclusion of proposed § 92.7, arguing that it is unnecessary and costly and has few benefits because discrimination in health programs and activities does not exist. Other commenters urged that Federal regulation in this area constrains covered entities' flexibility to decide how to address individuals' complaints of discrimination. Specifically, these commenters encouraged OCR to allow covered entities to retain existing internal grievance processes, leverage grievance processes within State agencies or within other entities, or develop new grievance procedures.

Response: We recognize commenters' concerns, but we disagree with commenters regarding the necessity of proposed § 92.7. To promote the effective and efficient implementation of Section 1557 and this part, it is necessary for covered entities with 15 or more employees to identify at least one individual accountable for coordinating the covered entity's compliance and to have a written process in place for handling grievances. We recognize that not all covered entities are organized and operate in the same way. Thus, we do not prescribe who in the covered entity must serve as the responsible employee—nor do we prohibit combining this function with other duties so long as there is no conflict of interest.

In addition, we disagree with commenters that proposed § 92.7 is costly, limits covered entities' flexibility, or conflicts with existing internal or State-mandated grievance procedures. As we stated in the proposed rule, recipients of Federal financial assistance with 15 or more employees, as well as the State-based Marketplaces, could increase the responsibilities of an already-designated coordinator to include the coordination of compliance with Section 1557 and this part.[93] These entities could also increase the scope of the existing grievance procedures required under Section 504 and the ADA to accommodate complaints of discrimination addressing all bases prohibited under Section 1557. Moreover, nothing in the rule bars a covered entity from combining the grievance procedure required under Section 1557 with procedures it uses to address other grievances, including those unrelated to individuals' civil rights. As described in the Regulatory Impact Analysis of the proposed rule[94] and reiterated in the Regulatory Impact Analysis to this final rule, the costs associated with these requirements are estimated to be minimal.

Comment: Some commenters stated that the final rule should specify minimum regulatory requirements for the grievance procedure required in § 92.7(b). Such minimum requirements would include, for instance: Timeframes for filing, resolving, and issuing written decisions regarding complaints; an appeal process; notice regarding retaliation protections; and clarification that no person needs to exhaust a covered entity's grievance procedure prior to filing a Section 1557 complaint with OCR. These commenters urged OCR to adopt regulatory requirements, instead of a model grievance procedure only, stating that a model policy alone is insufficient to ensure that an entity's grievance procedure provides meaningful rights and protections.

Response: We understand the commenters' concerns, but we decline to promulgate minimum standards for the content of the grievance procedure required in § 92.7(b); such an approach would be too prescriptive. Because Section 1557 and this part cover a variety of types of entities, we want to preserve flexibility for entities to adapt the rule's requirements to their own health programs and operational capacity, so long as the rules result in the prompt and equitable resolution of complaints. However, to provide covered entities an example of how to structure a grievance procedure that affords individuals appropriate procedural safeguards and provides for the prompt and equitable resolution of complaints, we have included a sample procedure as Appendix C. We disagree with commenters that a sample grievance procedure is insufficient; rather, a sample grievance procedure provides guidance to covered entities while also preserving their flexibility. In response to commenters' suggestion that we note that an individual need not exhaust a covered entity's grievance procedure prior to filing a Section 1557 complaint, we clarify that no such exhaustion requirement exists, as reflected in the sample grievance procedure included as Appendix C to the final rule.

Comment: Many commenters supported the alternate approach that would require covered entities with fewer than 15 employees to comply with § 92.7. These commenters reasoned that requiring all covered entities to designate a coordinator and establish a grievance procedure would give each entity the internal mechanisms to resolve compliance issues earlier and informally, allowing them to potentially avoid a formal investigation by OCR. Accordingly, these commenters asserted that the importance of extending

prohibition of disability discrimination and must have a written process in place for handling grievances. 45 CFR 84.7(a). Under Title IX, a recipient of Federal financial assistance must designate at least one individual to coordinate the recipient's compliance with Title IX's prohibition of sex discrimination with respect to the recipient's education program or activity and must have a written process in place for handling grievances. 45 CFR 86.8(a). Under Title II of the ADA, an entity with 50 or more employees must designate at least one individual to coordinate the covered entity's compliance with Title II's prohibition of disability discrimination and must have a written process in place for handling grievances. 28 CFR 35.107(a).

[93] *See* 80 FR 54172, 54202 (Sept. 8, 2015).

[94] *Id.*

required compliance with § 92.7 to covered entities with fewer than 15 employees justified the anticipated additional expense of compliance.

Some commenters observed that the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule already requires many entities covered by Section 1557 and this part to implement grievance policies and identify compliance coordinators, regardless of the number of employees of the entity.[95] The commenters suggested that the implementation of these requirements under the HIPAA Privacy Rule has given entities with fewer than 15 employees covered by both the HIPAA Privacy Rule and Section 1557 and this part the experience necessary to implement the similar requirements of § 92.7. Because many of the covered entities with fewer than 15 employees, such as most health care providers receiving Federal financial assistance, are subject to the HIPAA Privacy Rule, commenters asserted that extending the requirements of § 92.7 to covered entities with fewer than 15 employees would impose a limited burden.

Conversely, some commenters suggested that compliance with § 92.7 would be too time consuming and costly for covered entities with fewer than 15 employees. These commenters explained that due to the small number of employees, small covered entities may have difficulty identifying an unbiased third-party employee to investigate and respond to grievances. For instance, commenters noted that it is not uncommon for the chief physician or other professional to serve as the compliance coordinator for a small covered entity, but that such a role would be inappropriate if that individual was the subject of a grievance. These commenters also observed that requiring a covered entity to handle internal grievances under Section 1557 might expose the entity to the risk of civil liability, because Section 1557 allows for private enforcement. These commenters recommended that OCR allow small covered entities flexibility in determining when to defer to outside counsel or other independent, unbiased third parties to address grievances and thus mitigate their liability risk.

Response: We decline to extend the requirements of § 92.7 to covered entities with fewer than 15 employees. Although we recognize the benefits that extension of the requirements of § 92.7 would generate, we conclude that the costs, which would be borne by small entities, likely outweigh the benefits. Although many covered entities with fewer than 15 employees may have already identified a compliance coordinator and implemented a grievance policy to comply with the HIPAA Privacy Rule, extending the requirements of § 92.7 to such entities would create additional costs, as entities would need to revise their existing policies and retrain compliance coordinators.

Although we decline to extend the requirement of § 92.7 to covered entities with fewer than 15 employees, nothing in the final rule bars a covered entity with fewer than 15 employees from designating an employee to coordinate compliance with Section 1557 and this part or from adopting and implementing a grievance procedure. As we stated in the proposed rule, in OCR's experience, the presence of a coordinator and grievance procedure enhances the covered entity's accountability and helps bring concerns to prompt resolution, oftentimes prior to an individual bringing a private right of action.

Summary of Regulatory Changes

For the reasons described in the proposed rule and considering the comments received, we are finalizing the provisions as proposed in § 92.7 with one technical modification in § 92.7(a): We replaced the reference to the ''Office for Civil Rights'' with ''Director,'' as § 92.4 defines ''Director'' to mean the Director of the Department's OCR. We have also added a sample grievance procedure as Appendix C to the final rule to provide covered entities an example of a grievance procedure that meets the requirements of § 92.7(b).

Notice Requirement (§ 92.8)

In § 92.8, OCR proposed that each covered entity take initial and continuing steps to notify beneficiaries, enrollees, applicants, or members of the public of individuals' rights under Section 1557 and this part and of covered entities' nondiscrimination obligations with respect to their health programs and activities. We modeled this section generally after the notice requirements found in regulations implementing Title VI, Title IX, Section 504, and the Age Act, which require covered entities to have a notice in place.[96]

Paragraphs (a)(1)–(7) of proposed § 92.8 identify the components of the notice. Specifically, paragraph (a)(1) proposed that the notice include that the covered entity does not discriminate on the basis of race, color, national origin, sex, age, or disability.

Paragraph (a)(2) proposed that the notice include a statement that the covered entity provides auxiliary aids and services, free of charge, in a timely manner, to individuals with disabilities, when such aids and services are necessary to provide an individual with a disability an equal opportunity to benefit from the entity's health programs or activities. Paragraph (a)(3) proposed that the notice state that the covered entity provides language assistance services, free of charge, in a timely manner, to individuals with limited English proficiency, when those services are necessary to provide an individual with limited English proficiency meaningful access to a covered entity's health programs or activities.

Paragraph (a)(4) proposed that the notice include information on how an individual can access the aids and services referenced in (a)(2) and (a)(3).

Paragraph (a)(5) proposed that the notice provide contact information for the responsible employee coordinating compliance with Section 1557 and this part, where such a responsible employee is required by § 92.7(a).

Paragraph (a)(6) proposed that the notice state that the covered entity has a grievance procedure where such a grievance procedure is required by § 92.7(b), and information on how to file a grievance.

Paragraph (a)(7) proposed that the notice provide information on how to file a complaint with OCR. We noted that inclusion of this requirement ensures that covered entities inform individuals about the enforcement mechanisms outside of the covered entity's internal process.

Proposed paragraph (b) stated that within 90 days of the effective date of this part, each covered entity shall post the notice required in § 92.8(a) in English, consistent with paragraph (f) of this section.

Paragraph (c) proposed that the Director shall make available a sample notice. We provided that covered

[95] *See* 45 CFR 164.520(b)(1)(vi) and § 164.530(a)(1)(ii) (requires designation of ''contact person or office who is responsible for receiving complaints under this subsection'' and the provision of a notice ''that contains a statement that individuals may complain to the covered entity and to the Secretary if they believe their privacy rights have been violated, a brief description of how the individual may file a complaint with the covered entity, and a statement that the individual will not be retaliated against for filing a complaint,'' respectively.)

[96] 45 CFR 80.6(d) (requiring recipients to provide notice of individuals' rights under Title VI), 84.8(a)–(b) (requiring recipients to provide notice of individuals' rights under Section 504), 86.9(a)–(c) (requiring notice of individuals' rights under Title IX), 91.32 (requiring recipients to provide notice of individuals' rights under the Age Act).

entities may use this sample notice or may develop their own notices that convey the information in paragraphs (a)(1) through (7).

OCR invited comment on whether the proposed rule should permit covered entities to combine the content of the notice with the content of other notices that covered entities may be required to disseminate or post under Federal laws. OCR further invited comment on what steps covered entities may or should take to ensure that notices that combine the content required in § 92.8(a)(1)–(7) with other required notices do so without compromising the intent of § 92.8 to inform individuals of their civil rights under Section 1557 and this part. OCR also invited comment on whether the final rule should allow the notice to be modified for publications and other communication vehicles that may not have sufficient space to accommodate the full notice.

Paragraph (c) also proposed that the Director shall translate the sample notice into the top 15 languages spoken by individuals with limited English proficiency nationally and make the translated notices available to covered entities electronically and in any other manner the Director determines appropriate. We encouraged covered entities to post one or more of the translated notices that the Director provides and to make the notice available in non-English languages other than those provided by the Director. OCR sought comments on requiring, rather than merely encouraging, covered entities to post one or more of the notices in the most prevalent non-English languages frequently encountered by covered entities in their geographic service areas.

With regard to the proposal that the Director provide translations of the sample notice, we described that we selected the top 15 languages spoken by individuals with limited English proficiency nationally as a data driven policy.[97] We noted that we plan to review U.S. Census Bureau data as newer data become available to determine if and when the top 15 languages spoken nationally by individuals with limited English proficiency change, warranting the Director to make available notices in additional non-English languages.

Paragraph (d) proposed that within 90 days of the effective date of this part, each covered entity shall post, consistent with paragraph (f) of this section, taglines in at least the top 15 languages spoken nationally by individuals with limited English proficiency. We requested comment on a sample tagline in Appendix B to the proposed rule.

Paragraph (e) proposed that the Director shall make available taglines in the top 15 languages spoken nationally by individuals with limited English proficiency for use by covered entities. OCR proposed this approach to maximize efficiency and economies of scale by enabling covered entities to receive the benefits of having multi-language taglines available without incurring the associated translation costs.

In paragraph (f), we proposed that covered entities must post the English-language notice required in § 92.8(a) and taglines required in § 92.8(d) in a conspicuously-visible font size in: Significant publications or significant communications targeted to beneficiaries, enrollees, applicants, or members of the public, which may include patient handbooks, outreach publications, or written notices pertaining to rights or benefits or requiring a response from an individual; in conspicuous physical locations; and in a conspicuous location on the home page of a covered entity's Web site. We sought comment on the scope of significant publications and significant communications.

We noted that covered entities that distribute significant publications or significant communications will need to update these publications to include the notice required in § 92.8(a) and taglines required in § 92.8(d). However, we proposed allowing entities to exhaust their current stock of hard copy publications rather than requiring a special printing of the publications to include the new notice.

We stated that covered entities may satisfy the requirement to post the notice on the covered entity's home page by including a link in a conspicuous location on the covered entity's home page that immediately directs the individual to the content of the notice elsewhere on the Web site. Similarly, we stated with regard to the requirement to post taglines that covered entities can comply by posting ''in language'' Web links, which are links written in each of the 15 non-English languages posted conspicuously on the home page that direct the individual to the full text of the tagline indicating how the individual may obtain language assistance services. For instance, a tagline directing an individual to a Web site with the full text of a tagline written in Haitian Creole should appear as ''Kreyòl Ayisien'' rather than ''Haitian Creole.''

In the proposed rule, we invited comment on a State-based methodology for identifying the languages in which covered entities would be required to post taglines and for which the OCR Director would be required to translate the notice. We explained that the top 15 languages spoken by individuals with limited English proficiency nationally can differ from the languages spoken most frequently by individuals within the areas served by covered entities' health programs and activities. Thus, we invited comment on a requirement for entities to make taglines available in the top 15 languages spoken State-wide, rather than nationwide, by individuals with limited English proficiency. This threshold aligns with Federal regulations governing the Health Insurance Marketplaces and qualified health plan issuers.[98]

To reduce the burden on covered entities, proposed subsection (g) of this section stated that a covered entity's compliance with § 92.8 satisfies the notice requirements under HHS's Title VI, Section 504, Title IX, and Age Act regulations. We requested comment on this proposal.

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

Comment: Some commenters suggested that we revise the information required in § 92.8(a)(1)–(7) regarding the notice of individuals' rights. For instance, some commenters suggested that we specify that Section 1557 prohibits discrimination on the basis of ''national origin, including primary language and immigration status'' and ''sex, including pregnancy, gender identity, sex stereotypes, or sexual orientation. . . .'' These commenters asserted that the addition of these terms would more completely reflect the scope of protected classes under Section 1557. A few commenters recommended that the notice inform individuals of any religious accommodations or exemptions that the covered entity has received from compliance with civil rights laws and explain the services that

[97] *See* 80 FR 54179 (describing the methodology used in the proposed rule).

[98] *See* 45 CFR 155.205(c)(2)(iii)(A). This regulation, which requires taglines on certain documents and Web site content in at least the top 15 languages spoken State-wide by individuals with limited English proficiency is not the only tagline requirement with which qualified health plan issuers must comply. Qualified health plan issuers must comply with another tagline requirement applicable to group health plans and health insurance issuers, which requires taglines, on certain notices and on a health plan's summary of benefits and coverage, in languages in which 10% of individuals with limited English proficiency county-wide are exclusively literate. *See, e.g.,* 45 CFR 147.136(e)(2)(iii), (e)(3) (HHS regulations); 29 CFR 2590.715–2719(e)(2)(iii), (3) (DOL regulations for group health plans and health insurance issuers that are not grandfathered health plans).

the covered entity will and will not provide as a result of any religious exemptions or accommodations. Finally, a few commenters recommended revising §§ 92.8(a)(2) and (a)(3) to more closely parallel each other. For example, these commenters recommended that we list examples of language assistance services in paragraph (a)(3) and add a reference to providing meaningful access for persons with disabilities in paragraph (a)(2) of § 92.8.

Response: We decline to incorporate the suggestions made with regard to § 92.8(a)(1). The final rule defines the terms ''on the basis of sex'' and ''national origin'' in § 92.4, which is sufficient to define the scope of these protected classes as used in § 92.8(a)(1) and in Appendix A.[99] We are concerned that replicating the regulatory definitions of ''on the basis of sex'' and ''national origin'' in § 92.8(a)(1) and across-the-board in the final rule would dilute the concise, targeted message of the nondiscrimination statement and reduce the value of identifying the core bases on which discrimination is prohibited. Further, replicating the definitional text of these bases in § 92.8(a)(1) but not throughout the final rule may cause unnecessary confusion regarding the scope of discrimination prohibited by Section 1557 and this part. Accordingly, we decline to make the suggested revisions and are removing the terms ''including sex stereotypes and gender identity'' from the sample notice in Appendix A. OCR intended the nondiscrimination statement in § 92.8(a)(1) to convey covered entities' overarching nondiscrimination obligations in a simple and streamlined manner, as the notice requirements do in regulations implementing Title VI, Title IX, Section 504, and the Age Act.[100] The notice requirement of the Title IX implementing regulations does not require recipients of Federal financial assistance to identify exclusions from Title IX's application or exceptions to discrimination prohibited under Title IX.[101] Moreover, under the final rule, the availability of a religious exemption will depend on an analysis of the particular situation; thus, it would be difficult for an entity to state that it was exempt for all purposes. Accordingly, this final rule preserves the simplicity of the nondiscrimination statement consistent with other Federal civil rights laws.

We have revised § 92.8(a)(3) to list examples of language assistance services to parallel § 92.8(a)(2), which lists examples of auxiliary aids and services. We decline to modify the standards in paragraphs (a)(2) and (a)(3) because ''meaningful access'' is not the proper standard used in Section 504 for ensuring effective communication for individuals with disabilities.

Finally, as we stated in the proposed rule, Appendix A to part 92 is a sample notice. Covered entities are free to draft their own notices that convey the content in § 92.8(a)(1)–(7).

Comment: We received many comments addressing practical concerns about the size and length of required notices and taglines. Some commenters supported giving covered entities the flexibility to combine the content of the notice in § 92.8(a)(1)–(7) with other notices required under other Federal laws. For instance, a few comments stated that the State-based Marketplaces should be allowed to combine the content of the notice in § 92.8(a) with disclosures required by Federal regulations governing the Health Insurance Marketplaces at 45 CFR 155.230. Conversely, some commenters strongly opposed the idea of combining the content of the notice required in § 92.8(a) with other notices, reasoning that the combination, and likely modification, of the notice's content would diminish the clear message of the notice.

Some commenters expressed concern that posting the notice and the taglines in a ''conspicuously-visible font size'' as proposed in § 92.8(f)(1) and a ''conspicuous physical location'' as proposed in § 92.8(f)(1)(ii) would occupy prohibitive amounts of space for covered entities operating in small physical spaces, such as pharmacies. These commenters suggested that OCR permit covered entities operating in smaller physical spaces to post taglines in fewer than 15 non-English languages. Other commenters requested clarification from OCR on what constitutes a ''conspicuous physical location'' in § 92.8(f)(ii) and ''conspicuously visible font size'' in § 92.8(f)(1).

A number of commenters recommended that the final rule require covered entities to post the notice of individuals' rights—and not just taglines—in non-English languages.

Response: We intend to provide covered entities some flexibility to implement the requirements of § 92.8 in the manner that they determine meets the standards of this section while also reducing burden.

For instance, we will permit covered entities to combine the content of the notice in § 92.8(a)(1)–(7) with the content of other notices, such as notices required under other Federal civil rights laws. The content of the combined notice still must clearly convey the information required in § 92.8 (a)(1)–(7) and must separately meet any applicable notice requirements under relevant legal authorities. For instance, the regulations implementing Title IX and Section 504 require that a recipient provide a notice of individuals' rights to employees and applicants for employment.[102] Because this final rule is limited in its application to employment, it may not be sufficient for an entity covered by Title IX, Section 504, and Section 1557 and this part to rely on a notice conveying the content required in § 92.8(a)(1)–(7) as meeting its notice obligations under the regulations implementing Section 504 and Title IX. Accordingly, proposed paragraph (g), which is now re-designated as paragraph (h) of this final rule, no longer treats an entity's compliance with particular paragraphs of § 92.8 as constituting compliance with the notice provisions of other Federal civil rights authorities.

Specifically, § 92.8(h) now clarifies that covered entities may combine the content of the notice in § 92.8(a)(1)–(7) with the content of other notices as long as the combined notice clearly informs individuals of their civil rights under Section 1557 and this part. In addition to having flexibility with respect to combining notices, covered entities also have flexibility in determining the exact size and location of notices and taglines within their facilities as long as they do not compromise the intent of § 92.8 to clearly inform individuals of their civil rights under Section 1557 and this part.

The touchstone by which we will assess whether a covered entity's provision of notice and taglines is effective is whether the content is sufficiently conspicuous and visible that individuals seeking services from, or participating in, the health program or activity could reasonably be expected to see and be able to read the information.

[99] An individual's national origin is not the same as her citizenship or immigration status, and neither Title VI nor Section 1557 explicitly protects individuals against discrimination on the basis of citizenship or immigration status. However, as under Title VI, Section 1557 and this part protect individuals present in the United States, whether lawfully or not, who are subject to discrimination based on race, color, national origin, sex, age, or disability. *See* discussion *supra* note 53.

[100] *Supra* note 96.

[101] 45 CFR 86.9(a).

[102] *See* 45 CFR 86.9(a)(1) (requiring a recipient to provide a notice of individuals' rights to applicants for employment and to employees, among other groups of individuals); *id.* 84.8(a) (requiring a recipient to provide a notice of individuals' rights requiring notice to employees, among other groups of individuals).

Although we encourage covered entities to post the notice of individuals' rights in one or more of the most prevalent non-English languages frequently encountered by covered entities in their geographic service areas, we decline to require such posting in the final rule because of the resource burdens and opportunity costs to covered entities. Posted taglines sufficiently alert individuals to the language assistance services available and appropriately balance the educational value of the notices with the burdens to covered entities.

Given that we are not requiring covered entities to post notices in non-English languages, having taglines available in multiple languages is even more important to provide notice to individuals with limited English proficiency of the availability of language assistance services. Thus, we decline to reduce the number of languages in which taglines are required to appear, even for covered entities operating in smaller physical spaces. Covered entities have flexibility in determining the exact size and location of notices and taglines as long as they meet the requirements of this section.

Comment: We received many comments recommending alternative approaches to the proposed rule's requirement for taglines. A few commenters opposed the requirement in proposed § 92.8(d) as unnecessary because oral interpretation is generally available through the customer service telephone line listed on many consumers' health insurance cards. Some commenters suggested that the final rule should permit covered entities to include taglines on the inside of an envelope that a covered entity's health program or activity uses to mail a significant publication or a significant communication. A few commenters suggested replacing tagline text with an icon that would symbolize the availability of oral interpretation services. These commenters suggested that the icon would likely reach more language groups than taglines, and would also occupy substantially less space on significant publications and significant communications.

Response: We decline to eliminate the tagline requirement because such an approach would not provide adequate notice of language assistance services. We appreciate that many health insurance issuers provide telephonic oral interpretation services through their customer service lines/call centers—a number that usually appears on an insured individual's health insurance identification card. We do not, however, regard the mere availability of this information as adequate notice to individuals with limited English proficiency of the availability of language assistance services, much less as notice of each of the components of paragraphs (a)(1)–(7) of § 92.8. Moreover, this approach is not appropriate in all instances because not all covered entities rely on the use of an individual identification card.

In addition, we decline to authorize placement of taglines on the inside of an envelope. Such a placement would diminish the visibility of the taglines, downgrade their importance, and fail to adequately notify individuals because envelopes are generally torn open and then discarded.

With respect to use of an icon, we appreciate the commenters' suggestion and believe that it may hold promise in the future. However, we also decline to require the use of an icon in the final rule. At this point in time, use of an icon alone would not provide consumers with sufficient notice of the availability of language assistance services, which is the intent of § 92.8(d).

Comment: A small number of commenters provided feedback on the application of the requirement to post the notice and taglines in significant publications and significant communications that are small in size, such as brochures, postcards, targeted fliers, small posters, and those that are communicated through social media platforms. Some commenters recommended that the final rule exempt such communications and publications from the posting requirement in § 92.8(f)(1)(i); others recommended that the final rule provide covered entities latitude to substantially shorten the notice and taglines for these publications and communications. Commenters advocating for either of these two positions stated that the limited amount of space in such publications and communications makes them an impractical medium for disclosures of civil rights.

Other commenters opposed any exceptions for significant publications and significant communications that are small-sized, given the importance of notifying individuals about their rights under Section 1557, such as how to obtain auxiliary aids and services for individuals with disabilities and how to obtain language assistance services for individuals with limited English proficiency.

Response: We agree that the notice and tagline requirements for small-sized significant publications and communications should be distinguished from the requirements for significant publications and significant communications that are not small-sized. We also agree with commenters who suggested that small-sized significant publications and significant communications are not well-suited to extensive civil rights disclosures and that they function to drive consumers to other sources of information, such as a covered entity's Web site, where the full civil rights notice and taglines are required by § 92.8(f)(iii). Furthermore, posting the full notice and all 15 taglines to small-sized publications and communications may obscure the content and message of the document, thus undermining the value of such publication or communication. As a result, we are modifying § 92.8(f)(1)(i) to exclude small-sized significant publications and communications from requirements to have a notice and at least 15 taglines.

We disagree, however, with fully exempting significant publications and significant communications that are small-sized from the notice and tagline requirements because these documents, such as tri-fold brochures, pamphlets, and postcards, often serve as a gateway for an individual to apply for, or participate in, a particular health program or activity. To this end, the final rule establishes a separate requirement for small-sized significant publications and significant communications: A covered entity must include a nondiscrimination statement in lieu of the full notice, and taglines in two non-English languages in lieu of all 15 taglines, on small-size significant publications and significant communications.

Specifically, we moved most of the text from proposed paragraph (b) into a new paragraph (b)(1) and added paragraph (b)(2), which addresses the obligation to post a nondiscrimination statement that conveys the information in § 92.8(a)(1) on small-sized significant publications and significant communications. Similarly, we moved most of the text from proposed paragraph (d) into a new paragraph (d)(1) and added paragraph (d)(2), which addresses the obligation to post taglines in at least the top two languages spoken by individuals with limited English proficiency in the relevant State or States on small-size significant publications and significant communications. Finally, we re-designated proposed paragraph (g) as paragraph (h) and we added new paragraphs (g)(1)–(2) to address the posting standards applicable to small-sized significant publications and significant communications.

In choosing a lower threshold than at least the top 15 languages spoken by

individuals with limited English proficiency, we chose a concrete number of languages, rather than a threshold formulated as a percentage, because on average about two-thirds of the limited English proficient population in each State[103] is reached by the top two languages spoken by individuals with limited English proficiency in that State. Moreover, requiring a specific number of taglines makes the impact of the requirement predictable for all covered entities in planning how these two taglines, along with the nondiscrimination statement, will fit on their significant communications and significant publications that are small-sized. In almost all States, the top two languages spoken by individuals with limited English proficiency captures Spanish and the other most prevalent non-English language. This approach in paragraphs (b)(2), (d)(2), and (g)(1)–(2) of § 92.8 is more streamlined than requiring the full notice and all 15 taglines but still will inform the majority of individuals with limited English proficiency of their rights to be protected from discrimination under Section 1557 and this part.

In addition, we have added a sample nondiscrimination statement in Appendix A that conveys the information in § 92.8(a)(1), for which the Director will also provide translations. Accordingly, we have modified paragraph (c) of § 92.8 to state that the Director will provide translations of the sample nondiscrimination statement. The translations of the sample notice and sample nondiscrimination statement are for covered entities' discretionary use only—the final rule does not require the posting of the notice or nondiscrimination statement in non-English languages.

Comment: A substantial majority of commenters on § 92.8 provided feedback on the methodology for determining the number of languages in which covered entities will be required to post taglines. Some commenters supported the proposed rule's national methodology because of its simplicity, particularly for covered entities that operate in multiple States. Conversely, other commenters expressed concern that the national standard fails to account for concentrations of particular limited English proficient communities within areas served by covered entities' health programs and activities, including Native American languages spoken by those served in Tribal health programs. One commenter recommended that if the final rule includes a national standard, OCR should require taglines in the top 25 languages spoken nationally by individuals with limited English proficiency. This commenter further recommended that when calculating the top 25 languages, OCR should rely on a data set that ''unbundles'' bundled language groups, such as ''other Asian languages,'' because some languages represented in bundled categories may be highly prevalent in the service area of a particular covered entity's health program or activity.[104]

Most commenters disfavoring a national methodology recommended that the languages in which covered entities must post taglines should be the top 15 languages spoken State-wide by individuals with limited English proficiency. Commenters explained that the State-wide threshold would be more attuned to the diversity of languages spoken by individuals with limited English proficiency in each State and would align with Federal regulations governing the Marketplaces and qualified health plan issuers.[105] Some of these commenters also recommended that the final rule should require covered entities that serve individuals in multiple States to post more than 15 taglines if the composite list of each State's list aggregates to a total of more than 15 languages. These commenters reasoned that such an interpretation is necessary to further the purpose of addressing the diversity of languages spoken by individuals with limited English proficiency served by a particular covered entity.

Other commenters recommended other approaches, such as requiring taglines in languages in which at least 10% of individuals with limited English proficiency county-wide are exclusively literate,[106] or, in languages spoken by at least 5% of individuals with limited English proficiency or 500 individuals with limited English proficiency in the covered entity's service area, whichever yielded the greater number of languages. Still other commenters recommended that the rule allow covered entities to choose between a State-wide and a national methodology in determining the languages in which to post taglines, depending on the geographic scope of the intended audience for the ''significant publication or significant communication'' to which the taglines are posted. These commenters explained that a covered entity that operates nationally may choose to post on the covered entity's Web site taglines in languages based on a nationwide threshold but may choose to include on a significant communication to an individual taglines in languages based on a State-wide threshold for the State in which the individual resides.

Response: In response to commenters' recommendations, § 92.8(d)(1) of the final rule requires covered entities to post taglines in at least the top 15 languages spoken by individuals with limited English proficiency of the relevant State or States. Accordingly, paragraphs (d)(1)–(2) of § 92.8 refer to this State-based methodology rather than a national methodology. This threshold captures, on average, 90% of each State's LEP population.

We adopt a State-based approach for three main reasons. First, a State-based methodology is more attuned to the diversity of languages spoken by individuals with limited English proficiency and thus provides notice to more individuals with limited English proficiency.

Second, this State-wide approach better harmonizes with the number of languages in which taglines must be provided by Marketplaces and qualified health plan issuers under 45 CFR

[103] In estimating this percentage, we used the same data sources, *infra* notes 109 and 110, and the same methodology described in the discussion, *infra,* that we used to identify the languages under the State-based approach in which the Director will translate the sample notice and taglines, as required by § 92.8(c) and (e) of the final rule.

[104] In October 2015, for the second time since the U.S. Census Bureau's American Community Survey (ACS) began, the Census Bureau released detailed tables that unbundle the 39 languages and language groups that ACS publishes annually through its American Factfinder data set. U.S. Dep't of Commerce, U.S. Census Bureau, Data, Detailed Languages Spoken at Home and Ability to Speak English for the Population 5 Years and Over: 2009–2013, *http://www.census.gov/data/tables/2013/demo/2009-2013-lang-tables.html* [hereinafter U.S. Census Bureau, ACS 2009–2013 Detailed Languages] (last visited May 3, 2016). The unbundled data includes 380 possible languages or language groups spoken by individuals who speak English less than ''very well.'' In the proposed rule, HHS explained that it calculated the top 15 languages spoken nationally by individuals with limited English proficiency by relying on the American Factfinder data set that bundles languages. *See* 80 FR 54172, 54179 n.30 (Sept. 8, 2015) (describing the tagline methodology).

[105] 45 CFR 155.205(c)(iii)(A) (beginning no later than November 1, 2016, requiring taglines on Web site content and documents that are critical for obtaining coverage or access to health care services through a qualified health plan for certain individuals in at least the top 15 languages spoken by individuals with limited English proficiency in the relevant State; documents are deemed to be critical for obtaining health insurance coverage or access to health care services through a qualified health plan if they are required to be provided by law or regulation to certain individuals); *see infra* note 107 (describing other tagline requirements applicable to qualified health plan issuers as a result of market-wide regulations).

[106] This 10% county-level threshold for taglines applies to group health plans and health insurance issuers. *See, e.g.,* 45 CFR 147.136(e)(2)(iii), (e)(3) (HHS regulations); 29 CFR 2590.715–2719(e)(2)(iii), (3) (DOL regulations).

155.205(c)(2)(iii)(A).[107] Section 92.8 of this final rule applies to all entities covered by Section 1557, but for Marketplaces and qualified health plan issuers that are subject to the tagline requirements at 45 CFR 155.205(c)(2)(iii)(A) and § 92.8 of this final rule, our State-wide methodology lessens the burden to which Marketplaces and qualified health plan issuers might otherwise be subject.

Third, a county-level approach is impractical because detailed language data are not available for counties with populations of less than 100,000. For counties with populations of at least 100,000 for which detailed language data are available, there are limited data for individuals who speak English less than ''very well'' and speak a non-English language other than Spanish.[108] For county-level data that are available, moreover, we are concerned that sampling error would render many estimates of small language populations unreliable when assessed within the small geographic area of a county.

With regard to the data used to identify the languages under the State-based methodology in which the Director will translate the sample notice, sample nondiscrimination statement, and taglines, as required by § 92.8(c) and (e) of the final rule, we rely on the most recent bundled and unbundled five-year[109] data available from the U.S. Census Bureau. We rely on the data set that estimates the prevalence of foreign-language speakers who speak English less than ''very well,''[110] and we made technical adjustments, such as to remove any spoken languages that do not have a written equivalent in which the Director could translate a tagline.

We intend the threshold's application in § 92.8(d)(1)–(2), which applies to the ''relevant State or States,'' to permit covered entities that serve individuals in more than one State[111] to aggregate the number of individuals with limited English proficiency in those States to determine the top 15 languages required by § 92.8(d)(1), or the top 2 languages required by § 92.8(d)(2) where each respective provision applies.[112] The languages produced from this aggregation are static with respect to the posting requirement in § 92.8(f). Using one of the three posting methods as an example—the posting of the taglines in a covered entity's physical locations required by § 92.8(f)(1)(ii)—a covered entity that operates multiple health programs serving individuals within various States, or that operates a health program with a multi-State service area, complies with § 92.8(f)(1)(ii) when it posts, in its physical locations across the States it serves, taglines in at least the top 15 languages spoken by the aggregate limited English proficient populations of those States, rather than of each individual State. We do not intend to require a covered entity that operates health programs in multiple States (or in States nationwide), or that administers a health program with a multi-State service area (or even a nationwide service area), to tailor the taglines for the specific State in which the entity is physically located or in which an individual with limited English proficiency, with whom the entity communicates, lives. This interpretation best balances the burden on covered entities with the notification of language assistance services to individuals required by § 92.8(d).[113]

We reiterate, however, that the requirements of § 92.8(d)(1)–(2) establish a floor; covered entities are free to include taglines in additional languages beyond 15 languages. For instance, a covered entity that has chosen to aggregate languages may choose to post taglines in all languages on the aggregated list rather than posting just the top 15 languages. Moreover, a covered entity that that operates health programs in multiple States or that administers a health program with a multi-State service area may decide not to aggregate. Instead, the entity may choose to tailor the taglines posted in its physical locations for the specific State in which the physical location exists; similarly, the entity may choose to tailor the taglines on a certain significant communication based on the State in which an individual with limited English proficiency, with whom the entity communicates, lives.

In addition, we note that complying with § 92.8(d)(1)–(2) is not a substitute for complying with the prohibition of national origin discrimination as it affects individuals with limited English proficiency under Section 1557 or this part, including the general nondiscrimination provisions in § 92.101 and the meaningful access provisions in § 92.201 of this final rule. Thus, although this section identifies the languages in which covered entities must post taglines, it does not relieve those entities of the separate obligation to take reasonable steps to provide meaningful access to individuals with limited English proficiency who communicate in other languages.

Comment: One commenter recommended including American Sign

[107] Qualified health plan issuers are also bound by the tagline requirement in market-wide regulations at 45 CFR 147.136(e). Under § 147.136(e), taglines must appear on certain notices and on a health plan or issuer's summary of benefits and coverage, in languages in which 10% of individuals with limited English proficiency county-wide are exclusively literate. *See, e.g.,* 45 CFR 147.136(e)(2)(iii), (e)(3). This methodology applies to a narrower set of documents than those to which the tagline requirement applies in Federal regulations governing Marketplaces and qualified health plan issuers. *Compare* 45 CFR 147.136(e)(2)(iii) (requiring taglines on internal claims and appeals notices) *and* 45 CFR 147.200(a)(5) (requiring taglines on summaries of benefits and coverage) *with* 45 CFR 155.205(c)(2)(iii)(A) (requiring taglines on Web site content and documents that are critical for obtaining health insurance coverage or access to health care services through a qualified health plan). For CMS's most recent technical guidance on the tagline requirement at 45 CFR 155.205(c)(2)(iii)(A), *see* Guidance and Population Data for Exchanges, Qualified Health Plan Issuers, and Web-Brokers to Ensure Meaningful Access by Limited-English Proficient Speakers Under 45 CFR 155.205(c) and 156.250 (Mar. 30, 2016), *https://www.cms.gov/cciio/resources/regulations-and-guidance/index.html#*, Language Access Guide for Exchanges, Qualified Health Plan (QHP) Issuers, and Web-Brokers (last visited May 3, 2016).

[108] U.S. Census Bureau, ACS 2009–2013 Detailed Languages, *supra* note 104 (detailing data parameters in the user notes). At least 25,000 individuals who speak English less than ''very well'' must speak the same language for the ACS county-level data to identify such language speakers. *Id.*

[109] We rely on the American Community Survey (ACS) 5-year data set because its stability is superior to the 1-year data set, especially when analyzing small populations. U.S. Census Bureau, American Community Survey, When to Use 1-year, 3-year, or 5-year Estimates, *http://www.census.gov/programs-surveys/acs/guidance/estimates.html* (last visited May 3, 2016). The U.S. Census Bureau has discontinued the ACS 3-year data set, which is the data set on which we relied in the proposed rule. U.S. Census Bureau, Census Bureau Statement on the 3-Year American Community Survey Statistical Product (Feb. 2, 2015), *http://content.govdelivery.com/accounts/USCENSUS/bulletins/eeb4af* (last visited May 3, 2016).

[110] U.S. Dep't of Commerce, U.S. Census Bureau, American FactFinder, Language Spoken at Home by Ability to Speak English for the Population 5 Years and Older, ACS Estimates by State: 2010–2014 (released Dec. 2015); U.S. Census Bureau, ACS 2009–2013 Detailed Languages, *supra* note 104. We are not aware of a public data source providing as robust data as the ACS that estimates the languages in which individuals with limited English proficiency read, understand, or speak. Thus, we are relying on a data set identifying individuals who have a limited ability to speak English as a proxy for limited English proficiency population.

[111] This categorization includes covered entities that operate multiple health programs serving individuals within various States or that operate a health program with a multi-State service area.

[112] For a similar approach, *see* HHS Notice of Benefit and Payment Parameters for 2016; Final Rule, 80 FR 10750, 10788 (Feb. 27, 2015) (describing the Department's interpretation of 45 CFR 155.205(c)(2)(iii)(A) and (B) for entities with multi-State service areas).

[113] As newer ACS data become available with respect to the data sets on which we base our methodology, we will determine if and when the at least top 15 languages spoken by individuals with limited English proficiency State-wide change, warranting the Director to make available notices and taglines translated in additional non-English languages.

Language as a language for which a posted tagline be required in § 92.8(d). This commenter stated that taglines denoting the availability of American Sign Language Interpretation could communicate this message by displaying still images, rather than a written language.

Response: We decline to include American Sign Language as a language for which a tagline is required in § 92.8(d)(1)–(2) because the notice of individuals' rights in § 92.8(a)(2), which must be posted in a conspicuously-visible font size and location just like taglines, addresses this issue. Specifically, paragraph (a)(2) requires that the notice of individuals' rights state that the covered entity provides auxiliary aids and services, which include sign language interpreters, to individuals with disabilities when necessary to provide such individuals an equal opportunity to benefit from the entity's health programs or activities.

Comment: A few commenters recommended that the final rule prescribe the location of taglines at or near the beginning of significant publications and significant communications. These commenters provided anecdotal evidence that individuals with limited English proficiency who received multi-page English notices requiring time-sensitive responses failed to see taglines appearing on the last page. Commenters explained that to the individuals' detriment, they discarded the notices without responding, resulting in termination of health insurance coverage and other negative outcomes. A number of commenters recommended that covered entities be required to include the text of all required taglines, not just the in-language link, conspicuously on the homepage of their Web sites.

Response: Although we encourage covered entities to include notices and taglines at the beginning of significant publications and significant communications to ensure that they are meaningfully accessible to the consumer, we decline to require this prescriptive approach as part of the final rule. In some circumstances, such as lengthy publications, it may be necessary to include the notice and taglines at the beginning of a document to meet the requirements of § 92.8(f)(1)(i) and (g)(1)–(2); in others, posting elsewhere, including on a separate insert [114] accompanying the English-language significant publication or significant communication, may be adequate. Furthermore, in today's increasingly electronic and digital age where covered entities may make their first impressions through Web content (often on small mobile devices), we are sensitive to covered entities' need for autonomy in designing and managing the appearance of their public internet home pages.

Although the law requires that individuals receive sufficient notice of language assistance services available to assist individuals with limited English proficiency in understanding the content of a covered entity's Web site, we believe that the use of in-language links permitted under this provision of the proposed rule is the approach that best balances notice to individuals against burden to covered entities.

Comment: Some commenters described the proposed requirement to post the notice in ''significant publications and significant communications'' as onerous. One commenter recommended that health plans provide the notice to individuals on an annual basis, along with individuals' annual enrollment package, instead of on each ''significant publication and significant communication.'' Some commenters requested that OCR include, in regulation text, the examples of ''significant publications and significant communications'' we provided in the preamble to the proposed rule, specifically outreach publications and patient handbooks. A few commenters requested that OCR consult with other Federal agencies on the scope of ''significant publications and significant communications'' to establish a common understanding of this term so that covered entities whose publications and communications are regulated by more than one Federal agency are not subject to conflicting standards.

Other commenters were concerned about OCR's statement in the preamble of the proposed rule that OCR intended the scope of ''significant publications and significant communications'' to include not only documents meant for the public but also individual letters or notices to an individual, such as a letter to a consumer notifying the individual of a change in benefits. These commenters observed that, pursuant to existing Federal and State law, many letters already include disclosures and other legally mandated information; consequently, the requirement to post both the notice and taglines required in proposed § 92.8(a) and (d), respectively, might dilute the primary message of the letter and confuse or frustrate consumers. Some commenters requested clarification on how ''vital documents'' as used in the Department's LEP Guidance relates to ''significant publications and significant communications'' in § 92.8(f)(1)(i) of the proposed rule.

Response: We disagree with commenters' characterization of § 92.8(f)(1)(iii) as ''onerous.'' We acknowledge that compliance with this subsection may impose some limited burdens on covered entities. However, these burdens are outweighed by the benefits that § 92.8(f)(1)(iii) will generate for individuals with limited English proficiency by making them aware, in their own languages, of the availability of language assistance services. Notifying individuals of their rights under Section 1557 and this part, including the availability of language assistance services for individuals with limited English proficiency and the availability of auxiliary aids and services for persons with disabilities, is critical to providing an equal opportunity to access health care and health coverage. For these reasons, OCR intends to interpret ''significant communications and significant publications'' broadly, which is consistent with the notice provisions of other Federal civil rights authorities, such as Section 504 [115] and Title IX.[116]

We decline to limit the posting requirement in § 92.8(f)(iii) to an annual frequency. The notice requirements in other Federal civil rights laws on which we modeled § 92.8 do not contain a similar limitation. Moreover we also note that not every covered entity sends annual notices.

[114] For instance, Medicare Advantage Plans, Medicare Advantage Prescription Drug Plans, and Medicare Prescription Drug Plans must include a ''CMS Multi-Language Insert'' in the text of certain documents or as a separate page included with certain documents. U.S. Dep't of Health & Human Servs., Centers for Medicare & Medicaid Servs., Medicare Marketing Guidelines, § 30.5.1, 7–8 (Jul. 2, 2015), *https://www.cms.gov/Medicare/Health-Plans/ManagedCareMarketing/FinalPartCMarketingGuidelines.html.*

[115] 45 CFR 84.8(a)–(b) (indicating that methods of notifying individuals' of their rights under Section 504 may include ''publication in newspapers and magazines, placement of notices in [Federal financial assistance] recipients' publication[s], and distribution of memoranda or other written communications'' as well as ''recruitment materials or publications containing general information that . . .[the recipient] makes available to participants, beneficiaries, [and] applicants. . . .'').

[116] 45 CFR 86.9(a)(2)(i) (requiring initial notice of individuals' rights to appear in local newspapers, newspapers and magazines published by the recipient of Federal financial assistance, and ''memoranda or other written communications distributed to every student . . . of such recipient'') and 86.9(b)(1) (requiring each recipient of Federal financial assistance to ''prominently include a statement of . . . [the recipient's nondiscrimination policy] in each announcement, bulletin, catalog, or application form which it makes available . . .'').

We also decline to enshrine a list of examples of ''significant publications and significant communications'' in regulation for two main reasons. First, the final rule applies to such a diverse range of covered entities that codifying examples likely would not provide meaningful guidance to the full spectrum of covered entities regulated. Second, we intend to maximize covered entities' flexibility, and each covered entity is in the best position to determine which of its communications and publications with respect to its health programs and activities are significant.

In response to commenters who requested that ''significant publications and significant communications'' be limited to documents intended for the public, rather than those intended for specific individuals, we decline to limit the intended scope of such documents to those aimed only at the public at-large. We intend the scope of significant publications and significant communications to include not only documents intended for the public, such as outreach, education, and marketing materials, but also written notices requiring a response from an individual and written notices to an individual, such as those pertaining to rights or benefits. We have no reasoned basis to distinguish and exempt significant publications and significant communications intended for specific individuals from significant publications and significant communications intended for the public at-large. Indeed, in some situations, a written notice with information tailored to a specific individual's benefits or participation may be even more important to that individual than a significant publication or significant communication conveying information to the public. Accordingly, an individual's awareness of his or her rights under Section 1557, such as the availability of auxiliary aids and services for persons with disabilities (required in § 92.8(a)(2) to be in the nondiscrimination notice) is just as important as information communicated to the public at-large.[117]

The HHS LEP Guidance uses the term ''vital documents'' to refer to the documents for which covered entities should prioritize written translations for individuals with limited English proficiency.[118] The HHS LEP Guidance does not define vital documents. Rather, the Guidance states that ''[w]hether or not a document (or the information it solicits) is 'vital' may depend upon the importance of the program, information, encounter, or service involved, and the consequence to the LEP person if the information in question is not provided accurately or in a timely manner.''[119] The HHS LEP Guidance also provides examples of documents likely to be ''vital,'' such as ''consent and complaint forms, . . . [ ] written notices of eligibility criteria, rights, denial, loss, or decreases in benefits or services . . . [ ] [and] [a]pplications to participate in a recipient's program or activity or to receive recipient benefits or services.''[120]

OCR intends for ''vital documents'' to represent a subset of ''significant communications and significant publications'''' in which covered entities must post the notice (or nondiscrimination statement in § 92.8(b), where applicable) and taglines required by § 92.8(d) and (f), among other electronic and physical locations. In clarifying this point, we emphasize that the HHS LEP Guidance uses the term ''vital documents'' to address how a covered entity should meet its Title VI obligations to translate entire documents. By contrast, we refer to ''significant communications and significant publications'' in this rule to identify the documents in which covered entities are required to post the notice of individuals' rights (or nondiscrimination statement, where applicable) and taglines. We are not adopting an across-the-board requirement for covered entities to translate certain written documents into a threshold number of languages.

Comment: Some commenters recommended that OCR provide funding and other resources to non-profit organizations for the purpose of creating a national social media campaign to publicize the requirements of Section 1557.

Response: It is beyond scope of the final rule for OCR to fund organizations' education and outreach efforts. OCR continues, however, to conduct outreach and provide technical assistance to inform covered entities of their obligations and individuals of their rights under Federal civil rights laws, including Section 1557 and this part. OCR will continue to disseminate, via web and social media platforms, fact sheets and other useful materials to covered entities and individuals.

Comment: OCR received a number of comments suggesting revisions to the sample notice in Appendix A and the sample tagline in Appendix B to the proposed rule, such as revisions to improve adherence to plain language writing principles. For example, with respect to the sample notice, a few commenters recommended revisions with respect to the provision of language assistance services: Adding the word ''qualified'' prior to the word ''interpreters,'' which is listed as a type of language assistance service; replacing ''first language'' with ''primary language''; replacing ''translated into other languages'' with ''written in other languages''; and deleting ''when needed to communicate effectively with us.''

One commenter objected to the conditional tense of the sample tagline in Appendix B, which stated that ''[i]f you speak [insert language], language assistance services may be available to you . . . ,'' expressing concern that it might deter an individual from asking for or about language assistance services. In addition, commenters suggested that the conditional phrasing of ''may be available'' is inconsistent with covered entities' obligations under § 92.201 to take reasonable steps to provide meaningful access to each individual with limited English proficiency.

A few commenters recommended that the sample tagline in Appendix B be shortened but offered no specific recommendations on shorter language. Some commenters suggested that OCR consumer test the sample notice in Appendix A of the proposed rule before providing it as a sample in the final rule.

Response: We share commenters' views that the sample notice should clearly convey civil rights information, which can often be complex. We agree with the specific revisions from commenters to improve the sample notice's statement about a covered entity's provision of language assistance services. We have modified Appendix A to the final rule to reflect these

[117] For comparison, the meaningful access requirements of other Federal regulations governing qualified health plan issuers apply to all information that is critical for obtaining health insurance coverage or access to health services through the qualified health plan, including ''applications, forms, and notices'' and information is deemed to be critical for obtaining health insurance coverage or access to health care services if the issuer is ''required by law or regulation'' to provide the document to certain individuals. *See* 45 CFR 156.250. CMS's annual guidance to qualified health plan issuers lists examples of documents to which CMS interprets § 156.250 to apply, such as certain correspondence and notifications, summary of benefits and coverage disclosures, formulary drug lists, provider directories, and a plan's explanation of benefits or similar claim processing information. U.S. Dep't of Health & Human Servs., Centers for Medicare & Medicaid Servs., Final 2017 Letter to Issuers in the Federally-facilitated Marketplaces, 80–81 (Feb. 29, 2016), *https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Final-2017-Letter-to-Issuers-2-29-16.pdf.*

[118] HHS LEP Guidance, *supra* note 49, 68 FR at 47318–19.

[119] *Id.* at 47318.

[120] *Id.* at 47319.

revisions, and have made technical revisions to include OCR's contact information for filing a complaint. In our view, the sample notice, with these modifications, adequately apprises individuals of their civil rights under Section 1557 and this part without providing irrelevant or confusing information. We remind covered entities that nothing in the final rule prohibits covered entities from drafting their own notices to meet the requirements of § 92.8(a)(1)–(7), which covered entities are free to consumer test.

In addition, we have added a nondiscrimination statement to Appendix A that covered entities can post on significant publications and significant communications that are small-sized.

We appreciate commenters' attention to the details of the sample tagline's phrasing. We have modified Appendix B to the final rule to address commenters' concerns that the tagline's conditional wording might deter an individual from asking for or about language assistance services. With technological advancements in language assistance services, we are confident that covered entities have the ability, at a minimum, to obtain qualified oral interpretation services in the languages in which covered entities will provide taglines, consistent with § 92.8(d)(1)–(2); thus, the sample tagline as modified states that language services ''are'' available. In addition, we replaced the word ''contact'' with ''call'' to simplify the vocabulary used for average literacy levels. The modifications we have made amplify taglines' function as a critical gateway to language assistance services. Taglines derive value not only from informing individuals with limited English proficiency of language assistance services but also from prompting individuals to contact the covered entity to obtain language assistance. We decline to shorten the sample tagline because we are concerned that doing so would compromise the tagline's message and intent. We remind covered entities that Appendix B is a sample; covered entities are free to develop their own taglines as long as they provide taglines consistent with § 92.8(d)(1)–(2) of this part.

Summary of Regulatory Changes

For the reasons described in the proposed rule and considering the comments received, we have modified § 92.8 and Appendices A and B to part 92 as follows:

In § 92.8(a), we made technical modifications to paragraph (a) and paragraphs (a)(1)–(3). In paragraph (a) we replaced the conjunction ''or'' with ''and.'' In paragraph (a)(1), we clarified that the nondiscrimination statement of the notice applies to the health programs and activities of a covered entity. In paragraph (a)(2), we inserted the phrase ''for individuals with disabilities'' after ''qualified interpreters'' because the final rule now defines qualified interpreters for individuals with disabilities separately from qualified interpreters for individuals with limited English proficiency. In paragraph (a)(3), we added examples of language assistance services to promote alignment with paragraph (a)(2), which provides examples of auxiliary aids and services.

Most of the text in proposed § 92.8(b) is now reflected in new paragraph (b)(1). We added paragraph (b)(2) that requires a covered entity to post a nondiscrimination statement consistent with newly-designated paragraph (g)(1), which applies to significant publications and significant communications that are small-sized. In newly-designated paragraph (b)(1) and (f)(1), we eliminated ''English-language'' before ''notice'' to avoid the incongruous result that a significant publication or significant communication written in a non-English language must include a notice written in English.

In § 92.8(c), we added language to convey OCR's plans to translate the sample nondiscrimination statement for covered entities to use at their discretion.

In paragraph (d) of § 92.8, we added paragraph designations (1) and (2) to distinguish the final rule's tagline requirements for significant publications and significant communications that are not small-sized from those that are small-sized. Most of the text in proposed paragraph (d) is now reflected in paragraph (d)(1). In newly-designated (d)(1), we replaced the national threshold with a threshold requiring taglines in at least the top 15 languages spoken by the limited English proficient population of the relevant State or States. In addition, we added a reference to the posting requirement in paragraph (f)(1) of § 92.8 for clarity. Paragraph (d)(2) identifies the tagline requirement for significant publications and significant communications that are small-sized. In paragraphs (c) and (e) of § 92.8, we replaced the national threshold with a reference to the languages triggered by the State-wide methodology described in paragraph (d)(1).

In § 92.8(f), we revised paragraph (f)(1) and paragraphs (f)(1)(i) and (iii). Specifically, in paragraph (f)(1), we made a technical revision to remove an errant reference to paragraph (b) and we replaced the reference to paragraph (d) with (d)(1) to conform to the new paragraph designations of the final rule. In § 92.8(f)(1)(i), we replaced the conjunction ''or'' with ''and'' as a technical revision to align the text with the same technical revision in § 92.8(a). In addition, we excluded publications and significant communications that are small-sized from the requirement to post the notice conveying all content in § 92.8(a)(1)–(7) and from the requirement to post all 15 taglines. In paragraph (f)(1)(iii), we clarified the location of the tagline when posted to the covered entity's Web site.

We re-designated paragraph (g) in the proposed rule as paragraph (h) in this final rule. In the final rule, paragraph (g) addresses covered entities' requirements to post a nondiscrimination statement and taglines in significant publications and significant communications that are small-sized. Specifically, paragraph (g)(1) addresses the requirement to post a nondiscrimination statement and paragraph (g)(2) addresses the requirement to post taglines.

Newly re-designated paragraph (h) no longer treats an entity's compliance with particular paragraphs of § 92.8 as constituting compliance with the notice provisions of other Federal civil rights authorities. We revised the paragraph to address a covered entity's permissive authority to combine the content of the notice in paragraphs (a)(1)–(7) of this section with the content of other notices.

In Appendix A to the final rule, we made the following changes to improve the plain language reading of the sample notice and to streamline the sample notice's messaging:

- Deleted ''sex stereotypes and gender identity'' from the end of the first sentence;
- Replaced ''worse'' with ''differently,'' and deleted the pronoun ''their'' prior to listing the bases on which the covered entity does not discriminate;
- Replaced ''first language'' with ''primary language'';
- Deleted ''when needed to communicate effectively with us'';
- Added ''qualified'' to modify ''interpreters'' with respect to serving individuals with limited English proficiency;
- Replaced ''translated into other languages'' with ''written in other languages'';
- Added placeholders for a covered entity to provide not only the name of its civil rights coordinator but also the individual's title; and

• Added contact information for filing a complaint with OCR.

In addition, we added a sample nondiscrimination statement in Appendix A for covered entities to post in significant publications and significant communications that are small-sized and accordingly broadened the title of Appendix A to reflect its revised scope.

In Appendix B to the final rule, we modified the language by replacing ''may be available'' with ''are available'' and by adding language to improve the plain language reading of the sample tagline, by replacing ''[c]ontact'' with ''call.''

Subpart B—Nondiscrimination Provisions

Subpart B of the final rule incorporates regulatory provisions implementing the application of the civil rights statutes referenced in Section 1557(a): Title VI, Title IX, the Age Act, and Section 504.

Discrimination Prohibited (§ 92.101)

We proposed that § 92.101 of subpart B prohibit discrimination on the basis of race, color, national origin, sex, age, or disability under any health program or activity to which Section 1557 or this part applies. We proposed that paragraphs (a) and (b) follow the structure of the implementing regulations for Title VI, Section 504, Title IX, and the Age Act by including a general nondiscrimination provision in paragraph (a) followed by a provision identifying specific discrimination prohibited in paragraph (b). In paragraph (c), we proposed to address exceptions to discrimination prohibited under the Title VI, Section 504, and Age Act regulations. We proposed that paragraph (d) effectuate technical changes in terminology to apply the provisions incorporated from other regulations to the covered entities obligated to comply with this proposed rule.

In paragraph (a)(1) of § 92.101 of the proposed rule, we restated the core objective of Section 1557(a), which prohibits discrimination on the grounds prohibited under Title VI (race, color, or national origin), Title IX (sex), the Age Act (age), or Section 504 (disability) in any health program or activity to which this part applies.

In paragraph (a)(2), we proposed to limit the ways in which the proposed rule applies to employment. We noted that except as provided in § 92.208, which addresses employee health benefit programs, the proposed rule does not generally apply to discrimination by a covered entity against its own employees. Thus, the proposed rule would not extend to hiring, firing, promotions, or terms and conditions of employment outside of those identified in § 92.208; such claims could continue to be brought under other laws, including Title VII, Title IX, Section 504, the ADA and the Age Discrimination in Employment Act,[121] as appropriate. We invited comment on our proposal to exclude these forms of employment discrimination from the scope of the proposed rule.

We proposed that paragraph (b) incorporate into the regulation the specific discriminatory actions prohibited by each civil rights statute which Section 1557 references. We considered harmonizing each of the specific discriminatory actions prohibited across each civil rights law addressed by Section 1557. We noted that although harmonization could reduce redundancy in the specific discriminatory actions incorporated that are similar to one another, harmonization would likely lead to confusion and unintended differences in interpretation that are subtle yet significant. We therefore proposed that paragraphs (b)(1)–(4) incorporate the specific discriminatory actions prohibited under each civil rights law on which Section 1557 is grounded. We sought comment on this proposed approach.

We proposed that paragraph (b)(1) adopt the specific discriminatory actions prohibited by the Title VI implementing regulation, which appear at 45 CFR 80.3(b)(1)–(6).

In paragraph (b)(2)(i), we proposed to address the specific prohibition of discrimination on the basis of disability with which recipients and State-based Marketplaces must comply. In paragraph (b)(2)(i), we proposed to adopt relevant provisions in the Section 504 implementing regulation for federally assisted programs and activities at 45 CFR part 84. We provided that the provisions incorporated are the specific discriminatory actions prohibited at § 84.4(b); the program accessibility provisions at §§ 84.21 through 84.23(b); and the provisions governing education, health, welfare, and social services at §§ 84.31, 84.34, 84.37, 84.38, and 84.41–84.55.

We proposed that paragraph (b)(2)(ii) address the specific prohibitions of discrimination on the basis of disability with which the Department, including the Federally-facilitated Marketplaces, must comply. We proposed that this paragraph adopt relevant provisions in the Section 504 implementing regulation for federally administered programs and activities at 45 CFR part 85. We provided that the provisions adopted are the specific discriminatory actions prohibited at § 85.21(b) and the program accessibility provisions at §§ 85.41 through 85.42 and 84.44 through 84.51.

We proposed that paragraph (b)(3) adopt the specific discriminatory actions prohibited by the Title IX implementing regulation, which appear at 45 CFR 86.3(b)(1) through (8).

We also proposed that paragraph (b)(4) adopt the specific discriminatory actions prohibited by the Age Act implementing regulation, which appear at 45 CFR 91.11(b).

In paragraph (b)(5), we proposed that the specific discriminatory actions prohibited in § 92.101(b)(1) through (4) do not limit the general prohibition of discrimination in § 92.101(a). We noted that this statement is consistent with regulatory provisions in the implementing regulations for Title VI at 45 CFR 80.3(b)(5) and the Age Act at 45 CFR 91.11(c).

In paragraph (c), we proposed to incorporate the exceptions to the general prohibition of discrimination that appear in the implementing regulations for Title VI, Section 504, and the Age Act, as these exceptions have applied to health programs and activities for nearly 40 years. We noted that, generally, the exceptions in the Title VI, Section 504, and Age Act implementing regulations provide that it is not discriminatory to exclude a person from the benefits of a program that Federal law limits to a protected class. We did not address the sex-based distinctions authorized in Title IX and its implementing regulation in the context of education programs or activities. We noted that these distinctions do not necessarily apply in the health care context. However, we also noted that Title IX and the Department of Education's Title IX regulations allow some single-sex education programs when certain requirements are met.[122] We did not propose to prohibit separate toilet, locker room, and shower facilities where comparable facilities are provided to individuals, regardless of sex, but sought comment on what other sex-based distinctions, if any, should be permitted in the context of health programs and activities and the standards for permitting the distinctions.

Finally, we proposed that paragraph (d) effectuate technical changes to apply

[121] 29 U.S.C. 621–634.

[122] 34 CFR 106.34.

the provisions incorporated in § 92.101(b) and (c) to covered entities obligated to comply with the proposed rule by, among other things, replacing references to ''recipient'' in the incorporated provisions with ''covered entity.''

The comments and our responses regarding § 92.101 of subpart B are set forth below.

Comment: A few commenters recommended that OCR add the words ''or deterred'' to the general prohibition of discrimination, so that it would read as follows: ''Except as provided in Title I of the ACA, an individual shall not, on the basis of race, color, national origin, sex, age, or disability, be excluded or deterred from participation in, be denied the benefits of, or otherwise be subjected to discrimination under any health program or activity to which this part applies.''

Response: We believe the regulatory text, as it is currently written, conveys the intent to prohibit discriminatory deterrence from participation in a health program or activity. As OCR noted in the preamble to the proposed rule, paragraph (a)(1) of § 92.101 prohibits discrimination on the grounds prohibited under Title VI, Title IX, the Age Act, and Section 504 in any health program or activity to which this part applies. It is well established under these and other civil rights law that deterrence on the basis of a prohibited criterion is a form of discrimination. Similarly, discrimination on the basis of perceived race, color, national origin, sex, age, or disability is prohibited discrimination under the final rule, as it is under the authorities referenced in Section 1557.

Comment: One commenter asked for clarification that, when scientific evidence supports differential treatment to ensure safe, high-quality care, such treatment would not be considered discriminatory. This commenter pointed out that the risks and benefits of treatments may differ due to characteristics such as age, gender, physical stature, and genetics. For example, based on the best available science, experts have judged that, for men and younger women, absent a known family history, the risks associated with radiation exposure from routine mammograms outweigh the benefits. Thus, practice guidelines suggest not administering screening mammograms to women under a certain age or to men.

Response: Scientific or medical reasons can justify distinctions based on the grounds enumerated in Section 1557. We affirm this understanding of the final rule and believe that the regulatory text encompasses that approach.

Comment: A few commenters asked that OCR prohibit discrimination in health programs or activities on the basis of ''health status, claims experience, medical history, or genetic information'' in addition to race, color, national origin, sex, age, and disability.

Response: This rule implements Section 1557 of the ACA, which prohibits discrimination on the bases of race, color, national origin, sex, age, and disability. Accordingly, the commenters' request is beyond the scope of this rule. However, OCR recognizes that discrimination based on health status, claims experience, medical history, or genetic information can, depending on the facts, have a disparate impact that results in discrimination on a basis prohibited by Section 1557 and will process complaints alleging such discrimination accordingly. In addition, such discrimination also may violate other laws, such as other provisions of the ACA or the Genetic Information Nondiscrimination Act of 2008.[123]

Comment: Many commenters disagreed with the approach taken in the proposed rule to exclude discrimination in employment in areas other than employee health benefits. Commenters stated that the text of Section 1557 does not exclude employment discrimination; that Section 1557 protects ''individuals,'' similar to Title IX's protection of ''person[s];'' and that Title IX has been interpreted to protect not just students but employees of educational institutions. They also noted that Section 504 covers employment without exception and that Title VI covers employment discrimination when it affects beneficiaries of the covered program.[124]

Response: For the reasons stated in the preamble to the proposed rule, OCR declines to interpret Section 1557 to grant itself jurisdiction (outside the context of employee health benefit plans under circumstances set out in § 92.208) over claims of employment discrimination brought by employees against their employers that are covered entities. In holding that both Title IX and Section 504 broadly prohibit discrimination in employment, the Supreme Court relied heavily on the legislative history and underlying purpose of these statutes.[125] By contrast, there is no indication that broadly prohibiting employment discrimination was a chief purpose of Section 1557, which is focused on discrimination against participants in health programs and activities. To the extent that employees who are subject to discrimination are employed by entities that are covered under other employment discrimination laws, their complaints can be brought under those other laws. And as to employees of small employers, we do not believe that Congress in Section 1557 intended to alter, across the board, the longstanding exclusion of small employers from most employment discrimination laws. That said, nothing in this rule is intended to alter the established principles underlying the unlimited coverage of employment discrimination under both Title IX and Section 504, and OCR will process such claims brought under these statutes under its longstanding procedures.[126]

Comment: Some commenters asked that OCR clarify that Section 1557's prohibition of discrimination on the basis of race, color, national origin, sex, age, or disability includes intersectional discrimination that might affect persons who are part of multiple protected classes. For example, discrimination against an African-American woman could be discrimination on the basis of both race and sex.

Response: OCR is clarifying here that Section 1557's prohibition of discrimination reaches intersectional discrimination. We believe that the regulatory text encompasses this approach.

Comment: Commenters noted that various forms of harassment in health care can discourage individuals from seeking care and suggested that OCR include a separate provision that explicitly prohibits all forms of harassment based on protected characteristics, including sexual harassment and other forms of sex-based harassment.

Response: OCR recognizes that various forms of harassment can impede an individual's ability to participate in

[123] *Supra* note 3.

[124] *See North Haven Bd. of Educ.* v. *Bell*, 456 U.S. 512 (1982).

[125] *Id.* at 522–30; *Consolidated Rail* v. *Darrone*, 465 U.S. 624, 626 (1984).

[126] Moreover, nothing in this rule is intended to affect OCR's ability to address discrimination against patients on a prohibited basis, even where that discrimination is effectuated through actions against a covered entity's employee. If, for example, a medical practice that receives Federal financial assistance fired a Hispanic doctor because the practice no longer wished to serve the doctor's predominantly Hispanic, limited English proficient patients, OCR could pursue relief on behalf of affected patients to ensure that their access to the practice was not discriminatorily denied. *Cf.* 45 CFR 80.3(c)(3) (Title VI applies where discrimination in employment tends to exclude individuals, on the basis of race, color, or national origin, from participation in a covered program).

or benefit from a health program or activity and can thus constitute unlawful discrimination under Section 1557 and this part. Under Title IX, harassing conduct creates a hostile environment if the conduct is sufficiently serious to interfere with or limit an individual's ability to participate in or benefit from a program.[127] For example, a provider's persistent and intentional refusal to use a transgender individual's preferred name and pronoun and insistence on using those corresponding to the individual's sex assigned at birth constitutes illegal sex discrimination if such conduct is sufficiently serious to create a hostile environment. Similarly, a provider using derogatory language because an individual is an unmarried sexually active or pregnant woman constitutes illegal sex-based harassment if such conduct is sufficiently serious to create a hostile environment. Consistent with the well-established interpretation of existing civil rights laws, OCR interprets the final rule to prohibit all forms of unlawful harassment based on a protected characteristic. Because it has been long-established that harassment is a form of prohibited discrimination under each of the laws cited in Section 1557 and this part, OCR does not believe a separate harassment provision is necessary and therefore declines to revise the proposed rule to include one.

Comment: Many commenters recommended that OCR add regulation text stating that the Tri-Agency Guidance[128] imposes legally enforceable obligations on entities covered by Section 1557 and that OCR has direct authority to enforce the Tri-Agency Guidance as well as the statutory and regulatory provisions therein articulated.[129] The Tri-Agency Guidance describes how States can structure their application and enrollment processes in compliance with Title VI and program authorities to ensure that State agencies do not administer federally assisted public benefit programs in a manner that delays or denies services to eligible individuals, including children, living in mixed-immigration status households.

Commenters asked for such regulatory language based on concerns that some covered entities administer their programs in a manner that discriminates based on national origin by delaying or denying access to public benefits based on practices such as: Erecting onerous documentation requirements; denying eligible applicants the opportunity to prove eligible income, identity, citizenship status, or immigration status; or making generalized assumptions about applicants' eligibility based on the actual or perceived immigration status or national origin of any family member.[130] Commenters also expressed concern that some covered entities fail to understand the eligibility differences between various immigrant visa statuses and length of residency requirements, fail to distinguish between applicants and non-applicants in requests for Social Security numbers (SSNs), or require the disclosure of SSNs or immigration status without first explaining the use or confidentiality of this information.

Response: OCR appreciates hearing from commenters on this important issue. However, we decline to explicitly reference, in regulation, the Tri-Agency Guidance and the authorities therein articulated for two main reasons. First, it is beyond the scope of this final rule to address program authorities over which OCR does not have enforcement authority.

Second, regulatory modifications to the proposed rule are unnecessary to allow OCR to address a covered entity's policy or practice, such as requiring the disclosure of SSNs or certain citizenship or immigration status information, that raises compliance concerns under Section 1557's prohibition of national origin discrimination. OCR addresses such issues under Title VI.[131] We similarly have authority to address such issues under Section 1557 and this part when, for example, an individual's complaint alleges that a covered entity has implemented a facially-neutral policy, such as requiring the disclosure of immigration status from applicants and non-applicants, that has a disparate impact on individuals of a particular national origin group.

Thus, to the extent that the Tri-Agency Guidance identifies situations that may raise Title VI compliance concerns and offers best practices for resolving those concerns, this information is equally applicable to health programs and activities covered under Section 1557 as it is to the health and human service programs addressed in the Tri-Agency Guidance. The Department continues to adhere to the principles set forth in the Tri-Agency Guidance in the implementation of the Department's programs[132] and through OCR's enforcement of Title VI. OCR intends to apply these principles in our enforcement of Section 1557 and this part and will continue to accept complaints alleging that covered entities' actions deter eligible individuals from applying for benefits offered by health programs and activities on the basis of their national origin. Section 1557 and this part, however, do not alter programmatic laws and regulations that restrict eligibility for particular health programs to persons of certain immigration or

[127] *See, e.g.*, U.S. Dep't of Educ., Office for Civil Rights, Questions and Answers on Title IX and Sexual Violence (2014) at A–2, available at *http://www2.ed.gov/about/offices/list/ocr/docs/qa-201404-title-ix.pdf.*

[128] U.S. Dep't of Health & Human Servs. and U.S. Dep't of Agriculture, Policy Guidance Regarding Inquiries into Citizenship, Immigration Status and Social Security Numbers in State Applications for Medicaid, State Children's Health Insurance Program (SCHIP), Temporary Assistance for Needy Families (TANF), and Food Stamp Benefits (2000) [hereinafter Tri-Agency Guidance], *http://www.hhs.gov/civil-rights/for-individuals/special-topics/national-origin/tri-agency/index.html* (describing how States can structure their facially-neutral policies and practices to enroll eligible children and families of all national origins to reduce and eliminate access barriers).

[129] In addition to Title VI, the Tri-Agency Guidance addresses the Privacy Act of 1974 and program authorities authorizing and implementing Medicaid, CHIP, Temporary Assistance for Needy Families, and the Food Stamp Program. *Id.* at 1–2, Q2.

[130] The Tri-Agency Guidance addresses the circumstances under which a State may not deny benefits when a non-applicant applying on behalf of a child, or a non-applicant household member, does not provide information regarding his or her citizenship status, immigration status or a Social Security number. The Guidance recommends that public benefits applications allow non-applicants to declare early in the process whether they are seeking benefits only on behalf of an eligible child or family member so that further inquiry is limited to factors necessary for determining the child's or family member's eligibility. *Id.* at 206, Q3–Q7.

[131] *See* HHS OCR VRA with AZ Agencies, *supra* note 53, (resolving cognizable complaints of national origin discrimination under Title VI following implementation of an Arizona State law requiring State employees, in the administration of public benefits programs, to report ''discovered violations of federal immigration law'' to U.S. Immigrations and Customs Enforcement).

[132] *See, e.g.*, 77 FR 18310, 18355 (Mar. 27, 2012) (applying the principles of the Tri-Agency Guidance to Marketplace SM regulations on the health insurance application process); U.S. Dep't of Health & Human Servs., Office of Community Servs., Admin. on Children & Families, HHS Guidance on the Use of Social Security Numbers and Citizenship Status Verification for Assistance by LIHEAP Grantees' Programs, A6 (2014), *http://www.acf.hhs.gov/programs/ocs/resource/liheap-im-hhs-guidance-on-the-use-of-social-security-numbers-ssns-and-citizenship-status-verification* (strongly encouraging LIHEAP Grantees to structure their eligibility processes to avoid the delay or denial of benefits to eligible persons in mixed-immigration status households); U.S. Dep't of Health & Human Servs., Admin. on Children & Families, Office of Child Care, Clarifying Policy Regarding Limits On The Use Of Social Security Numbers Under the Child Care and Development Fund and the Privacy Act Of 1974, Program Instr. No. ACYF–PI–CC–00–04 (2000), *http://www.acf.hhs.gov/programs/occ/law/guidance/current/pi0004/pi0004.htm* (requiring States to make clear that the provision of a SSN is voluntary and child care benefits will not be denied or withheld for failure to provide a SSN).

citizenship statuses, and thus allow covered entities to make requests for that information when required by such authorities.[133]

Comment: A few commenters recommended that HHS clarify its longstanding position that the regulations implementing Section 504 require health care entities with fewer than 15 employees to provide auxiliary aids and services to persons with impaired sensory, manual, or speaking skills, where necessary to afford such persons an equal opportunity to benefit from the service in question. These commenters pointed out that while 45 CFR 84.52(d)(1) requires the provision of auxiliary aids only by covered entities with 15 or more employees, 45 CFR 84.52(d)(2) provides that the Director may require recipients with fewer than 15 employees to provide auxiliary aids where the provision of aids would not significantly impair the ability of the recipient to provide its benefits or services. The commenters recognized that in 2000, HHS issued a notice in the **Federal Register** announcing that the Director had decided to require recipients with fewer than 15 employees to provide appropriate auxiliary aids pursuant to 42 CFR 84.52(d)(2).[134] However, the commenters also asserted that some judicial decisions have questioned whether the Director's notice constitutes a binding legislative rule or merely a policy statement by HHS.[135] Accordingly, these commenters were concerned that the proposed rule's incorporation of 45 CFR 84.52(d) might not be clear enough to also incorporate the Director's notice that health care entities with fewer than 15 employees must provide auxiliary aids and services on the same basis as health care entities with 15 or more employees.

Response: To ensure clarity as to our intent, we have revised the language in § 92.101(b)(2)(i) to delete the reference to 45 CFR 84.52(d) and have added new language to that section requiring covered entities—regardless of the number of people they employ—to provide appropriate auxiliary aids and services to persons with impaired sensory, manual, or speaking skills where necessary to afford such persons an equal opportunity to benefit from the service in question.

As explained in the Director's original notice adopting this policy, OCR believes that Section 504's auxiliary aids and services requirement should be applied to covered entities with fewer than 15 employees in the interest of uniformity and consistent administration of law. Under Title III of the ADA, privately operated public accommodations are obligated to provide appropriate auxiliary aids and services, regardless of their size, where necessary to ensure effective communication with individuals with disabilities, unless they can demonstrate that taking such steps would fundamentally alter the nature of their program, services or activities, or would result in undue financial and administrative burdens.[136] OCR's decision to require all entities, regardless of size, to provide auxiliary aids and services under Section 1557 and this part thus furthers consistency among disability discrimination laws; importantly, it also furthers the ACA's goal of improving access to health coverage and health care because requiring all entities to provide auxiliary aids and services will result in enhanced services for people with disabilities. Moreover, because this requirement has been OCR's policy for more than a decade, covered entities are familiar with the obligations it imposes.

Comment: A few commenters asked that OCR add language to the rule declaring that medical treatment for individuals with disabilities must be as effective as treatment for individuals without disabilities.

Response: At § 92.101(b)(2)(i), the final rule incorporates 45 CFR 84.4(b)(1)(iii) of the Section 504 implementing regulation, which states that recipients may not provide qualified individuals with disabilities ''with an aid, benefit, or service that is not as effective as that provided to others. . . .'' Such benefits include medical treatment, though recipients cannot, and are not required under the rule to, ensure equally effective outcomes.

Comment: A number of commenters urged that OCR make clear that, consistent with the requirements of Title II of the ADA and Section 504,[137] disability-based discrimination under Section 1557 encompasses the needless segregation of individuals with disabilities. They pointed, in particular, to the need to make clear that covered entities must make coverage and reimbursement decisions that support serving individuals with disabilities in integrated settings unless doing so would fundamentally alter the entities' service systems, citing to the HHS Guidance on Medicaid Managed Care.[138]

Response: We agree that since Section 1557 explicitly incorporates Section 504's prohibitions against disability-based discrimination, it therefore encompasses a ban on the unnecessary segregation of individuals with disabilities. As such, and as required by Title II of the ADA and Section 504 and interpreted in *Olmstead* v. *L.C.*[139] and its progeny, public entities (State and local governments) must administer services to individuals with disabilities in the most integrated setting appropriate to their needs unless doing so is a fundamental alteration of the public entity's service delivery system. The ''most integrated setting'' mandate applies to the full spectrum of the public entity's service delivery system, including coverage and reimbursement decisions, when the entity ''(1) directly or indirectly operates facilities and or/ programs that segregate individuals with disabilities; (2) finances the segregation of individuals with disabilities in private facilities; and/or (3) through its planning, service system design, funding choices, or service implementation practices, promotes or relies upon the segregation of individuals with disabilities in private facilities or programs.'' [140] OCR will continue its ongoing *Olmstead* enforcement efforts under Section 504 and Title II of the ADA, as well as Section 1557 and this part, where appropriate.

Comment: Several commenters recommended that OCR specify that age-related distinctions are prohibited, apart from exclusions in the Age Act for (1) age distinctions contained in a

[133] *See, e.g.,* 45 CFR 155.305(f)(6) (in some cases, a Marketplace℠ must require the SSN of an individual who is not requesting coverage for himself or herself, but whose SSN could be used to verify eligibility information for a household member who is requesting Marketplace℠ coverage and financial assistance, such as a child).

[134] *See* U.S. Dep't of Health & Human Servs., Office for Civil Rights; Section 504 of the Rehabilitation Act of 1973; Notice of Exercise of Authority Under 45 CFR 84.52(d)(2) Regarding Recipients With Fewer Than Fifteen Employees, 65 FR 79368 (Dec. 19, 2000).

[135] *See, e.g., Columbia* v. *Gregory,* Civ. No. 08–cv–98, 2008 WL 4192437, *4 (D.N.H. Sep. 9, 2008).

[136] *See* 42 U.S.C. 12182(b)(2)(A)(iii).

[137] *See* 28 CFR 35.130(b)(7) (requiring public entities to administer services to individuals with disabilities in the most integrated setting appropriate to their needs); 45 CFR 84.4(b)(2); *Olmstead* v. *L.C.*, 527 U.S. 581 (1999).

[138] U.S. Dep't of Health & Human Servs., Centers for Medicare & Medicaid Services, Guidance to States Using 1115 Demonstrations or 1915(b) Waivers for Managed Long Term Services and Supports Programs 3 (May 20, 2013), *https://www.medicaid.gov/medicaid-chip-program-information/by-topics/delivery-systems/downloads/1115-and-1915b-mltss-guidance.pdf.*

[139] *527 U.S. 581 (1999).*

[140] U.S. Dep't of Justice, Statement of the Department of Justice on Enforcement of the Integration Mandate of Title II of the Americans with Disabilities Act and *Olmstead* v. *L.C.*, (June 21, 2011), *http://www.ada.gov/olmstead/q&a_olmstead.htm.*

Federal, State or local statute or ordinance that provide benefits based on age, establish criteria for participation in age-related terms, or describe intended beneficiaries to target groups in age-related terms, and (2) actions that reasonably take into account age as a factor necessary to the normal operation or the achievement of any statutory objective of such program or activity. Under these comments, for example, a decision to limit coverage of a service to individuals in a particular age range, even though that service is also effective for individuals of other ages, would violate Section 1557 if the age limitation is not based on a statute or ordinance and is not necessary for the normal operation or achievement of the goals of the service.

Response: OCR declines to adopt the standard recommended by the commenters. As noted elsewhere, the rule permits actions based on age to overcome the effects of conditions that resulted in limited participation in the covered entity's health program or activity based on age.[141] We also note that other provisions of the rule incorporate provisions in the regulation implementing the Age Act that permit age distinctions in HHS regulations and a recipient's provision of special benefits to the elderly or children.[142]

Comment: A few commenters asked that OCR clarify that State mandates that have age limits are exempt and that States are allowed to create new State mandates that have age distinctions if that is clinically appropriate.

Response: As reflected in the provision of the final rule at § 92.2(b)(1), age distinctions contained in Federal, State, or local statutes or ordinances adopted by an elected, general purpose legislative body are not covered by the final rule. States may adopt new laws that contain age distinctions; those distinctions would not violate the final rule.[143]

Comment: One commenter asked us to clarify the application of Section 1557 with respect to age rating in health insurance plans and related employer contributions.

Response: As we noted above, OCR is incorporating in the final rule the exclusions found in the Age Act, such that the provisions of the proposed rule would not apply to any age distinction contained in that part of a Federal, State, or local statute or ordinance adopted by an elected, general purpose legislative body which provides any benefits or assistance to persons based on age, establishes criteria for participation in age-related terms, or describes intended beneficiaries to target groups in age-related terms.[144] For instance, age rating in premium rates within a 3:1 ratio in Marketplace℠ plans would not violate Section 1557 because it is permitted under the ACA.[145] Further, this rule would not prohibit a covered entity from establishing and applying, or offering a plan on a Marketplace℠ that establishes or applies, in a nondiscriminatory manner, neutral rules related to employer contribution amounts, such as contributing a fixed percentage or dollar amount of each employee's premium or placing a cap on the total amount of employer contributions, even though the dollar amount of the contribution or the employee's share of the premium may be smaller or greater for some employees than for others based on the permissible age rating of the employee's premium.

Comment: One commenter recommended that OCR clarify that in order to operate in a nondiscriminatory manner, issuers must ensure that their plans do not impose arbitrary age, visit, or coverage limits. This commenter pointed out that children often need more frequent preventive and supportive services than adults, including immunizations, developmental assessments and screenings, and nutritional counseling, to enable them to maintain or improve their health into adulthood. Furthermore, children with special health needs may need additional services, such as speech or physical therapy, on a more frequent basis than adults to enable them to develop specific skills or meet their developmental potential. Similarly, children will also require replacement of durable medical equipment or devices on a much more frequent schedule than is provided in an adult benefit package.

Response: OCR agrees that arbitrary age, visit, or coverage limitations could constitute discrimination, including discrimination based on age, in certain cases, for example where consideration of age is not necessary to the normal operation of a health program. In addition, as noted above, where differential treatment is justified by scientific or medical evidence, such treatment will not be considered discriminatory. The general prohibition of discrimination in the rule applies to these issues.

Comment: Commenters noted that due to the educational context for which they were created, Title IX regulations do not reach the full breadth of discriminatory actions on the basis of sex that are prohibited by Section 1557; these commenters recommended that the final regulation incorporate prohibitions from Title VI, Section 504, and the Age Act to more fully address discrimination on the basis of sex in health programs and activities. In addition, commenters stated that the final rule should make clear that in the absence of a finding of discrimination, a covered entity may take affirmative action to overcome the effects of conditions which resulted in limited participation by persons on the basis of sex.

Response: OCR appreciates the concern raised by the commenters that, due to the fact that Title IX applies only to educational programs, the full range of specific discriminatory actions prohibited under other laws is not explicitly included in Title IX's regulations. OCR has revised the final regulation to incorporate additional language in § 92.101(b)(3) to help clarify the full breadth of discriminatory actions that can constitute sex discrimination under Section 1557. Additionally, both the proposed and the final rule make clear in § 92.6 (Remedial Action and Voluntary Action) that covered entities are permitted, but not required, to take voluntary action in the absence of a finding of discrimination to overcome the effects of conditions that result or resulted in limited participation by persons based on any prohibited ground covered under the regulation.

Comment: Several commenters noted that although sex-specific programs may be clinically necessary in some instances, for example, in clinical trials that aim to determine whether sex differences exist in the manifestation or recommended treatment of certain diseases, the Department should clarify that sex-specific programs—*i.e.*, those in which participation is limited to members of one sex only—are permissible only when they are narrowly tailored and necessary to accomplish an essential health purpose.

Response: OCR agrees with commenters that sex-specific programs (programs limited exclusively to one sex) should be permitted only under limited circumstances. OCR believes that the constitutional standard established by the Supreme Court in

[141] *See* § 92.101(c).

[142] *See* § 92.101(c) (incorporating 45 CFR 91.17).

[143] We note that age limits may violate CMS regulations under the ACA and covered entities are responsible for ensuring compliance with all applicable CMS regulations and other Federal laws.

[144] *See* 42 U.S.C. 6103(b).

[145] 42 U.S.C. 300gg(a)(1)(A)(iii). *See also* 45 CFR 147.102.

United States v. *Virginia*[146] provides the most appropriate level of protection and thus has chosen to adapt this standard for application in evaluating the lawfulness of sex-specific health programs or activities under Section 1557 and this part. In *Virginia*, the Court stated that a governmental entity attempting to justify a sex-specific program must demonstrate an ''exceedingly persuasive justification'' for a sex-based classification in accordance with the U.S. Constitution's Equal Protection Clause.[147] As the Court explained, this means that the governmental entity must show ''at least that the [challenged] classification serves important governmental objectives and that the discriminatory means employed are substantially related to the achievement of those objectives.''[148] In *Virginia*, which challenged Virginia Military Institute's male-only admissions policy, the Court found that the governmental entity had fallen ''far short of establishing the exceedingly persuasive justification'' necessary to sustain a sex-based classification.[149] The Court made clear that proffered justifications cannot rely on overbroad generalizations and cannot be hypothesized or invented post hoc in response to litigation.[150]

Under this demanding standard, as adapted in this rule, a sex-specific health program or activity classification is unlawful unless the covered entity can show an exceedingly persuasive justification for it, that is, that the sex-based classification is substantially related to the achievement of an important health-related or scientific objective. In evaluating a complaint of discrimination challenging a covered entity's sex-specific health program or activity, OCR may consider a variety of factors relevant to the particular program or activity. In all cases, however, OCR will expect a covered entity to supply objective evidence, and empirical data if available, to justify the need to restrict participation in the program to only one sex. In no case will OCR accept a justification that relies on overly broad generalizations about the sexes.

Under this standard, OCR anticipates that most health researchers will be able to justify sex-specific clinical trials, such as those that test treatments for sex-specific conditions or that evaluate differences in responses to treatment regimens among the sexes, based upon the scientific purposes of the study. Where there is no clinical or scientific rationale for making a program sex-specific, by contrast, a covered entity that offers such a program would need to demonstrate, through such means as research literature, empirical data, accepted professional standards, and/or facts specific to participants in the program, that maintaining the sex segregation of the program is necessary for the program to achieve its purpose. Overly broad generalizations would not be sufficient.

No commenters asked OCR to adopt the sex-specific standards authorized in Title IX or the Department of Education's Title IX regulations. OCR has chosen to apply an adapted constitutional standard under Section 1557 rather than the standard authorized in Title IX and the Department of Education's Title IX regulations because, as noted in the proposed rule, and by several commenters, the single-sex educational exceptions found in Title IX and the Department of Education's Title IX regulations—such as exceptions for some single-sex education programs (*e.g.*, contact sports in physical education classes; classes on human sexuality; and choruses) when certain requirements are met—do not readily apply in a context grounded in health care.

In addition, we note that OCR's adaptation of the constitutional standard as the standard to be applied to sex-specific health programs or activities under Section 1557 is consistent with the constitutional standard that already applies to sex-specific public health programs and activities, which are covered entities under this rule if they receive Federal financial assistance. OCR has adapted the standard to use the term ''important health-related or scientific objective,'' in recognition of the fact that the rule's provision on sex-specific programs or activities applies to both private and public covered entities in the context of health programs and activities. The same Section 1557 nondiscrimination standards, including this adapted standard, apply to health programs or activities subject to this rule whether public or private covered entities operate them.

Finally, as we initially noted in the proposed rule, we do not intend to prohibit separate toilet, locker room, and shower facilities where comparable facilities are provided to individuals, regardless of sex. OCR recognizes that under some existing Federal, State and local laws, rules or regulations, certain types of sex-specific facilities such as restrooms may be permitted. The approach taken by OCR is consistent with the long standing approach taken to these types of facilities.

However as previously stated in the discussion of the definition of ''on the basis of sex'' in § 92.4, even where it is permissible to make sex-based distinctions, individuals may not be excluded from health programs and activities for which they are otherwise eligible based on their gender identity.[151] Courts have rejected claims that any legal right to privacy is violated and that one person suffers any cognizable harm simply by permitting another person access to a sex-specific program or facility which corresponds to their gender identity.[152]

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 § 92.101 with the following modifications:

We have re-designated § 92.101(b)(1) as § 92.101(b)(1)(i), and added a new section § 92.101(b)(1)(ii), which prohibits aiding or perpetuating discrimination against an individual by providing significant assistance to an entity or person that discriminates on the basis of race, color, or national origin against beneficiaries of the covered entity's health program or activity. Similarly, we have re-designated § 92.101(b)(4) as § 92.101(b)(4)(i), and added a new section § 92.101(b)(4)(ii), which prohibits aiding or perpetuating discrimination against an individual by providing significant assistance to an entity or person that discriminates on the basis of age against health program or activity beneficiaries. These provisions complement similar provisions incorporated in the final rule with respect to disability and sex discrimination and are included to ensure that we are providing the same protections from race, color, national origin, and age discrimination as are provided with respect to sex and disability discrimination.

In addition, we have changed the language in § 92.101(b)(2)(i) to exclude reference to 45 CFR 84.52(d). We are re-designating the existing regulation text at § 92.202 as § 92.202(a), and adding a

[146] 518 U.S. 515 (1996).

[147] *Id.* at 531–32.

[148] *Id.* at 532–33 (internal citations omitted).

[149] *Id.* at 533–34.

[150] *Id.* at 533.

[151] *See Lusardi* v. *McHugh*, U.S. Equal Employment Opportunity Comm'n Appeal No. 0120133395, Agency No. ARREDSTON11SEP05574, 2015 WL 1607756 (April 1, 2015) (finding Agency's denial of Complainant's access to the common women's restroom on account of her gender identity violated Title VII), *http://www.eeoc.gov/decisions/0120133395.txt*.

[152] *See, e.g.*, *Crosby*, 763 F. Supp. 666; *cf Cruzan*, 294 F.3d 981.

new subsection, § 92.202(b) that requires covered entities—regardless of the number of people they employ—to provide appropriate auxiliary aids and services to persons with impaired sensory, manual, or speaking skills, where necessary to afford such persons an equal opportunity to benefit from the service in question.

We have re-designated the existing regulation text at § 92.101(b)(3) as § 92.101(b)(3)(i). We have added new subsections, § 92.101(b)(3)(ii) and § 92.101(b)(3)(iii) to clarify the full breadth of discriminatory actions prohibited by Section 1557 on the basis of sex. Last, we have added a new subsection, § 92.101(b)(3)(iv) to clarify when covered entities may provide a sex-specific health program or activity.

Subpart C—Specific Applications to Health Programs and Activities

Section 1557 is unique among Federal civil rights laws in that it specifically addresses discrimination in health programs and activities. To provide additional specificity regarding nondiscrimination requirements in this setting, Subpart C builds upon pre-existing civil rights regulations referenced in Subpart B.

Meaningful Access for Individuals With Limited English Proficiency (§ 92.201)

Overview of § 92.201

In § 92.201, OCR proposed to effectuate Section 1557's prohibition on national origin discrimination as it affects individuals with limited English proficiency in health programs and activities of covered entities.

We explained that for individuals with limited English proficiency, lack of proficiency in English—and the use of non-English languages—is a direct outgrowth of, and is integrally tied to, their national origins.[153] It is well-established under Title VI and its implementing regulation that a prohibition on national origin discrimination requires covered entities to take reasonable steps to provide meaningful access to individuals with limited English proficiency.[154] The U.S. Supreme Court has held that the provision of language assistance services is essential to ensure the equality of opportunity promised by nondiscrimination laws.[155] As we stated in the Department's 2000 LEP Policy Guidance:

> The key to providing meaningful access for LEP persons is to ensure that the recipient/covered entity and LEP person can communicate effectively. The steps taken by a covered entity must ensure that the LEP person is given adequate information, is able to understand the services and benefits available, and is able to receive those for which he or she is eligible. The covered entity must also ensure that the LEP person can effectively communicate the relevant circumstances of his or her situation to the service provider.[156]

General Requirements § 92.201(a), (b) and (c)

In § 92.201(a), we proposed to adopt the well-established principle that covered entities must take reasonable steps to provide meaningful access to health programs and activities for all individuals with limited English proficiency whom the covered entities serve or encounter.[157] We provided that, consistent with our longstanding enforcement of Title VI, we intended the general obligation in paragraph (a) to be a context-specific standard that the Director considers in light of the particular facts.[158]

We stated that the proposed standard balances two core principles critical in effectuating Section 1557's prohibition of national origin discrimination. First, the Department must ''ensure that [health programs and activities] aimed at the American public do not leave some behind simply because they face challenges communicating in English.'' [159] We noted that provider-patient communication is essential to the concept of patient centeredness, which is a core component of quality health care and has been shown to improve patients' health and health care.[160] Second, we stated that the level, type and manner of language assistance services required under paragraph (a) should be assessed based on the relevant facts, which may include the operations and capacity of the covered entity.

For these reasons, proposed paragraph (b) identified how the Director will evaluate whether a covered entity has met the requirement in paragraph (a).[161] In paragraph (b)(1), we proposed to require the Director to consider, and give substantial weight to, the nature and importance of the health program or activity, including the particular communication at issue. In paragraph (b)(2), we proposed to require the Director to take other relevant factors into account and identified some of those that might be relevant.

In paragraphs (b)(2)(i) and (ii), OCR proposed to identify the length, complexity, and context of the

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[153] *See, e.g.,* 80 FR at 54182.

[154] *See, e.g., Lau* v. *Nichols,* 414 U.S. 563, 566 (1974) (interpreting Title VI and its implementing regulations to require a school district with students with limited English proficiency of Chinese origin to take affirmative steps to provide the students with a meaningful opportunity to participate in Federally funded educational programs); HHS LEP Guidance, *supra* note 49, 68 FR at 47313 (''[T]he failure of a recipient of [F]ederal financial assistance from HHS to take reasonable steps to provide LEP persons with [a] meaningful opportunity to participate in HHS funded programs may constitute a violation of Title VI and HHS's implementing regulations''); U.S. Dep't of Health & Human Servs., Office for Civil Rights, Policy Guidance, Title VI Prohibition against National Origin Discrimination As It Affects Persons with Limited English Proficiency, 65 FR 52762, 52765 (August 30, 2000) (''The most important step in meeting this [meaningful access] obligation is for recipients of Federal financial assistance such as a grants, contracts, and subcontracts to provide the language assistance necessary to ensure such access, at no cost to the LEP person.''). *See also* Exec. Order No. 13166, *Improving Access to Services for Persons with Limited English Proficiency,* 65 FR 50121 (Aug. 11, 2000) (requiring each Federal Department to improve access to Federally assisted programs and activities by persons with limited English proficiency and to implement a system by which individuals with limited English proficiency can meaningfully access the Departments' Federally conducted programs and activities).

[155] 80 FR at 54182 (citing *Lau,* 414 U.S. at 566) (reasoning that a federally funded educational program's failure to take affirmative steps to rectify the language deficiency of limited English proficient students of Chinese ancestry denies them a meaningful opportunity to participate in the educational program on the basis of their national origin).

[156] 65 FR at 52765.

[157] The Department's LEP Guidance provides an in-depth explanation of Title VI's prohibition against national origin discrimination as it affects limited English proficient populations and how recipients can determine what steps are reasonable to provide all individuals with limited English proficiency meaningful access. HHS LEP Guidance, *supra* note 49.

[158] Under Title VI, OCR investigates each complaint and conducts its compliance reviews on a case-by-case basis and tailors each case resolution to the particular facts of each case. For highlights of OCR's Title VI enforcement specific to the prohibition of national origin discrimination as it affects individuals with limited English proficiency, see Enforcement Success Stories Involving Individuals with Limited English Proficiency, U.S. Dep't of Health & Human Servs., Office for Civil Rights, *http://www.hhs.gov/ocr/civilrights/activities/examples/LEP/index.html* (last visited May 4, 2016).

[159] 80 FR 54172, 54183 (quoting HHS LEP Guidance, *supra* note 49, 68 FR at 47312).

[160] *Id.* (citing U.S. Dep't of Health & Human Servs., Agency for Health Care Research & Quality, Chapter 6, Patient Centeredness, National Healthcare Quality Report (2013), *http://www.ahrq.gov/research/findings/nhqrdr/nhqr13/chap6.html*). Person-centered and family centered care is one of the six priorities of the National Quality Strategy. Dep't. of Health & Human Servs., Agency for Health Care Research & Quality, 2014 National Healthcare Quality and Disparities Report, Person- and Family-Centered Care Chartbook, AHRQ Pub. No. 15–0007–14, at 3 (May 2015), *http://www.ahrq.gov/sites/default/files/wysiwyg/research/findings/nhqrdr/2014chartbooks/personcentered/personcenteredcare-chartbook.pdf.*

[161] *Id.* at 54183 n.53 (stating that the Department's LEP Guidance takes a similar approach by identifying the factors that OCR will consider, in determining the extent of a recipient's obligations to individuals with limited English proficiency). *See* HHS LEP Guidance, *supra* note 49, 68 FR at 47314–16.

communication as potentially relevant factors in a particular case. We noted that where a communication is particularly long or complex, a covered entity might be required to provide a means for an individual with limited English proficiency to be able to refer back to the information communicated by providing, for instance, a document written in the individual's primary language or an audio file of the information conveyed orally.

In paragraph (b)(2)(iii), we provided that the prevalence of the primary language in which the individual with limited English proficiency communicates, among those eligible to be served or likely to be encountered by the health program or activity, might also be relevant.

In paragraphs (iv) and (v) of proposed § 92.201(b)(2)—the final illustrative factors listed—we noted that the resources available to the covered entity and the costs of language assistance services might also be relevant in a particular case.

In proposed paragraph (c), we clarified that language assistance services required under paragraph (a) must be provided free of charge, be accurate and timely, and protect the privacy and independence of the individual with limited English proficiency.[162]

Specific Requirements for Interpreter Services and Restricted Use of Certain Persons to Interpret or Facilitate Communication § 92.201(d) and (e)

In paragraphs (d) and (e), OCR proposed to codify standards described in the Department's LEP Guidance regarding qualified interpreters for individuals with limited English proficiency and the use of family members or friends as interpreters or to facilitate communication.[163] These proposed standards account for issues of competency, confidentiality, privacy, and conflict of interest that arise as a result of relying on informal (or ad hoc) interpreters. We noted that paragraphs (d) and (e) are consistent with oral interpretation standards that OCR has advanced through its resolution of Title VI cases and compliance reviews.[164]

Specifically, in paragraph (d), OCR proposed to address standards applicable to oral interpretation. We provided that when a covered entity is required by paragraph (a) to provide oral interpretation as a reasonable step to provide meaningful access to an individual with limited English proficiency, the covered entity must offer that individual a qualified interpreter.

In paragraph (e), we proposed restrictions on the use of certain persons to interpret or facilitate communication for an individual with limited English proficiency. We proposed that paragraph (e) apply in addition to, and regardless of, the appropriate level, type or manner of language assistance services a covered entity is required to provide. In paragraph (e)(1), we proposed to prohibit a covered entity from requiring an individual with limited English proficiency to provide his or her own interpreter. However, in paragraphs (e)(2)(i) and (ii), we proposed to identify narrow and finite situations in which a covered entity may rely on an adult accompanying an individual with limited English proficiency to interpret. In paragraph (e)(3), we proposed to prohibit a covered entity from relying on a minor child to interpret or facilitate communication and identified an exception to this prohibition that is narrower in scope than the exception identified in (e)(2)(i) and (ii).

We explained that in lieu of the approach we proposed in paragraphs (d) and (e), we considered proposing that all covered entities have the capacity to provide, in their health programs or activities, qualified interpreters for individuals with limited English proficiency through telephonic oral interpretation services available in at least 150 non-English languages. OCR invited comment on what oral interpretation services, if any, we should require and how such approaches appropriately balance the provision of meaningful access to individuals with limited English proficiency and covered entities' flexibility to identify the means of providing such access.

Acceptance of Language Assistance Services Not Required § 92.201(f)

In paragraph (f), we proposed that no individual with limited English proficiency should be required to accept language assistance services, consistent with an individual's right to self-determination. We provided that a covered entity cannot coerce an individual to decline language assistance services. We also provided that if an individual with limited English proficiency voluntarily declines an offer of language assistance services from the covered entity, a covered entity could denote, in the individual's file or records, the language assistance services offered and the declination.[165]

Alternative Approaches

In the proposed rule, we described alternate approaches we considered and requested comment on these approaches and any others to effectuate Section 1557's prohibition of national origin discrimination as it affects individuals with limited English proficiency. For instance, we noted that independent of the proposed requirements of § 92.201, covered entities, including Health Insurance Marketplaces, State agencies administering Medicaid and Children's Health Insurance Program (CHIP) programs, and qualified health plan issuers, must comply with any applicable language access requirements in other laws and regulations.[166] We invited comment on whether the requirements under different authorities should be harmonized and if so, to what extent and how.

We also stated that we considered a regulatory scheme requiring covered entities to provide meaningful access to each individual with limited English proficiency by providing effective language assistance services, at no cost, unless such action would result in an undue burden or a fundamental alteration of the health program or activity.[167]

We further noted that we considered a regulatory scheme requiring covered entities to provide a range of language assistance services in the non-English languages spoken by State-wide populations with limited English proficiency that meet defined thresholds. Such thresholds would provide a minimum number of non-English languages in which covered entities would be required to deliver oral interpretation services; to translate written vital documents and Web site content; and to include taglines on vital documents and on Web sites.[168] We requested comment on whether OCR

[162] 80 FR at 54183 (citing HHS LEP Guidance, *supra* note 49, 68 FR at 47318, 47323 (with respect to privacy), 47316–17, 47322 (with respect to timeliness), and 47318–19, 47320, 47322 (with respect to services free of charge)).

[163] *Id.* at 54183–84 (citing HHS LEP Guidance, *supra* note 49, 68 FR at 47317–18, 47323).

[164] *See, e.g.,* HHS OCR VRA with Mee Memorial Hosp., *supra* note 82, at pt. II.J (defining qualified interpreter); HHS OCR VRA with Montgomery County DSS, *supra* note 82, at pts. II.E (defining qualifications of an ''interpreter''), IV.H (requiring timely, competent language assistance), & IV.L (identifying interpreter standards).

[165] 80 FR at 54184 (citing HHS LEP Guidance, *supra* note 49, 68 FR at 47318, 47320 (suggesting that recipients consider whether to record the primary language of an individual with LEP or an individual's choice to provide his or her own interpreter)).

[166] The proposed rule discusses these entities' requirements at 80 FR at 54184–85.

[167] *Id.* at 54185.

[168] *See id.*

should require thresholds, and if so, what thresholds should be required, and to what geographic areas or service areas the thresholds should apply. We also sought comment on whether OCR should permit covered entities to implement their obligations with a phased-in approach.

We also noted that we considered a regulatory scheme that would impose enhanced obligations on a subset of covered entities. We sought comment on what characteristics should define covered entities that could have enhanced obligations, such as whether the covered entity is of a certain type or size, has frequent contact with individuals with limited English proficiency, or operates particularly important health programs or activities, among other potential factors. We listed potential categories of covered entities that could have enhanced obligations, such as State agencies administering Medicaid or CHIP; Health Insurance Marketplaces; the Department in its operation of its health programs or activities; or covered entities that have a minimum number of beds, employees, or locations, such as hospitals, nursing homes or skilled nursing facilities, home health agencies, and retail pharmacies (including mail-order pharmacies).[169] We described that under this alternate approach, instead of evaluating each case on its particular facts, the Director would evaluate a covered entity's compliance based on whether the entity provided the range of language assistance services in the non-English languages specified.[170] We invited comment on this proposal.

We further requested comment on whether covered entities should be required to systematically prepare to provide language assistance services in their health programs or activities, such as through the establishment of policies and procedures or through other advance planning mechanisms. We stated that in OCR's experience, covered entities are in a better position to meet their obligations to provide language assistance services in a timely manner to individuals with limited English proficiency when those entities identify, in advance, the types and levels of services that will be provided in each of the contexts in which the covered entity encounters individuals with limited English proficiency.

OCR noted that an advance planning requirement could require each covered entity to identify all resources for providing language assistance services; annually assess the frequently-encountered or highly prevalent languages in the service area of the health program or activity; establish written procedures to which frontline staff could refer when encountering individuals with limited English proficiency; and monitor and oversee the quality of language assistance services provided. We also noted that an advance planning requirement could require each covered entity to build its capacity to provide language assistance services to meet the needs of the national origin populations that the entity serves. We requested comment on the types of advance planning mechanisms, if any, that should be required and why.

In the proposed rule, OCR advised that covered entities that are already developing or implementing language access plans, or otherwise assessing their language assistance needs, should continue such efforts. However, OCR stated that engaging in such planning is not a defense for failing to provide language assistance services to any particular individual at all, or in an untimely manner, if such services are reasonable steps to provide meaningful access. We advised that covered entities that are conducting advance planning should consider how they can ensure that language assistance services are available in their health programs and activities as they simultaneously improve their operational capacities to provide effective language assistance services into the future.

The comments and our responses regarding § 92.201 are set forth below:

Overall, commenters supported the proposed rule's inclusion of specific provisions addressing meaningful access for individuals with limited English proficiency. We received numerous comments written in non-English languages submitted by individuals with limited English proficiency who expressed how essential it is to have language assistance services, at no cost, to understand forms, invoices, and medication instructions. Many comments from the health care provider and insurance industry, as well as from organizations representing individuals with limited English proficiency, agreed that it is essential that individuals, regardless of national origin, be able to access covered entities' health programs and activities. We received many comments, however, regarding the scope and parameters of covered entities' obligations under the final rule.

Comment: Many commenters recommended revising the categories of individuals to whom a covered entity has an obligation to take reasonable steps to provide meaningful access. Specifically, commenters recommended that a covered entity's obligation should apply to those ''eligible to be served'' or ''likely to be affected by'' the covered entity's health programs and activities. Commenters suggested that proposed § 92.201(a), which stated that the obligation of a covered entity runs to those who the entity ''serves or encounters in its health programs and activities,'' unduly narrowed the scope of the covered entity's obligation.

Response: In response to commenters' recommendations, we have replaced the phrase ''that it serves or encounters'' with ''eligible to be served or likely to be encountered.'' We agree with commenters that a covered entity must be prepared to take reasonable steps to provide meaningful access to individuals beyond those who actually walk into, or contact, that entity. Where a covered entity is likely to encounter, but is unprepared to assist, individuals of particular national origin groups in the languages in which they communicate, those individuals are unlikely to seek services from, or participate in, the entity's health programs or activities, thereby perpetuating barriers to individuals' access to care.

We chose the phrase ''eligible to be served or likely to be encountered'' because it is one of the formulations in the HHS LEP Guidance of the population to which a covered entity has an obligation.[171] In addition, commenters' proposal that a covered entity's obligation applies to individuals ''likely to be affected by'' the covered entity's health programs and activities gave covered entities less concrete guidance about their obligations relative to the phrase ''likely to be encountered.''

Comment: Numerous commenters recommended that OCR revise the general obligation in § 92.201(a) to require that covered entities ''provide meaningful access'' to each individual with limited English proficiency rather than ''take reasonable steps to provide meaningful access.'' Commenters explained that because ''meaningful access'' is already a subjective standard, requiring ''reasonable steps to provide meaningful access'' substantially dilutes covered entities' obligations to provide language assistance services.

These commenters suggested that language assistance should be provided in every situation and that oral interpretation, in particular, should be provided ''on demand.'' Commenters

[169] *See id.*

[170] *See id.*

[171] *See* HHS LEP Guidance, *supra* note 49, 68 FR at 47314, 47320, 47322.

suggested that the final rule make this basic obligation clear because some covered entities turn away individuals with limited English proficiency, stating that the entity does not provide language assistance services. For instance, one commenter shared that it is common for individuals with limited English proficiency to use a hospital emergency department as a source of primary care because the individuals' physicians do not offer qualified interpreters for individuals with limited English proficiency. Commenters also suggested that the Director's weighing of the illustrative factors set out in § 92.201(b) should focus exclusively on whether the covered entity provided the appropriate type, form, and manner of language assistance.

Response: We decline to modify the general obligation in § 92.201(a) because it reflects familiar and longstanding requirements applicable under Title VI.[172] In addition, the regulatory scheme provides in 92.201(b)(1) that in assessing this standard, the Director will consider, and give substantial weight to, the nature and importance of the health program or activity and the particular communication at issue, which places covered entities on notice about the way in which we will evaluate the Title VI standard within the context of health programs and activities. OCR interprets the requirement that covered entities take ''reasonable steps to provide meaningful access'' to demand that each entity, as an initial step, assess the need to provide language assistance services to each individual with limited English proficiency and respond to that need by providing the appropriate language assistance services on a timely basis.

As we stated in the proposed rule, safe and quality health care requires an exchange of information between the health care provider and patient for the purposes of diagnoses, treatment options, the proper use of medications, obtaining informed consent, and insurance coverage of health-related services, among other purposes.[173] This exchange of information is jeopardized when the provider and the patient speak different languages and may result in adverse health consequences and even death.[174] Indeed, the provision of health care services, by its ''very nature[,] requires the establishment of a close relationship with the client or patient that is based on sympathy, confidence and mutual trust,'' [175] which cannot be established without effective communication.

Comment: Some commenters expressed concern about the potential financial and administrative burden to provide language assistance services. Many of these commenters expressed support for the proposed rule's inclusion of specific provisions addressing access for individuals with limited English proficiency but also urged that public and private health insurance issuers update medical codes and fee schedules to allow providers to receive reimbursement for the provision of language assistance services.

Some commenters offered proposals for minimizing the costs to covered entities for providing language assistance services—oral interpretation services in particular. These recommendations included that OCR facilitate access to telephonic oral interpretation, at no cost to covered entities, and that OCR ensure that covered entities have adequate funding to provide qualified interpreters for individuals with limited English proficiency.

Response: We appreciate hearing commenters' concerns and having the benefit of commenters' recommendations to lessen potential cost and administrative barriers that covered entities may face. It is beyond the scope of this rulemaking to adopt recommendations that OCR fund qualified interpreters or direct issuers to modify medical codes and fee schedules to reimburse health care providers for their provision of language assistance services.[176]

OCR encourages covered entities to work together to leverage their ability to provide language assistance services in the most cost-effective and efficient ways to meet their respective obligations under § 92.201(a) before using costs as a reason to limit language assistance services.[177] OCR also encourages professional associations and organizations to consider what role they can play in helping their members meet the requirements of § 92.201; we provided similar encouragement in the HIPAA Privacy Rule.[178]

We further remind State agencies receiving Federal financial assistance for Medicaid and the Children's Health Insurance Program that States may claim Federal matching funds for the costs of written translation and oral interpretation as administrative expenses or as medical assistance-related expenses.[179] Further, increased

[172] *See Lau* v. *Nichols, supra* note 154 (interpreting Title VI to require the covered entity to take affirmative steps to provide students with limited English proficiency of Chinese origin with a meaningful opportunity to participate in Federally-funded educational programs); HHS LEP Guidance, *supra* note 49, 68 FR at 47313 (''[T]he failure of a recipient of [F]ederal financial assistance from HHS to take reasonable steps to provide LEP persons with [a] meaningful opportunity to participate in HHS funded programs may constitute a violation of Title VI and HHS's implementing regulations'').

[173] 80 FR at 54183 (citing to the 2000 HHS LEP Guidance, *supra* note 49, 65 FR at 52763). *See generally* Cindy Brach et al., *Crossing the Language Chasm,* Health Affairs, vol. 24, no.2 424, at 424–25 (2005) (describing the impacts of language barriers in health care). In addition, the 2014 National Healthcare Quality and Disparities Report Chartbooks include metrics showing disparities between national origin groups, one of which expressly identifies trends of non-English speaking children who need health care for an illness, injury, or condition who sometimes or never got care as soon as wanted. *See* U.S. Dep't of Health & Human Servs., Agency for Health Care Research & Quality, 2014 National Healthcare Quality and Disparities Report, Chartbook on Health Care for Hispanics at 47, 57 (May 2015), *http://www.ahrq.gov/sites/default/files/wysiwyg/research/findings/nhqrdr/2014chartbooks/hispanichealth/2014nhqdr-hispanichealth.pdf;* U.S. Dep't of Health & Human Servs., Agency for Health Care Research & Quality, Person- and Family-Centered Care Chartbook, *supra* note 160, at 12.

[174] 80 FR at 54183.

[175] *Id.*

[176] We note, however, that the Department's National Stakeholder Strategy for Achieving Health Equity identifies financing and reimbursement for ''health interpreting services'' as a strategy to achieve the goal of improving cultural and linguistic competency. *See* U.S. Dep't of Health & Human Servs., Office of Minority Health, National Partnership for Action to End Health Disparities. National Stakeholder Strategy for Achieving Health Equity, Section 3, 131 (2011), *http://minorityhealth.hhs.gov/npa/files/Plans/NSS/NSS_07_Section3.pdf.*

[177] We note, for example, that the Washington State Medicaid Interpreter Services Program centralizes the provision of language assistance services to achieve economies of scale. *See* Washington State Health Care Auth., Interpreter Services Program, *www.hca.wa.gov/medicaid/interpreterservices* (last visited May 4, 2016). Similarly, through OCR's Effective Communication in Hospitals Initiative, the Kentucky Hospital Association built the capacity to offer its approximately 120 member hospitals access to a telephonic interpretation service contract that offers a volume-based discount rate. *See* Kentucky Hospital Association, Effective Communication in Hospitals, *http://www.kyha.com/CM/Initiatives/Safety_and_Quality_Resources/Effective_Communication_in_Hospitals.aspx* (last visited May 4, 2016). Although OCR cannot certify that these approaches uniformly enable entities to meet the requirements of Section 1557, they do represent examples of the types of collaborative action that covered entities may consider.

[178] Standards for Privacy of Individually Identifiable Health Information, 65 FR 82462, 82749 (Dec. 28, 2000) (final rule) (codified at 45 CFR pts. 160 and 164) (encouraging professional associations to assist their members in developing policies and procedures required under the Privacy Rule); Standards for Privacy of Individually Identifiable Health Information, 64 FR 59918, 59992 (Nov. 3, 1999) (proposed rule) (encouraging professional associations to assist their members in developing policies and procedures required under the Privacy Rule).

[179] U.S. Dep't. of Health & Human Servs., Center for Medicare & Medicaid Servs., Increased Federal Matching Funds for Translation and Interpretation Services under Medicaid and CHIP 1 (Jul. 1, 2010), *http://www.medicaid.gov/Federal-Policy-Guidance/downloads/SHO10007.pdf* [hereinafter CMS

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funding may be available when States claim the cost of written translation and oral interpretation as administrative expenses if such language assistance services are provided for the ''enrollment, retention, and use of services'' for individuals with limited English proficiency eligible for CHIP and for Medicaid-eligible children and their families.[180] In addition, we remind qualified health plan issuers that the ACA requires, as a condition of an issuer's health plan receiving certification as a qualified health plan, that the issuer implement a quality improvement strategy for the qualified health plan that provides increased reimbursement or other incentives for the implementation of activities to reduce health and health care disparities, including through the use of language services.[181] We encourage health insurance issuers to structure their health plan payment structures to consider health care providers' expenses in providing language assistance services.

We decline to accept the recommendation that OCR facilitate access to telephonic oral interpretation services for all covered entities. Such facilitation is beyond the scope of the Federal government's role and is an impractical solution to address the needs of diverse Section 1557 covered entities. However, OCR does share best practices and useful resources, such as through the Federal government's Interagency Working Group on Limited English Proficiency, at *www.LEP.gov.*

Comment: We received numerous comments on whether the final rule should include an advance planning requirement for covered entities to be systematically prepared to provide language assistance services in their health programs and activities. The vast majority of these comments recommended that the final rule include such an advance planning requirement—specifically, the development and implementation of a language access plan that addresses the needs of the limited English proficient population in the service area of a covered entity's health program or activity. Commenters reasoned that a regulatory requirement is the most effective method of holding covered entities accountable for engaging in meaningful advance planning.

One commenter observed that many covered entities already evaluate the type of language assistance services they are obligated to provide, pursuant to the current HHS LEP Guidance, and thus that codifying this requirement would not impose a significant additional burden on covered entities. This commenter also asserted that an advance planning requirement is analogous to the approach of § 92.7, which requires certain covered entities to have a grievance procedure in place. Another commenter shared that in updating her employer's language access plan, the availability of online tools and resources greatly reduced the commenter's anticipated burden of what advance planning would require.

We received many comments recommending that the final rule identify specific required components of a language access plan, including the types of language access services the covered entity will provide and in what languages, based on the languages spoken by eligible individuals with limited English proficiency in the covered entity's service area. One commenter underscored that to increase efficiency and maximize cost savings, a language access plan should identify multiple types of language assistance services that a covered entity can use for different situations or even within one encounter. This commenter asserted that relying on just one kind of language assistance service may not be appropriate for all communications.

Another commenter recommended that the final rule mirror California's regulations on advance planning mechanisms for the provision of language assistance services.[182] This commenter stated that, consistent with California's regulations, OCR should require that language access plans identify all points of contact with individuals with limited English proficiency; provide a procedure for recording individuals' primary language; identify vital documents; provide a procedure for the translation of vital documents; provide a procedure to request translation of specific other documents; require training on language access services for all staff likely to have contact with individuals with limited English proficiency; require the assessment of the qualifications of bilingual/multilingual staff; and adopt written policies and procedures regarding the provision of language assistance services, including a procedure for contracting with language service vendors. Other commenters agreed that prior to using individuals to provide interpretation or translation services, covered entities should be required to evaluate or verify the individuals' knowledge, skills and abilities to confirm that they meet the definition of a qualified interpreter or a qualified translator for an individual with limited English proficiency.

We received a small number of comments opposing a requirement for advance planning. One commenter acknowledged that a language access plan is important in ensuring that covered entities are systematically prepared to provide language assistance services but recommended that OCR should merely encourage, not require, advance planning activities. The commenter observed that developing a language access plan may be too burdensome for small covered entities.

Response: Based on the comments received, we have added a factor—the only illustrative factor in § 92.201(b)(2)—that requires the Director to consider, if relevant, whether the entity has developed and implemented an effective written language access plan, appropriate to its particular circumstances. The language ''appropriate to its particular circumstances'' conveys our recognition that the nature and extent of the voluntary planning in which a covered entity may choose to engage will vary depending on the entity's particular health programs and activities, its size, its geographic location, and other factors. A language access plan need not be long, complex, or burdensome.

We note that a written language access plan has long been recognized as an essential tool to ensure adequate and timely provision of language assistance services, including compliance with the general obligation in § 92.201(a) and the quality standards in § 92.201(d)–(f). For instance, for over 15 years, Executive Order 13166 has required each Federal agency to create and implement a language access plan responsive to the needs of the limited English proficient population it serves.[183] Moreover, the

Increased Federal Matching Funds]; *id.*, Recently Released Policy Guidance—CHIPRA and the ACA, Information Bulletin 1–2 (Jul. 9, 2010), *http://www.medicaid.gov/Federal-Policy-Guidance/downloads/07-09-2010-CHIPRA-and-ACA.pdf* [hereinafter CMS Information Bulletin 7/9/10].

[180] CMS Increased Federal Matching Funds, *supra* note 179, at 1–2; CMS Information Bulletin 7/9/10, *supra* note 179, at 1–2; U.S. Dep't. of Health & Human Servs., Center for Medicare & Medicaid Servs., Information Bulletin 2 (Apr. 26, 2011), *http://www.medicaid.gov/Federal-Policy-Guidance/downloads/Info-Bulletin-4-26-11.pdf.*

[181] *See* 42 U.S.C. 18031(c)(1)(E), (g)(1)(E) (describing qualified health plan certification requirements in a quality improvement strategy).

[182] *See* 28 CCR 1300.67.04(c) (requiring each health care service plan to develop and implement a language assistance program that contains standards for enrollee assessment; providing language assistance services; staff training; and compliance monitoring).

[183] E.O. 13166, 65 FR 50121 (2000). In 2011, the U.S. Department of Justice renewed the Federal Government's commitment to the Executive Order. Office of the Att'y General, U.S. Dep't of Justice, Federal Government's Renewed Commitment to Language Access Obligations Under Executive

development and implementation of a written language access plan is consistent with OCR's longstanding enforcement processes[184] and resolution agreements regarding Title VI.[185] Although we are not requiring language access plans, we encourage entities to consider whether and how they can engage in advance planning to facilitate their ability to meet their obligations under § 92.201 to serve individuals with limited English proficiency on a timely basis.

We decline to outline the minimum expectations for a language access plan, if a covered entity chooses to develop and implement one, because that approach would be too prescriptive. Nonetheless, in our experience, effective language access plans often, among other components, address how the entity will determine an individual's primary language, particularly if the language is an unfamiliar one; identify a telephonic oral interpretation service to be able to access qualified interpreters when the need arises; identify a translation service to be able to access qualified translators when the need arises; identify the types of language assistance services that may be required under particular circumstances; and identify any documents for which written translations should be routinely available. OCR remains available to covered entities as a resource for technical assistance in the development and implementation of language access plans in their health programs and activities. HHS offers helpful guidance on this subject,[186] as does the U.S. Department of Justice.[187] We encourage covered entities to refer to these materials to assist their advance planning activities.

Comment: Many commenters recommended modifications to, and additional clarification regarding, the list of factors that the Director will take into account, if relevant, among other relevant factors in evaluating a covered entity's compliance with its general obligation in § 92.201(a). These comments fall into four main categories. First, many commenters requested that we add additional factors to the list in § 92.201(b)(2)(i)–(v). Commenters were concerned that absent explicit references to these factors, the Director would not, or could not, consider them. Examples of factors that commenters requested that we add include:

- The frequency with which a covered entity encounters, or is likely to encounter, a particular non-English language;
- the impact to the consumer if language assistance services are not provided;
- the extent to which covered entities can lessen their own cost burdens through technology and reasonable business practices, if the Director considers the costs of language assistance services; and
- if and when a covered entity is permitted to choose a less costly language assistance service than the one an individual may request.

Second, many commenters recommended that we combine the ''costs of language assistance services'' in proposed § 92.201(b)(2)(v) with ''[a]ll resources available to the covered entity'' in proposed § 92.201(b)(2)(iv) into a single factor because the two are inherently intertwined.

Third, some commenters requested that OCR clarify in the final rule how the factors in proposed § 92.201(b)(2)(i)–(v) would be weighted relative to each other, if relevant and thus evaluated by the Director in a given case. Most commenters who requested clarification recommended that the costs of language assistance services and the resources available to the covered entity not be weighted more heavily than the other factors or become dispositive.

Fourth, a number of commenters requested clarification on the function that the length and complexity of the communication in proposed § 92.201(b)(2)(i) would have in the Director's evaluation of a particular case.

Response: After considering the comments received, we have revised the final rule to eliminate the illustrative factors and to articulate only one factor: Whether a covered entity has developed and implemented an effective written language access plan appropriate to its circumstances. We agree with some commenters' concerns that including multiple illustrative factors in the regulatory text may create the erroneous impression that the Director will not consider relevant factors absent from § 92.201(b)(2). Were OCR to modify § 92.201(b)(2) to include all factors suggested by commenters, however, the long list of factors might unintentionally create an unworkable regulatory scheme in the attempt to capture any possible factor that might be relevant in some circumstances.

Given these concerns, § 92.201(b)(1)–(2) of the final rule requires the Director to 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 requires the Director to take into account all other relevant factors, including whether the entity has developed and implemented an effective language access plan. We have identified this factor in particular to provide a concrete reminder to covered entities that they may wish to take action to prepare to provide language assistance services to the individuals with limited English proficiency that they will serve or encounter. We reiterate, however, that adoption of a language access plan is a voluntary measure that is not required by the rule; we will continue to evaluate, on a case-by-case basis, whether entities have taken reasonable steps to provide meaningful access and will evaluate all relevant factors in making that assessment.

We recognize that the absence of illustrative factors in regulation text may diminish clarity regarding the Director's evaluation of a covered entity's compliance with § 92.201(a). To provide guidance to covered entities on our intended interpretation of § 92.201(b)(2) and to be responsive to

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Order 13166 (Feb. 17, 2011) *https://www.justice.gov/crt/about/cor/AG_021711_EO_13166_Memo_to_Agencies_with_Supplement.pdf.*

[184] For example, as part of the certification process to ensure that recipients of Medicare Part A are in compliance with Title VI, OCR requires Medicare Part A providers to document their written procedures on communicating effectively with individuals with limited English proficiency. U.S. Dep't of Health and Human Servs., Office for Civil Rights, Civil Rights Information Request for Medicare Certification, Form OMB No. 0945–0006, pt. II.7, *http://www.hhs.gov/sites/default/files/ocr/civilrights/clearance/ocr_mctap.pdf* (identifying written policies and procedures with respect to serving individuals with limited English proficiency as required in a provider's application for Medicare certification).

[185] *See, e.g.,* HHS OCR VRA with Mee Memorial Hosp., *supra* note 82, at pt. IV.B (requiring the development and implementation of a language access policy), pt. IV.C.1 (determining the language needs of the affected population), pt. IV.C.2 (determining the language needs of each individual with limited English proficiency); HHS OCR VRA with Montgomery County DSS, *supra* note 82, at pt. IV.B (requiring the development and implementation of a language access policy), pt. IV.C.1 (determining the language needs of the affected population), pt. IV.C.2 (determining the language needs of each individual with limited English proficiency).

[186] *See* HHS LEP Guidance, *supra* note 49, 68 FR at 47319–21 (encouraging recipients to develop a language access plan [called an ''LEP Plan'' in the Guidance]). HHS's updated language access plan may be a useful model for covered entities. *See* U.S. Dep't of Health & Human Servs., Language Access Plan (2013), *http://www.hhs.gov/sites/default/files/open/pres-actions/2013-hhs-language-access-plan.pdf.*

[187] *See* U.S. Dep't of Justice, Civil Rights Div., Language Access Assessment and Planning Tool for Federally Conducted and Federally Assisted Programs (May 2011), *http://www.lep.gov/resources/2011_Language_Access_Assessment_and_Planning_Tool.pdf. See also* the Federal government's Interagency Working Group on Limited English Proficiency, at *www.LEP.gov.*

comments received on the illustrative factors proposed, the following preamble discussion sets forth a range of factors that may be relevant in any given case.[188]

As an initial matter, we note that one of the factors commenters recommended we add, which is the impact to the individual of failing to provide language assistance services, is necessarily encompassed within § 92.201(b)(1) regarding an evaluation of the nature and importance of the health program or activity and the particular communication at issue.[189]

Factors that may be relevant in a particular case for the Director to consider pursuant to § 92.201(b)(2) include but are not limited to: the length, complexity, and context of the communication; the prevalence of the language in which the individual communicates among those eligible to be served or likely to be encountered by the health program or activity; the frequency with which a covered entity encounters the language in which the individual communicates; whether a covered entity has explored the individual's preference, if any, for a type of language assistance service, as not all types of language assistance services may work as well as others in providing an individual meaningful access to the covered entity's health program or activity; the cost of language assistance services and whether a covered entity has availed itself of cost-saving opportunities; and all resources available to the covered entity, including the entity's capacity to leverage resources among its partners or to use its negotiating power to lower the costs at which language assistance services could be obtained.

We decline to adopt commenters' suggestions to create a regulatory scheme that assigns particular weight to any specific relevant factor because the Director will consider and weigh all relevant factors pursuant to § 92.201(b)(2) on a case-by-case basis.

Because we have eliminated the factors in proposed 92.201(b)(2)(i)–(v), it is moot whether OCR should combine the proposed factor on the costs of language assistance services with the proposed factor on resources available to the covered entity. Nevertheless, costs and resources are intertwined, which is a principle reflected in the HHS LEP Guidance with respect to Title VI[190] and a principle we reiterated with respect to Section 1557 in the proposed rule.[191]

With respect to commenters' requests for clarification on the relevance that the length and complexity of a particular communication has on the type of language assistance a covered entity should provide, we note that this factor is emblematic of the fact-based nature of the inquiry described in § 92.201(b)(1)–(2). Where a document is long and complex, it may in some cases be necessary for a covered entity to provide a written translation so that an individual with limited English proficiency can refer back to or study it at a later time. In other cases, however, a covered entity may meet the requirements of this section by summarizing the document orally for a qualified interpreter to then convey to the individual with limited English proficiency, if such approach is sufficient to provide the individual with limited English proficiency meaningful access to the information.[192]

Comment: Many commenters supported the requirement in proposed § 92.201(c) that a covered entity provide language assistance services to an individual with limited English proficiency in a timely manner. Some commenters further suggested that the final rule set out specific time frames for the provision of oral interpretation, written translation, and taglines. For instance, some commenters recommended that we revise § 92.201(c) to require oral interpretation immediately upon request, written translations within 30 days after the English version is finalized, and taglines simultaneously with English documents. These commenters asserted that oral telephonic interpretation services should be available, at a minimum, no more than 30 minutes after a covered entity encounters an individual with limited English proficiency.

Response: We decline to include prescriptive timeframes for the provision of language assistance services. There is no one definition of ''timely'' that applies to every type of interaction with every covered entity at all times. Consequently, consistent with the overarching framework of § 92.201, a determination of whether language assistance services are timely will depend on the specific circumstances of each case. We reiterate our statement from the proposed rule that language assistance is timely when it is provided at a place and time that ensures meaningful access to persons of all national origins and avoids the delay or denial of the right, service, or benefit at issue.[193]

Comment: Some commenters suggested that the final rule prohibit the use of computer-automated translation. These commenters suggested that reliance on automated translation is not accurate for the highly specialized vocabulary and terminology used in the health care and health insurance settings, especially for less common non-English languages.

Response: We decline to codify a prohibition on the use of automated translation as part of the final rule because such a requirement may unintentionally stifle innovation in this rapidly developing area. Furthermore, depending on the language at issue as well as the content of the translation, some translation technologies are advantageous to facilitate the translation of written content when used along with a qualified translator who independently verifies the accuracy and quality of the translation.[194] For

[188] Some of these factors were proposed in § 92.201(b)(2)(i)–(v), were suggested by commenters', are grounded in the HHS LEP Guidance, or are staples of the effective communication analysis in § 92.202 of this final rule, consistent with Federal disability rights law.

[189] *See* HHS LEP Guidance, *supra* note 49, 68 FR 47311, at 47315 (describing how and why a recipient of Federal financial assistance should consider the nature and importance of the program or activity in determining the extent of its language access obligations under Title VI).

[190] *See* HHS LEP Guidance, *supra* note 49, 68 FR at 47315 (''Resource and cost issues, however, can often be reduced by technological advances; the sharing of language assistance materials and services among and between recipients, advocacy groups, and Federal grant agencies; and reasonable business practices.'' ''Large entities and those entities serving a significant number or proportion of LEP persons should ensure that their resource limitations are well-substantiated before using this factor as a reason to limit language assistance.'').

[191] *See* 80 FR at 54183.

[192] A third party to the communication, such as a qualified interpreter for an individual with limited English proficiency, would orally interpret the covered entity's oral summary from English to a non-English-language and would not alter, summarize, omit, or distort the oral summary that the covered entity provides or judge which information is relevant or important. *See e.g.,* The Nat'l Council on Interpreting in Health Care, A National Code of Ethics for Interpreters in Health Care 8, 13 (2004), *http://www.ncihc.org/assets/documents/publications/NCIHC%20National%20Code%20of%20Ethics.pdf* (discussing the ethical principle of fidelity to the original message).

[193] 80 FR 54172, 54183. The National Standards for Culturally and Linguistically Appropriate Services in Health and Health Care (the National CLAS Standards) emphasize the importance of timely language assistance. U.S. Dep't of Health & Human Servs., Office of Minority Health, The National CLAS Standards, *http://minorityhealth.hhs.gov/omh/browse.aspx?lvl=2&lvlid=53* (last visited May 4, 2016).

[194] Jessica Sperling, Migration Policy Institute, Communicating More for Less: Using Translation and Interpretation Technology to Serve Limited English Proficient Individuals (2011), 12 *http://www.migrationpolicy.org/research/communicating-more-less-using-translation-and-interpretation-technology-LEP* (noting that translation memory programs are used in the public and private sector to increase the efficiency of translating a high-

instance, translation memory software stores segments of previously translated phrases and can improve a qualified translator's efficiency, especially when updating documents.[195]

We do, however, agree with commenters' concerns regarding the use of some automatic translation technologies, which ''is particularly dangerous, and can lead to very serious misunderstandings and adverse consequences for medical documents.'' [196] For example, machine translation programs translate text by performing simple substitution of words using statistical techniques, which may produce highly unreliable translations for certain languages and written content.[197] As a result, using automated translation as the only tool for translating written documents would fulfill a covered entity's obligation under § 92.201(a) only if a qualified translator reviewed the translation for accuracy and edited it as needed.[198] OCR encourages covered entities to understand the strengths and weaknesses of the technology and software programs that qualified translators use.[199]

Comment: Commenters identified that some covered entities lack policies or practices to confirm or evaluate a staff member's skills as a qualified translator or to serve as a qualified interpreter for an individual with limited English proficiency. For instance, commenters stated that they are aware of situations where individuals who are qualified to interpret—but not translate—are nonetheless translating complex documents such as informed consent forms and discharge instructions. Comments recommended that the final rule require covered entities to evaluate staff members' non-English language proficiency and other skills to ensure that they are qualified before permitting them to interpret, translate, or communicate with individuals with limited English proficiency in the individuals' primary languages.

Response: We share commenters' concerns and, in response, have modified the rule in two ways. First, the final rule requires a covered entity to use a qualified translator for translating written content with respect to its health programs and activities. As the Department stated in its LEP Guidance, ''[t]he permanent nature of written translations [ ] . . . imposes additional responsibility on the recipient to take reasonable steps to determine that the quality and accuracy of the translations permit meaningful access by LEP persons.'' [200] We broadened the title of § 92.201(d) to reflect that this paragraph now addresses specific requirements for written translation in addition to oral interpreter services. The text in proposed paragraph (d) addressing specific requirements for oral interpretation is now reflected as paragraph (d)(1); new paragraph (d)(2) addresses the use of qualified translators.

Second, we added a new paragraph (4) to § 92.201(e) to restrict covered entities from relying on staff who do not meet the definition of ''qualified bilingual/multilingual staff'' in § 92.4. In OCR's enforcement experience, covered entities too frequently rely on staff members who possess only a rudimentary familiarity speaking and understanding a non-English language (for example relying on their ''high school'' level of language proficiency) to communicate with individuals with limited English proficiency. This can result in miscommunication and the omission of relevant information, which can in turn result in a lower standard of care and raise questions about whether consent provided by an individual with limited English proficiency was truly informed. Similarly, we have found that qualified bilingual staff members sometimes serve as interpreters even though they do not possess the non-verbal skills of interpreting nor adhere to generally accepted principles of interpreter ethics.

Comment: Some commenters recommended that the final rule not restrict covered entities from relying on friends or family of individuals with limited English proficiency to provide oral interpretation, even when the companion is a minor. These commenters noted that some individuals with limited English proficiency prefer to use their companions to interpret; they also observed that minor children are frequently involved in many aspects of their parents' health care; accordingly, commenters stated that awareness of their parents' health care needs may equip children of individuals with limited English proficiency to act as patient advocates for their parents.

In contrast, numerous commenters supported the proposed rule's standards for oral interpretation and the proposed restrictions on certain persons to interpret or facilitate communication. For instance, one health care provider shared that a high risk hospital was unprepared to provide oral interpretation to a woman in labor. The patient's child had to interpret what her mother was saying but the child did not know the proper terminology to understand the provider's medical questions about a fatal high risk condition.

In addition, many commenters who are limited English proficient shared that some covered entities have required individuals to bring their own interpreters, at a cost to the individual. Others shared that family members and children have served as interpreters for them, which has been insufficient because such family members and children do not have the requisite skills to interpret accurately.

Response: We decline to eliminate the specific requirements in § 92.201(d)-(e) of the proposed rule regarding oral interpretation or the restrictions on certain persons to facilitate communication or interpret. Commenters' recommendations run contrary to HHS's longstanding guidance under Title VI [201] and to OCR's experience and enforcement practices.[202] In many circumstances,

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volume of documents and to assist a qualified translator in improving consistency among translated documents).

[195] *Id.*

[196] Int'l Medical Interpreters Assoc., IMA Guide on Medical Translation, *supra* note 85, at 3.

[197] *Id.* at 3; EM Balk et al., Assessing the Accuracy of Google Translate To Allow Data Extraction From Trials Published in Non-English Languages, (Prepared by the Tufts Evidence-based Practice Center for the Agency for Healthcare Research & Quality, U.S. Dep't of Health & Human Servs.), 12–15, 21- 24, Pub. No. 12(13)–EHC145–EF (2013), *https://www.effectivehealthcare.ahrq.gov/ehc/products/329/1386/Methods_Paper-Google-Translate_1-17-13.pdf.*

[198] This position is consistent with the position on this issue taken by the U.S. Department of Justice and the U.S. Department of Education. *See* U.S. Dep't of Justice & U.S. Dep't of Educ., Dear Colleague Letter: English Learner Students and Limited English Proficient Parents, 38 n.103 (Jan. 7, 2015), *http://www2.ed.gov/about/offices/list/ocr/letters/colleague-el-201501.pdf.*

[199] For considerations on ensuring the quality of translations, see Kleber Palma, Migration Policy Institute, Strategies to Help Covered Entities Ensure Quality of Translations, *http://www.migrationpolicy.org/programs/language-access-translation-and-interpretation-policies-and-practices/practitioners-corner* (last visited Mar. 23, 2016); Jessica Sperling, Migration Policy Institute, Practitioner's Corner: Drafting Request for Proposals and Contracts for Language Assistance Services, *http://www.migrationpolicy.org/programs/language-access-translation-and-interpretation-policies-and-practices/practitioners-corner-drafting* (last visited May 4, 2016).

[200] HHS LEP Guidance, *supra* note 49, 68 FR at 47317.

[201] HHS LEP Guidance, *supra* note 49, 68 FR at 47317–18, 47323.

[202] *See, e.g.,* Voluntary Resolution Agreement between U.S. Dep't of Health & Human Servs., Office for Civil Rights and the Rhode Island Department of Human Services, OCR Transaction No. 0876828, pt. IV.K. (Jan. 19, 2011) *http://www.hhs.gov/sites/default/files/ocr/civilrights/activities/agreements/ridhhsagreement.pdf* (containing restrictions on the use of family members and friends as interpreters).

family members, friends, and especially children, are not competent to provide quality, accurate oral interpretation. For communications of particularly sensitive information, oral interpretation by an individual's family or friend often also implicates issues of appropriateness, confidentiality, privacy, and conflict of interest. Thus, covered entities may not rely on family members, friends, or other informal interpreters to provide language access services unless the situation meets an applicable exception in § 92.201(e)(2)-(3) of the final rule. This exception sufficiently balances an individual's preferences with an interest in ensuring competent language assistance services by allowing individuals to use accompanying adults to interpret in some circumstances.

Comment: One commenter suggested that entities should be exempt from complying with the HIPAA Privacy Rule when providing a qualified interpreter for an individual with limited English proficiency when required under § 92.201(a) of this final rule. Specifically, the commenter was concerned that Section 1557 covered entities would be forced to use or disclose protected health information in violation of the Privacy Rule when engaging interpreter services.

Response: OCR is responsible for enforcing the HIPAA Privacy Rule in addition to the rule implementing Section 1557. We note that, in most instances, a qualified interpreter will be a business associate or a workforce member of the covered entity. If a qualified interpreter is a business associate, a covered entity may disclose protected health information to the qualified interpreter if it obtains satisfactory assurances that the interpreter will use the information only for the purposes for which the interpreter was engaged and will safeguard the information from misuse. Such satisfactory assurances must be in writing and in the form of a contract between the covered entity and the qualified interpreter. If a qualified interpreter is a workforce member of the covered entity, a covered entity may share information with that interpreter as an employee or another type of agent of the entity (*e.g.,* hired through a contract or on the covered entity's staff as a volunteer).

Determining the relationship between the interpreter and the covered entity is a covered entity's HIPAA obligation and is unchanged by Section 1557 or this part. We encourage covered entities to review OCR's HIPAA Frequently Asked Questions (FAQ) regarding business associates at *http://www.hhs.gov/ocr/privacy/hipaa/faq/business_associates/760.html,* and OCR's HIPAA FAQ regarding interpreters at *http://www.hhs.gov/hipaa/for-individuals/faq/528/can-my-health-care-provider-discuss-my-health-information-with-an-interpreter/.*

Comment: A few commenters suggested that the final rule urge covered entities to provide an in-person qualified interpreter for an individual with limited English proficiency as the default type of oral interpretation. These commenters explained that covered entities should rely on remote interpretation via telephone or video only in urgent situations or if an in-person interpreter is unavailable. These commenters reasoned that use of remote interpretation technologies may miss nuances of the communication and result in less accurate or less comprehensible communication. A few commenters recommended that a covered entity's use of remote interpretation services, via phone or video, be limited to administrative matters that can be addressed in 10 minutes or less. Moreover, in response to comments received in 2013 on OCR's Request for Information on Section 1557, some commenters identified concerns with the use of video remote interpretation services because the video connections used often were of a poor quality.

Response: We believe that commenters' recommendations regarding restrictions on remote oral interpretation are unnecessarily prescriptive and inconsistent with the fact-based, contextualized analysis under Title VI and this final rule. However, in situations where visual cues and other messages depend on physical as well as verbal communication, remote interpretation may not be adequate to provide meaningful access to an individual with limited English proficiency.

To address concerns that video remote interpreting technologies may result in less comprehensible communication, we are setting performance standards in § 92.201(f) of this final rule for video remote interpreting services [203] used for oral interpretation for an individual with limited English proficiency. These standards are designed to achieve parity with the regulation in the disability rights context regarding video remote interpreting technologies. Thus, the standards in § 92.201(f)(1)-(4) of the final rule closely parallel the standards on video remote interpreting services in § 92.202 regarding effective communication for individuals with disabilities, which in turn rely on the standards under Title II for the use of sign language interpreters.[204]

Comment: We received a few comments expressing concern about proposed § 92.201(f), re-designated in the final as § 92.201(g), which provides that an individual with limited English proficiency shall not be required to accept language assistance services offered by a covered entity. Some commenters recommended that proposed § 92.201(f) permit a covered entity to require the presence of a qualified interpreter, even if an individual with limited English proficiency has declined language assistance services.

Commenters suggested that when the individual who declines language assistance services is a patient, the health care provider's ability to accurately diagnose medical conditions is undermined. Commenters similarly stated that when the individual who declines language assistance services is a limited English proficient health care decision-maker for a child, that decision-maker would not be able to appropriately consent to, or participate in, a child's treatment plan. These commenters recommended requiring that a covered entity's insistence on a qualified interpreter be made in a non-coercive and culturally-appropriate manner.

Response: OCR interprets proposed § 92.201(f), which this final rule re-designates as § 92.201(g), to allow a covered entity to use a qualified interpreter when it is a reasonable step to provide an individual with limited English proficiency access to the covered entity's health program or activity. Although an individual with limited English proficiency can decline a qualified interpreter for herself, nothing in the rule is intended to bar a

[203] We intend that ''video remote interpreting services'' used for oral interpretation for individuals with limited English proficiency means the same that it does when used to provide interpretation for individuals with disabilities as defined by reference in § 92.4 of this final rule: ''an interpreting service that uses video conference technology over dedicated lines or wireless technology offering high-speed, wide-bandwidth video connection that delivers high-quality video images as provided in [28 CFR] 35.160(d).'' *See infra* § 92.4 (defining ''auxiliary aids and services'' to include ''video remote interpreting services,'' as defined in Title II of the ADA, 28 CFR 35.104).

[204] 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, paragraph (f)(2) of § 92.201 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.

provider from using a qualified interpreter to assist the provider in communicating with, and assuring appropriate treatment to, the individual.[205] As a result, OCR does not intend for § 92.201(g) of the final rule to restrict a covered entity from using a qualified interpreter in either of the situations commenters raised. We also remind covered entities that, as we stated in the proposed rule, they may not discourage individuals with limited English proficiency from accepting language assistance services.

Comment: Some commenters proposed that OCR regulate the data sources to which covered entities may refer to assess the prevalence of languages spoken by individuals with limited English proficiency in their respective service areas. Commenters also recommended that OCR provide covered entities with resources, such as data-driven maps of languages spoken by limited English proficient populations in their respective service areas, to facilitate covered entities' assessments.

Response: We decline to accept commenters' suggestions, but we support covered entities' efforts to assess the language needs of their respective service areas. An assessment is a foundational best practice for a language assistance services program.[206] Data sources that may be useful include data from the United States Census Bureau, particularly the American Community Survey; utilization data from the covered entity's files for individuals with limited English proficiency; data from State and local governments; school system data; data from community agencies and organizations; and data from refugee or immigrant serving agencies.[207] Covered entities, however, are in the best position to determine what local or regional data sources are best suited to their needs. When using any data source, covered entities should look at the reliability, stability, and currency of the data to understand its strengths and weaknesses.

Comment: Many commenters provided feedback on OCR's request for comments on whether the final rule should set thresholds for the non-English languages in which covered entities must provide a range of language assistance services. The majority of comments on this issue focused on thresholds for the translation of vital documents.

Commenters supporting thresholds for written translation suggested that this policy improves access for individuals with limited English proficiency; streamlines OCR's compliance determinations; eliminates ambiguity by providing clear, quantifiable standards for covered entities; is consistent with other Departmental regulations specifying thresholds for written translation; and mitigates the risk that covered entities forgo written translation entirely.

Commenters recommended a variety of thresholds, such as those requiring translation based on the number of languages, percentage of language speakers, or the number of language speakers in a covered entity's service area, or composite thresholds mixing and matching these approaches. Some commenters simply stated that vital documents should be translated into the most commonly encountered languages in a covered entity's service area. Others suggested that OCR codify the threshold for translation of vital documents that is articulated as a safe harbor in the HHS LEP Guidance: translation into languages spoken by at least 1,000 persons or at least 5% of those present in the service area.[208] Other commenters asserted that numeric thresholds for translation are too rigid to be applied universally, and recommended that the final rule focus on translating materials for certain health programs, such as clinical research or health insurance programs.

Response: Although we have extensively considered whether to include thresholds for written translation and/or oral interpretation as either a safe harbor or as an across-the-board minimum requirement, we decline to set such thresholds in the final rule. First, although thresholds may improve access for some national origin populations, the approach does not comprehensively effectuate Section 1557's prohibition of national origin discrimination. Setting thresholds would be both under-inclusive and over-inclusive, given the diverse range, type, and sizes of entities covered by Section 1557 and the diverse national origin populations within the service areas of entities' respective health programs and activities.

For instance, a threshold requiring all covered entities, regardless of type or size, to provide language assistance services in languages spoken by 5% of a county's limited English proficient population could result in the provision of language assistance services in more languages than the entity would otherwise be required to provide under its obligation in § 92.201(a). This threshold would apply regardless of the number of individuals with limited English proficiency who are eligible to be served or likely to be encountered by the covered entity's health program or activity and regardless of the covered entity's operational capacity. Similarly, this threshold could leave behind significant numbers of individuals with limited English proficiency, served by a covered entity's health program or activity, who communicate in a language that constitutes less than 5% of the county's limited English proficient population.

Although some Departmental regulations set thresholds, those regulations address entities or health programs of similar sizes and types, such as qualified health plan issuers, Marketplaces, Medicare Advantage, and Medicare Part D. In comparison, Section 1557 and this part regulate more diverse types of covered entities with potentially more diverse limited English proficient populations. We are concerned that significant limited English proficient populations might receive no or inadequate language assistance services under a threshold-based regulation. We are also concerned about the burden an across-the-board translation threshold might place on small covered entities.

Moreover, we value the flexibility inherent in the contextualized approach we have chosen to assess compliance with the requirement to take reasonable steps to provide meaningful access. We thus decline to impose the prescriptive standards recommended by the commenters as inconsistent with this customized regulatory approach.

Comment: We received many comments in response to whether the rule should require enhanced language access obligations for some types of

[205] This understanding is consistent with the HHS LEP Guidance, *supra* note 49, 65 FR at 47318 (stating that even if an individual with limited English proficiency declines a qualified interpreter, where precise, complete, and accurate information is critical, or where the competency of the preferred interpreter that the individual desires to use is not established, "a recipient may want to consider providing its own, independent interpreter, even if the LEP person wants to use his or her own interpreter as well.").

[206] *See* HHS LEP Guidance, *supra* note 49, 68 FR at 47314, 47320.

[207] *See* Voluntary Resolution Agreement between U.S. Dep't of Health & Human Servs., Office for Civil Rights and Memorial Health System, OCR Transaction No. 08–79513, pt. V.B.1.b, *http://www.hhs.gov/sites/default/files/ocr/civilrights/activities/agreements/mhs_vra.pdf* (last visited Mar. 11, 2016) (listing data sources for an assessment of language needs).

[208] The safe harbor further provides that if a language group with fewer than 50 individuals constitutes 5% of the recipient's service area, the recipient is not obligated to translate written materials but must provide written notice in the primary language of that language group of the right to receive oral interpretation, at no cost to the individual. HHS LEP Guidance, *supra* note 49, 68 FR at 47319.

covered entities and if so, what types of entities should be subject to enhanced obligations. Some commenters suggested that enhanced obligations would be appropriate for certain covered entities that offer particularly significant or large health programs or activities, such as the Department, State agencies administering Medicaid or CHIP, Marketplaces, and qualified health plan issuers. These commenters asserted that these covered entities possess both the resources and the means to meet enhanced obligations and that they can leverage economies of scale. The commenters also asserted that imposing enhanced obligations on these entities would benefit smaller entities by making translated documents more widely available.

Commenters also addressed the scope of enhanced language access obligations, suggesting that such obligations should include requiring oral interpretation in at least 150 languages and the translation of documents into languages spoken by individuals with limited English proficiency when such individuals constitute 5% of, or 500 people in, the State population or the covered entity's service area.

A few commenters opposed enhanced language access obligations for certain types of covered entities. Specifically, one commenter asserted that there was no principled reason for retail pharmacies, which the proposed rule listed as an example of a covered entity that could have enhanced obligations under § 92.201,[209] to be subject to enhanced language access obligations.

Response: We reiterate our view that the contextualized approach in § 92.201 best considers both the needs of individuals with limited English proficiency and the potential burden on covered entities. Creating uniform, across-the-board requirements for particular categories of covered entities is, like thresholds, both under-inclusive and over-inclusive. For example, some smaller entities may operate in areas with significant concentrations of individuals with limited English proficiency; these entities may need to provide a broader scope of language assistance services to meet the requirements of § 92.201 than do other entities of similar size in less diverse areas. Similarly, State agencies that administer Medicaid and CHIP programs will differ with respect to the size and diversity of the limited English proficient populations they serve and the resources available to them.

Comment: Some commenters asserted that HHS, other Federal Departments, and States already heavily regulate health insurance issuers covered by Section 1557, thus subjecting them to multiple language access regulations at the State and Federal level. These commenters recommended two policy approaches to streamline Federal and State language access requirements: (1) Harmonize nondiscrimination rules across all Federal and HHS programs to create a national standard; and/or (2) permit a deeming approach that allows compliance with Federal or State language access laws to suffice for compliance with Section 1557, and similarly allow compliance with Section 1557 to suffice for compliance with other Departmental regulations addressing language access. In contrast, numerous commenters supported our fact-specific, contextualized approach and urged consideration of additional factors (*see* discussion *supra*) that would require the more robust provision of language assistance services.

Response: The Department understands the potential for confusion and burden that can be imposed where entities are subject to multiple sets of overlapping requirements. For this reason, we have harmonized, to the extent possible, the tagline requirement in § 92.8(d)(1) with the tagline requirement applying to Marketplaces and qualified health plan issuers under 45 CFR 155.205(c)(2)(iii)(A).[210] We will continue to coordinate as appropriate within HHS and with other Federal departments to ensure that the application and enforcement of requirements under Section 1557 is consistent with other provisions of Federal law or regulations.

However, we decline to adopt an approach that otherwise automatically harmonizes nondiscrimination rules or deems compliance with other laws sufficient for compliance with Section 1557. As we noted above in the discussion of deeming in the General Comments, it is common for entities to be subject to multiple State and Federal regulations, even when some of those regulations have been adopted by a single Federal agency. Indeed, even under CMS regulations for instance, Health Insurance Marketplaces,[211] State agencies administering Medicaid and CHIP programs,[212] and qualified health plan issuers,[213] are subject to multiple differing requirements with regard to language assistance services.

With specific regard to language assistance services, there are likely numerous situations in which a qualified health plan issuer's compliance with the meaningful access provisions of 45 CFR 155.205(c) would suffice to meet the requirements of Section 1557; indeed, there are instances in which 45 CFR 155.205(c) (*e.g.,* requiring that Marketplaces and qualified health plan issuers provide

[209] *See* 80 FR at 54185.

[210] Qualified health plan issuers are also bound by the tagline requirement in market-wide regulations at 45 CFR 147.136(e) (effective Jan. 19, 2016) described in the preamble to § 92.8, *supra* note 107.

[211] Health Insurance Marketplaces have language access obligations under laws independent of Federal civil rights laws requiring the following to be accessible to individuals with limited English proficiency: a Marketplace's toll-free call center, *see* 45 CFR 155.205(a); a Marketplace's Web site, *see id.* 155.205(b); applications, forms, and notices required to be sent by a Marketplace℠; *see id.* 155.230(b); and a Marketplace's consumer assistance functions, including a Marketplace's outreach and education activities and a Marketplace's Navigator program authorized by 42 U.S.C. 18031(i) and regulated at 45 CFR 155.210, *see id.* 155.205(d) and (e). In making information accessible to individuals with limited English proficiency, Marketplaces must do so through a combination of written translation, oral interpretation, posting of taglines, and translation of certain Web site content. *See* 45 CFR 155.205(c)(2)(i)(A) (oral interpretation), (ii) (written translation), (iii)(A) (taglines), (iv)(A) (translation of certain Web site content). With respect to a Marketplace's Navigator program, Navigators are required to provide information in a manner that is culturally and linguistically appropriate to the needs of the population being served by the Marketplace℠, including individuals with LEP. *See* 42 U.S.C. 18031(i)(3)(E) (statutory requirement); 45 CFR 155.210(e)(5) (regulatory requirement).

[212] State agencies administering Medicaid programs and CHIP have language access obligations under laws independent of Federal civil rights laws. *See, e.g.,* 42 CFR 435.905(a)–(b)(1) (requiring State agencies administering Medicaid programs to provide language assistance services for applicants and beneficiaries who are limited English proficient); 457.340(a) (requiring State agencies administering CHIP to comply with certain regulatory requirements applicable to Medicaid, including 435.905(a)–(b)(1), which requires that program information be accessible to individuals with LEP); 435.1200(f)(2) (requiring States to make their Medicaid Web sites accessible to individuals with limited English proficiency); 438.10(c)(1)–(5) (specifying obligations for States delivering benefits and services through Medicaid managed care plans, including managed care organizations and certain plans themselves, to make written information available in certain non-English languages, to provide oral interpretation, and to notify individuals with limited English proficiency of the availability of language assistance).

[213] *See, e.g.,* 42 U.S.C. 18031(e)(3)(B) (requiring health plans seeking certification as qualified health plans to provide certain information, including claims payment and rating practices, cost-sharing, and enrollee and participant rights in plain language, which means language that the intended audience, including individuals with limited English proficiency, can readily use and understand); 45 CFR 155.205(c)(2)(i)(A), (ii), (iii)(A), (iv)(B) (requiring telephonic interpreter services, written translation, taglines, and translations of certain Web site content, respectively, for information provided to individuals with limited English proficiency); 156.250 (requiring meaningful access to certain qualified health plan information in accordance with the standards described in 155.205(c)).

telephonic oral interpretation in 150 languages[214]) might require more than would be required in a particular case under the fact-based analysis we adopt for Section 1557. However, we are concerned that there may be cases in which using CMS regulations alone to define a covered health insurance issuer's obligations could leave significant numbers of individuals with limited English proficiency without any, or adequate, access to language services.

In addition, automatically harmonizing requirements imposed on particular entities regulated by both Section 1557 and other laws that the Department enforces would undermine an equally important form of consistency: consistency in enforcement of the standards of Section 1557 and this part across all of the diverse categories of entities covered under the law.

For these reasons and the reasons discussed in the General Comments *supra,* we decline to adopt an approach that automatically deems compliance with CMS or other Federal regulations to be sufficient to demonstrate compliance with Section 1557. However, in circumstances where qualified health plan issuers' compliance with § 92.201 requires steps in addition to those required for compliance with 45 CFR 147.136 or 155.205, OCR will work with qualified health plan issuers to bring them into compliance with § 92.201. In addition, OCR will consider a qualified health plan issuer's compliance with other applicable regulations in determining the appropriate enforcement action.

Summary of Regulatory Changes

For the reasons set forth in the proposed rule and considering the comments received, we are finalizing the provisions in § 92.201 with several modifications.

In § 92.201(a), we replaced the phrase ''that it serves or encounters'' with ''eligible to be served or likely to be encountered.''

In § 92.201(b), we implemented a technical revision in paragraph (b)(1) and we modified paragraph (b)(2). With respect to the technical revision in paragraph (b)(1), we modified this proposed phrase: ''the nature and importance of the health program or activity, including the particular communication at issue, to the individual with limited English proficiency'' by replacing ''including'' with the conjunction ''and.'' This technical revision clarifies OCR's intent that the particular communication at issue will routinely be a component of the Director's evaluation when the Director gives substantial weight to the nature and importance of the health program or activity. In addition, we modified § 92.201(b)(2) to state that the Director, in evaluating compliance, will take into account all relevant factors, which includes whether a covered entity has developed and implemented an effective written language access plan, appropriate to its circumstances. We eliminated paragraphs (i) through (v) of § 92.201(b)(2).

In § 92.201(d), we broadened the title to reflect that this paragraph now addresses specific requirements for written translation in addition to oral interpretation services. The text in proposed paragraph (d) addressing specific requirements for oral interpretation is now reflected under a new paragraph (d)(1). We added paragraph (d)(2) to require covered entities to use a qualified translator when translating written content in paper or electronic form for its health programs or activities.

In § 92.201(e)(2)(i) and (e)(3), we added ''for the individual with limited English proficiency'' after ''qualified interpreter'' to conform to the revision of this term as defined in § 92.4 of the final rule. In addition, we added a new paragraph (e)(4) to address restrictions on a covered entity's use of staff other than qualified bilingual/multilingual staff to communicate directly with individuals with limited English proficiency, in their primary languages.

We re-designated paragraph (f) of § 92.201 in the proposed rule as paragraph (g) of § 92.201 in this final rule, and we added a new paragraph (f). New paragraph (f) provides that when a covered entity uses video remote interpreting services as the means to provide an individual with limited English proficiency oral language assistance, the video remote interpreting technology must meet the standards listed in § 92.201(f)(1)–(4) of this final rule.

Effective Communication for Individuals With Disabilities (§ 92.202)

In § 92.202 of the proposed rule, we proposed to incorporate the provisions governing effective communication with individuals with disabilities found in the regulation implementing Title II of the ADA, which applies to State and local government entities and requires covered entities to ensure that communications with individuals with disabilities are as effective as they are with individuals without disabilities. We noted that OCR typically looks to the ADA for guidance in interpreting Section 504 as the two laws contain very similar standards.

In the proposed rule, OCR considered whether to incorporate the standards in the regulation implementing Title II of the ADA or in the regulation implementing Title III of the ADA, or the standards in both regulations. Standards regarding effective communication under both regulations are very similar. We noted that there are, however, limited differences between the Title II and Title III regulations, regarding limitations on the duty to provide a particular aid or service where doing so may impose undue financial and administrative burdens, and the obligation under the Title II regulation to give primary consideration to the choice of an aid or service requested by the individual with a disability.

OCR proposed to apply the Title II standards to all entities covered under the proposed rule. We noted that although OCR could apply Title II standards to States and local government entities and Title III standards to private entities, we believe it is appropriate to hold all recipients of Federal financial assistance from HHS to the higher Title II standards as a condition of their receipt of that assistance. We also noted that it is appropriate to hold HHS itself to the same standards to which the Department subjects the recipients of its financial assistance.

We also proposed that where the regulatory provisions referenced in § 92.202 use the term ''public entity,'' that term shall be replaced with ''covered entity.''

The comments and our responses regarding § 92.202 are set forth below.

Comment: A few commenters suggested that HHS urge covered entities to consider the gender preferences of patients for interpreters. These commenters suggested that patients may not be comfortable with interpreters of the opposite gender, particularly in settings that involve nudity such as in an obstetrics and gynecology appointment.

Response: We recognize the commenters' privacy concern, but we decline to accept the commenters' suggestion. We believe that identification with a certain gender specified by the patient is not a characteristic necessary to interpret for an individual with a disability or an individual with limited English proficiency. The definitions of qualified interpreter for an individual with a disability and qualified interpreter for an individual with limited English proficiency set forth in § 92.4 require an

[214] *See* 45 CFR 155.205(c)(2)(i)(A).

interpreter who adheres to generally accepted interpreter ethics, which would include respecting a patient's privacy and comporting oneself with discretion and professionalism in sensitive situations such as the settings described by the commenters. We believe that an interpreter of any gender can display these qualities and thus adequately perform the interpretation duties required of him or her. In those cases where an interpreter is unable to provide interpretation consistent with these standards, the interpreter would be unqualified for those reasons. In addition, acceding to the commenter's request could result in gender discrimination, which contravenes the purpose of other provisions of this rule.

Comment: A few commenters suggested that OCR apply cultural competency standards, such as the National Standards for Culturally and Linguistically Appropriate Services in Health and Health Care (CLAS), to entities serving people with disabilities.

Response: Although OCR does not codify the CLAS standards as part of this regulation, OCR agrees that the CLAS standards provide valuable guidance to covered entities regarding the provision of services that are responsive to diverse cultural beliefs and practices, preferred languages, health literacy and other communication needs, and that promote compliance with the final rule. OCR encourages adoption of the CLAS standards by covered entities for interactions with all their patients and not simply for those with disabilities.

Comment: Some commenters suggested that OCR strengthen effective communication regulations by including the proposed provision regarding the restricted use of certain persons to interpret or facilitate communication contained in § 92.201(e) for individuals with limited English proficiency in § 92.202 for individuals with disabilities.

Response: We appreciate the commenters' suggestion, and note that § 92.202 incorporates provisions of the ADA regarding the restricted use of certain persons to interpret or facilitate communication; it is comparable to the provision in the final rule regarding restrictions on the use of certain persons to interpret or facilitate communication with individuals with limited English proficiency.

Summary of Regulatory Changes

For the reasons set forth in the proposed rule and considering the comments received, including comments regarding the auxiliary aids and services requirement in § 92.101(b)(2)(i) (discussed above), we are finalizing the provisions proposed in § 92.202 by re-designating the existing regulation text at § 92.202 as § 92.202(a), and adding a new subsection, § 92.202(b) requiring covered entities—regardless of the number of people they employ—to provide appropriate auxiliary aids and services to persons with impaired sensory, manual, or speaking skills, where necessary to afford such persons an equal opportunity to benefit from the service in question.

Accessibility Standards for Buildings and Facilities (§ 92.203)

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. In § 92.203 of the proposed rule, we proposed to establish specific accessibility standards for new construction and alterations. We noted that these standards are consistent with existing standards under the ADA.

Under paragraph (a), we proposed that 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-based Marketplace℠ shall comply with the 2010 ADA Standards for Accessible Design (2010 Standards), as defined in the ADA Title II regulations,[215] if construction or alteration was commenced on or after January 18, 2018. We proposed that all newly constructed or altered buildings or facilities subject to this section shall comply with the requirements for a ''public building or facility'' as defined in Section 106.5 of the 2010 Standards.

We also proposed that new construction and alterations of such facilities would also be subject to the new construction standards found in the Section 504 implementing regulation at 45 CFR 84.23(a) and (b).

Under paragraph (b), we proposed that 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-based Marketplace℠ before January 18, 2018 in conformance with UFAS, the 1991 ADA Standards for Accessible Design (1991 Standards), or the 2010 Standards be deemed to comply with the requirements of this section and with 45 CFR 84.23 (a) and (b), cross referenced in § 92.101(b)(2)(i) with respect to those facilities. Thus, we proposed that if the construction or alteration of facilities began prior to the effective date of paragraph (a) of this section, the facilities be deemed in compliance if they were constructed or altered in conformance with applicable standards at the time of their construction or alteration.

In paragraph (c), we proposed that each building or part of a building that is constructed or altered by or on behalf of, or for the use of, the Department must be designed, constructed, or altered so as to be readily accessible to and usable by individuals with disabilities. We proposed that the definitions, requirements, and standards of the Architectural Barriers Act, as established in Appendices C and D to 36 CFR pt 1191, apply to buildings and facilities covered by this section.

OCR considered adding specific language regarding accessibility standards for medical diagnostic equipment. However, we noted that the United States Access Board is currently developing standards for accessible medical diagnostic equipment and, therefore, we are deferring proposing specific accessibility standards for medical equipment. We further noted that a health program or activity's use of medical diagnostic equipment would be covered by Section 1557 under the general prohibition of discrimination on the basis of disability in § 92.101.

The comments and our responses regarding § 92.203 are set forth below.

Comment: Numerous comments supported requiring immediate compliance with the 2010 ADA Standards for new construction and alterations. Commenters urged that OCR not give covered entities an 18-month grace period for compliance because the 2010 Standards already apply to the vast majority of facilities covered by this proposed rule. They maintained that an approach which emphasizes the uniform application of the 2010 Standards upon publication of the 1557 rule will enable greater consistency among implementing agencies, given the overlapping jurisdiction that OCR has with the Department of Justice.

Response: OCR agrees with the comments in part. Because the great majority of entities covered by the final rule are already subject to the 2010 Standards, the regulation has been revised to require covered entities that were covered by the 2010 Standards prior to the effective date of this final rule to comply with the 2010 Standards for new construction or alterations that commence on or after the effective date of the final rule. However, there may be some entities covered by the final rule that were not covered by the 2010 Standards prior to the effective date of the final rule. For those entities,

[215] 28 CFR 35.104.

application of the 2010 Standards would be new; thus, these entities are given 18 months to comply with the final rule with respect to new construction and alterations. We anticipate that these changes will have only a de minimis impact on cost as nearly all of the entities affected are already subject to the 2010 Standards.

Comment: Numerous commenters recommended that OCR not deem compliance with the UFAS as compliance with Section 1557 for facilities that were constructed or altered prior to 18 months after publication of the final rule. They stated that the UFAS is functionally deficient for people with disabilities; barriers are permitted under the old standard that negatively affect people with mobility and strength disabilities; and, as recognized in the preamble to the proposed rule, nearly all of the facilities covered under the proposed rule are already subject to the 2010 Standards.

Response: OCR appreciates the concern raised by the commenters and agrees with the reasoning underlying the recommendation. OCR has thus modified the language in § 92.203(b) to state that 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-based Marketplace[SM] in conformance with the 1991 Standards or the 2010 Standards is deemed to comply with the requirements of the final rule with respect to those facilities, if the construction or alteration was commenced before the effective date of the final rule. Conformance with the UFAS will constitute compliance with the requirements of the final rule only with respect to facilities where construction or alteration was commenced before the effective date of the final rule and only where the facility or part of the facility was not covered by the 1991 Standards or 2010 Standards.

Comment: One commenter recommended that OCR limit the facility accessibility requirements to areas of facilities that actually host consumers (patients of providers, in-person enrollees, etc.) and not apply them to covered entities' facilities more generally. The commenter observed that the ADA standards apply to places of public accommodation, and that if a facility is not public–facing, existing ADA requirements for employees already apply and do not need to be incorporated into this rule. The commenter believed that limiting these requirements to public-facing areas of entities would address consumer needs without creating undue financial and administrative burdens. As an example, the commenter stated that many issuers operate call centers that do not provide face-to-face services to their consumers; therefore, the commenter asserted, it is unclear why the call center would need to comply with physical facility accessibility standards.

Response: OCR notes that applying the building accessibility requirement to facilities or parts of facilities not used in any manner by customers or other program beneficiaries in most cases would be inconsistent with the limited application of the final rule to employment and employees. Thus, this provision is interpreted in light of the limitations on coverage of employment in § 92.101(a) (2); as such, the building accessibility requirement does not apply to facilities or parts of facilities that are visited only by employees of the covered entity except as provided in § 92.208. We believe that this approach is consistent with the ACA's goal of increasing consumer access to health care services and with Section 1557's focus on discrimination against patients, enrollees and other beneficiaries in health programs and activities.

However, we also note that the ADA applies to employment and, in addition, that 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. Complaints of discrimination related to program accessibility can be brought by employees under the ADA and Section 504, and entities should ensure that they are in compliance with accessibility requirements, including the 2010 Standards, under the ADA.

Comment: Several commenters recommended that OCR require covered entities to make each of their existing facilities accessible to and usable by persons with disabilities. These commenters were concerned that if the accessibility requirement is not applied to each individual facility, then a large for-profit insurance carrier could decide that, among the great majority of its providers who operate in existing facilities, only a small percentage need to be physically accessible or have accessible equipment. Moreover, commenters expressed concern that those accessible providers could be clustered together in some central location, and whenever a member called member services and mentioned the need for accessibility, that member would be actively directed toward the more limited subset of accessible provider offices.

Response: The change urged by the commenter would constitute a new requirement that is inconsistent with existing standards under Title II of the ADA and Section 504, neither of which has been interpreted to require each existing facility to be accessible; rather, they require that the recipient operate each program or activity so that, when viewed in its entirety, it is readily accessible to individuals with disabilities.[216] Thus, we decline to accept the recommendation. We do note that issuers covered by this rule are responsible for ensuring that their health programs provide equal access to individuals without discrimination on the basis of disability. OCR also notes that most providers are recipients of Federal financial assistance from HHS and are themselves independently subject to the nondiscrimination requirements, including program accessibility requirements, in the final rule as well as under Title III of the ADA.

Comment: Some commenters urged that the requirement to comply with accessibility standards be primarily placed on the owners of buildings and facilities, rather than on the providers who rent space. One commenter said that OCR should provide resources and training to small business renters so that they understand what terms in their leases are necessary to ensure that landlords take reasonable responsibility for ensuring their facilities comply with Section 1557.

Response: OCR declines to accept the recommendation to place primary responsibility for compliance with accessibility standards on building owners. Under longstanding legal interpretations of the ADA and Section 504, building owners and lessees each have obligations to refrain from discriminating with respect to program access. OCR also is declining to develop resources and training specifically for small business renters, but notes that the Department of Justice has materials on compliance with accessibility standards under the ADA that may be of use to these entities.[217] In addition, the ADA National Network in HHS supports ten regional centers that provide information, guidance and training on the ADA through services tailored to meet the needs of business, government and individuals at local, regional and

[216] *See* 28 CFR 35.150(a); 45 CFR 84.22(a); *Bird.* v. *Lewis and Clark Coll,* 303 F.3d 1015, 1021 (9th Cir. 2002), *cert. denied,* 538 U.S. 923 (2003) (''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'').

[217] *See* U.S. Dep't of Justice, ADA Title III Technical Assistance Manual Covering Public Accommodations and Commercial Facilities (1993), § III–1.2000, *http://www.ada.gov/taman3.html.*

national levels.[218] OCR also will develop and make available, before the effective date of the final rule, training materials that cover requirements related to accessibility for individuals with disabilities.

Comment: Some commenters urged OCR to exempt entities that are places of public accommodation under Title III of the ADA from the requirements for physical accessibility under Section 1557, stating that additional requirements are confusing and burdensome for small providers. Another commenter recommended that if a health program or activity would not, under Title III of the ADA, be required to be in compliance with a given standard under the 2010 Standards, then the health program or activity should also be exempt from that standard for the purposes of Section 1557 enforcement.

Response: While entities subject to Title III of the ADA include both entities that receive Federal financial assistance and those that do not, the final rule applies only to entities that receive Federal financial assistance, as well as the Department and entities established under Title I of the ACA. We believe it is reasonable to hold entities that receive Federal financial assistance to the accessibility requirements under the final rule, regardless of the standards to which they might be subject under Title III.

Comment: Some commenters said that OCR should require covered entities to make publicly available information on whether medical diagnostic equipment is accessible, so that individuals with disabilities can make informed decisions when choosing a health care provider. A number of commenters recommended that new accessibility standards should be applicable only when physicians upgrade or replace their existing equipment.

Response: As the preamble to the proposed rule noted, standards for accessible medical equipment are in development by the Access Board; thus, OCR is not requiring compliance with specific accessibility standards at this time. In the absence of such standards, covered entities are not in a position to advise or publicize whether their equipment complies with particular standards. Nonetheless, we noted and reiterate here that general accessibility standards that apply to health programs and activities apply to medical equipment, and health service providers must ensure that their health programs and activities offered through the use of medical equipment are accessible to individuals with disabilities.

Summary of Regulatory Changes

For the reasons set forth above and considering the comments received, we have revised § 92.203(a) to state that each covered facility must comply with the 2010 Standards, if the construction or alteration was commenced on or after the effective date of the final rule, except that if a covered facility was not covered by the 2010 Standards prior to the effective date of the final rule, it must comply with the 2010 Standards if the construction was commenced after 18 months after the effective date of the final rule.

For the reasons set forth above and considering the comments received, we have also modified the language in § 92.203(b) to state that each covered facility constructed or altered in conformance with the 1991 Standards or the 2010 Standards will be deemed to comply with the requirements of this section and with 45 CFR 84.23(a) and (b), cross-referenced in § 92.101(b)(2)(i) with respect to those facilities, if the construction or alteration was commenced before the effective date of the final rule. Further, each covered facility that was constructed or altered in conformance with UFAS will be deemed to comply with the requirements of this section and with 45 CFR 84.23(a) and (b), cross-referenced in § 92.101(b)(2)(i) with respect to those facilities, if the construction was commenced before the effective date of the final rule and the facility was not covered by the 1991 Standards or 2010 Standards.

Accessibility of Electronic and Information Technology (§ 92.204)

In § 92.204(a), we proposed to require covered entities to ensure that their health programs or activities provided through electronic and information technology 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 an entity's health program or activity.[219] For example, we stated that a Health Insurance Marketplace[SM] creating a Web site for application for health insurance coverage must ensure that individuals with disabilities have an equal opportunity to benefit from the Web site's tool that allows comparison of health insurance coverage options, quick determination of eligibility, and facilitation of timely access to health insurance coverage by making its new Web site accessible to individuals who are blind or who have low vision.

We noted that this provision is consistent with existing standards applicable to covered entities. Specifically, Section 508 of the Rehabilitation Act requires that electronic and information technology developed, procured, maintained, or used by Federal agencies be accessible for individuals with disabilities. Section 508 applies to HHS administered health programs or activities, including the Federally-facilitated Marketplaces. Section 504, which applies to recipients of Federal financial assistance, including issuers that receive Federal financial assistance, and Titles II and III of the ADA, which apply to State and local government entities and places of public accommodation, respectively, similarly have been interpreted to require that covered entities' programs, services, and benefits provided through electronic and information technology be accessible to individuals with disabilities.[220] In addition, some States have adopted Section 508 or Web Content Accessibility Guidelines (WCAG) standards for State agency Web sites or electronic and information technology more broadly.

In paragraph (b), we proposed to require State-based Marketplaces and recipients of Federal financial assistance to ensure that their health programs and activities provided through Web sites comply with the accessibility requirements of Title II of the ADA. We noted that our proposed regulatory text cross-references the Title II regulations as a whole, therefore incorporating any future changes to the Title II regulations. We also noted that these requirements are informed by the Department's extensive experience with web-based technology through Federal grant-making programs, including programs that provide funds for State infrastructure changes to allow electronic applications for coverage through the Medicaid program and the Health Insurance Marketplaces, provider adoption of electronic health records, and the development of web-based curricula for health care professionals.

In the proposed rule, we explained that based on the Department's prior experience in this field, we believe that

[218] For more information or to contact your regional center, please see *https://adata.org/* and *https://adata.org/national-network.*

[219] The terms ''undue financial and administrative burdens'' and ''fundamental alteration'' as used in this part have the same meaning that they have under the ADA.

[220] *See, e.g.,* discussion of case law in U.S. Dep't of Justice, Accessibility of Web Information and Services of State and Local Government Entities and Public Accommodations (Advanced Notice of Proposed Rulemaking), 75 FR 43460, 43463-(Jul. 26, 2010).

including an explicit, rather than implicit, requirement for electronic and information technology is necessary to clarify the obligations of covered entities to make this technology accessible. In addition, we noted that absent an explicit requirement for accessible electronic and information technology, people with disabilities might not have opportunities to participate in services, programs, and activities that are equal to and as effective as those provided to others, further exacerbating existing health disparities for persons with disabilities.

Given the existing requirements under Section 504, Section 508, and the ADA applicable to information provided through electronic and information technology as a whole, and given the importance of technologies, such as kiosks and applications, to access to health care, health-related insurance and other health-related coverage, we proposed to include an explicit accessibility requirement that applies to all of a covered entity's electronic and information technology, rather than to web access only. We sought comment on this proposal.

We also proposed a general accessibility performance standard for electronic and information technology, rather than a requirement for conformance to a specific set of accessibility standards. We provided that the application of this general accessibility performance standard would be informed by future rulemaking by the Access Board and the Department of Justice. We sought comment on whether the regulation should impose a general accessibility performance standard for electronic and information technology or require that electronic and information technology comply with standards developed pursuant to Section 508 by the Access Board,[221] or the Worldwide Web Consortium's Web Accessibility Initiative's WCAG 2.0 AA.

As noted above, we proposed that covered entities would have a defense to making their health programs and activities provided through electronic and information technology accessible if doing so would impose undue financial and administrative burdens or would result in a fundamental alteration in the nature of the health program or activity. In determining whether an action would impose such undue burdens, we proposed that a covered entity must consider all resources available for use in the funding or operation of the health program or activity.

We noted that when undue financial and administrative burdens or a fundamental alteration are determined to exist, the covered entity is still required to provide information in a format other than an accessible electronic format that would not result in such undue financial and administrative burdens or a fundamental alteration, but would ensure, to the maximum extent possible, that individuals with disabilities receive the benefits or services of the health program or activity that are provided through electronic and information technology.

The comments and our responses regarding § 92.204 are set forth below.

Comment: A few commenters objected to § 92.204's focus on individuals with disabilities. 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 OCR state in § 92.204 that covered entities must ensure that their health programs or activities provided through electronic information and technology are accessible to individuals in all protected classes, not just individuals with disabilities.

Response: Section 92.204 addresses the unique accessibility issues for individuals with disabilities. However, § 92.204's focus on disability does not limit the application of general nondiscrimination principles to the accessibility of health programs and activities offered through electronic and information technology to other groups. Thus, the general prohibition of discrimination set forth in § 92.101(a) requires the accessibility of health programs and activities offered through electronic and information technology, without discrimination on the basis of race, color, national origin, sex, age, or disability.

Comment: One commenter expressed concern that many patients and clients lack internet connectivity in their homes and communities. This commenter stated that while providers should design web-based tools and resources that are user-friendly, appropriate, and effective for patients and clients with disabilities, the providers will need to use alternative creative means to meet the needs of those they serve who lack such connectivity in their homes or communities.

Response: OCR recognizes that many persons lack internet connectivity in their homes and communities and may therefore be unable to access web-based tools and resources provided by covered entities, and encourages entities to develop creative means to meet the needs of these individuals.

Comment: Several commenters asked that OCR clarify the scope of the electronic and information technology requirements. Specifically, these commenters asked OCR whether § 92.204's requirements are limited to the provision of health services.

Response: Section 92.204's requirements are coextensive with, and bounded by, the coverage of Section 1557. Thus, the rule requires covered entities to make all health programs and activities provided through electronic and information technology accessible. Accordingly, this requirement reaches activities such as an online appointment system, electronic billing, and comparison of health plans offered by a Health Insurance Marketplace SM. OCR believes that the regulatory text encompasses this approach.

Comment: A few commenters asked OCR to clarify whether the general requirement under subsection (a) to make health programs and activities that are provided through electronic and information technology accessible applies only to health programs or activities provided through electronic and information technology that are accessed by consumers or also to a covered entity's internal facing electronic information technology. Other commenters urged OCR to limit the application of the general requirement under subsection (a) only to health programs or activities provided through electronic and information technology that are directly related to the activity that made the organization a covered entity and that are accessed by consumers. Conversely, several other commenters recommended that OCR extend the application of subsection (a) to employees of covered entities.

Response: OCR addressed a similar issue in considering facility access requirements above. There, OCR noted that extending the facility accessibility requirement to facilities not used in any manner by customers or other program beneficiaries in most cases would be inconsistent with the limited application of the final rule to employment and employees. Thus, we noted that the facility accessibility requirement is interpreted in light of the limitations on coverage of employment in § 92.101(a)(2).

Similarly, in considering the application of the requirement in the final rule to accessibility of health programs and activities offered through electronic and information technology,

[221] 36 CFR pt. 1194.

we are mindful that the final rule has limited application to employment and employees. In consideration of this limitation, we clarify that the accessibility requirements in the final rule are limited to health programs and activities offered through electronic and information technology that is used by consumers or other program beneficiaries and do not apply to electronic and information technology that is used only by employees of a covered entity and that does not affect or impact customers or program beneficiaries, except as provided in § 92.208.

We also note that the ADA and Section 504 apply to employment, and virtually all of the entities subject to the requirement for accessibility of health programs and activities offered through electronic and information technology in the final rule are also subject to similar general accessibility requirements in the ADA and Section 504. Entities covered by the final rule should be mindful of their obligations under these other laws.

Comment: Some commenters recommended that OCR require different standards for accessibility of electronic and information technology for entities covered under Title II of the ADA, which applies to State and local government entities, and entities covered under Title III of the ADA, which applies to places of public accommodation and commercial facilities.

Response: OCR declines to apply different standards under the final rule. As noted above, State or local government entities that are covered under Section 1557 are already subject to the Title II standards. In addition, the other entities covered under Section 1557 are health programs and activities that either receive Federal financial assistance from HHS or are conducted directly by HHS. Although OCR could apply Title II standards to States and local entities and Title III standards to private entities, we believe it is appropriate to hold all recipients of Federal financial assistance from HHS to the higher Title II standards as a condition of their receipt of that assistance. As a result, OCR declines to impose different standards as recommended by the commenters. This approach is consistent with our approach to § 92.202, in which we are applying Title II standards to all entities covered under Section 1557 with respect to effective communication.

Comment: One commenter asked that OCR exempt places of public accommodation under the ADA from the requirements to make electronic and information technology accessible. Other commenters suggested that the electronic and information technology requirements in the proposed rule are too confusing and burdensome for small providers.

Response: Places of public accommodation covered under the ADA already are required to make health programs and activities offered through electronic and information technology accessible to individuals with disabilities. The ADA does not exempt small providers from this requirement. Thus, the requirements under this final rule should be familiar to entities covered under the ADA.

Comment: Many commenters recommended that OCR require compliance with the accessibility standards set forth in WCAG 2.0, with Level AA as the minimum benchmark. These commenters suggested that compliance with a specific standard would offer clarity to covered entities and consistency to consumers. These commenters also favored WCAG over Section 508 because WCAG is technology agnostic, meaning it is broken down by function rather than product-type, and can apply to future innovations as well as current uses of technology. These commenters also noted that the Access Board is modeling the refreshed Section 508 standards on WCAG 2.0 Level AA, ensuring that HHS's adoption of such a technical standard guarantees that there will be one, universal set of accessibility benchmarks.

Conversely, one commenter stated that OCR should not impose a specific accessibility standard for electronic and information technology, arguing that a specific standard may slow innovation and the establishment of potentially effective electronic information technology alternatives.

Response: OCR has decided not to adopt specific accessibility standards at this time. Nonetheless, we are still requiring covered entities to ensure that health programs and activities provided through electronic and information technology 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 an entity's health program or activity. Thus, when a covered entity chooses to provide a health program or activity through electronic and information technology, the entity must ensure that the technology is accessible as necessary for individuals with disabilities to have equal access to the health program or activity. In our experience, where a covered entity chooses to provide health programs and activities through electronic and information technology, it is difficult to ensure compliance with accessibility requirements without adherence to standards such as the WCAG 2.0 AA standards or the Section 508 standards. Accordingly, OCR strongly encourages covered entities that offer health programs and activities through electronic and information technology to consider such standards as they take steps to ensure that those programs and activities comply with requirements of this regulation and other Federal civil rights laws. Due to the increasing importance of electronic and information technology in health care and health insurance coverage, OCR will continue to closely monitor this area, including developments in the standards developed by the Department of Justice and the Access Board.

Comment: A few commenters asked that OCR give covered entities at least 24 months to come into compliance with the requirements of § 92.204 because they believe there is a significant shortage of available expertise on electronic and information technology. Other commenters recommended that physicians should not be required to comply with new standards until they are ready to upgrade or purchase a new technology product. Still others asked that OCR delay enforcement pertaining to electronic and information technology until health programs and activities can easily select appropriate accessible technology that has been certified by OCR to comply with established standards for accessible technology.

However, many other commenters urged OCR to reject any requests to delay or phase-in the requirements of § 92.204. These commenters pointed out that § 92.204 builds on and reinforces other longstanding accessibility requirements in Federal law; accordingly, it should not be overly burdensome for covered entities to adjust to the requirements of this rule.

Response: OCR is requiring compliance with the requirements of § 92.204 as of the effective date of this regulation. Section 92.204 largely reflects existing standards under the ADA and Section 504, and accordingly, most covered entities are already required to meet § 92.204's standards. Moreover, and with respect to those few covered entities that were not previously subject to the ADA and Section 504 standards, existing undue burden analysis provides adequate safeguards for covered entities that are unable to comply with the requirements of § 92.204 by the effective date.

Comment: One commenter suggested that the responsibility for redesigning health information and technology to improve accessibility should be placed on software vendors and developers rather than on issuers and providers.

Response: The final rule applies to, among other entities, entities that conduct health programs or activities and that receive Federal financial assistance from HHS. Those entities, consistent with longstanding requirements under the ADA and Section 504, must make health programs and activities offered through electronic and information technology accessible to individuals with disabilities. This obligation is not new. Covered entities are not obligated to redesign health information and technology; accessible technology exists and is available to entities covered by the final rule. Thus, HHS is declining to make the change proposed.

Comment: Several commenters suggested that OCR include a reference to specific ADA regulations requiring effective communication in § 92.204.[222] These commenters noted that some of these regulations are the legal origin of the final rule's statement that covered entities must make health programs and activities provided through electronic and information technology accessible. Although these commenters acknowledged that not all of the regulations concerning auxiliary aids and services will apply in the electronic and information technology context, they believe that the explicit incorporation of relevant aspects of these ADA regulations would inform covered entities of other obligations that they might otherwise overlook, such as the obligation to consult and work with individuals with disabilities as part of the entity's effective communication obligation.

Response: OCR believes that intent is clear in the regulation as written. Although OCR is declining to include a reference to 28 CFR 35.160 and succeeding sections in § 92.204, as proposed by the commenters, these sections are incorporated in § 92.202 of the final rule, addressing effective communication with individuals with disabilities. Covered entities are required to comply with both sections of the final rule.

Comment: A few commenters asked OCR to state that electronic information and technology must be functional so that a person with a disability can enjoy all of the same functionality in an equally effective manner and with substantially equivalent ease of use as a user without a disability.

Response: OCR is clarifying here that a covered entity's electronic and information technology must be functional as necessary to ensure that an individual with a disability has equal access to a covered entity's health program and activity. We believe that the regulatory text encompasses this approach.

Comment: Several commenters called attention to problems that persons with disabilities frequently encounter when attempting to access health care. For example, one commenter pointed out that health care service providers' Web sites often include content like videos with audio components. The commenter noted that these videos often lack closed captioning or American Sign Language (ASL) translations that would make the information provided in the video accessible to people with hearing-related disabilities. Accordingly, this commenter suggested that OCR modify § 92.204 to require covered entities to caption or provide ASL translations of audio-based content on their Web sites so that all audio based content is accessible for deaf and hard of hearing individuals.

Another commenter pointed out that, when blind patients seek treatment at a doctor's office, they are often expected to make appointments or fill out required documentation expected of new patients using an inaccessible online portal. In these situations, the blind patient is forced to rely on a third party for assistance and, regardless of their personal relationship, disclose confidential information to that person such as the patient's medical history, illnesses, medications, and history of disease or genetic patterns running in the patient's family. Accordingly, this commenter asked that OCR clarify that covered entities need to make online portals accessible so that blind individuals have the same level of privacy and confidentiality as other individuals.

Response: Under the final rule, covered entities must ensure that the health programs and activities they offer through electronic and information technology are accessible to individuals with disabilities. OCR is not prescribing specific standards for ensuring accessibility and so declines to adopt the commenters' recommendation. However, OCR notes that under § 92.202(a), which incorporates 28 CFR 35.160(b)(2), ''[i]n order to be effective, auxiliary aids and services must be provided [to individuals with disabilities] . . . in such a way as to protect the privacy and independence of the individual with a disability.'' We further remind covered entities to consider the range of accessibility issues that arise for individuals with disabilities and the technology-based solutions that are available to address these issues. The confidentiality of health information is a critical issue, and covered entities must ensure that the private health information of individuals with disabilities is appropriately protected.

Summary of Regulatory Changes

For the reasons set forth in the proposed rule and considering the comments received, we are finalizing the provisions proposed in § 92.204 without modification.

Requirement To Make Reasonable Modifications (§ 92.205)

In § 92.205, we proposed to require covered entities to make reasonable modifications in policies, practices, or procedures when necessary to avoid discrimination on the basis of disability, unless they can demonstrate that the modification would fundamentally alter the nature of the health program or activity.

We did not receive any significant comments regarding § 92.205. For the reasons set forth in the proposed rule, we are finalizing the provisions proposed in § 92.205 without modification.

Equal Program Access on the Basis of Sex (§ 92.206)

In § 92.206, we proposed that covered entities be required to provide individuals equal access to their health programs or activities without discrimination on the basis of sex and to treat individuals consistent with their gender identity. We proposed that this provision applies to all covered health programs and activities, and prohibits, among other forms of adverse treatment, the discriminatory denial of access to facilities administered by a covered entity. We noted that this proposed approach is consistent with the principle that discrimination on the basis of sex includes discrimination on the basis of gender identity and that failure to treat individuals in accordance with their gender identity may constitute prohibited discrimination.

We proposed one limited exception to the requirement that covered entities treat individuals consistent with their gender identity: That a covered entity may not deny or limit health services that are ordinarily or exclusively available to individuals of one gender based on the fact that the individual's

[222] Commenters wanted OCR to cite to 28 CFR 35.160(a)(1), (2); 35.160(d); 35.163; and 35.164.

sex assigned at birth, gender identity, or gender otherwise recorded in a medical record or by a health insurance plan is different from the one to which such health services are ordinarily or exclusively available. For example, a covered entity may not deny, based on an individual's identification as a transgender male, treatment for ovarian cancer where the treatment is medically indicated.

For clarity and consistency within the final rule, we have made some technical revisions to § 92.206. First, regarding a covered entity being prohibited from denying or limiting health services, we are adding the words ''to a transgender individual'' after ''a covered entity shall treat individuals consistent with their gender identity, except that a covered entity may not deny or limit health services, that are ordinarily or exclusively available to individuals of one gender,'' to clarify that the exception is limited to transgender individuals. We note that similar to the discussion in § 92.207(b)(3), we recognize that not every health service that is typically or exclusively provided to individuals of one sex will be a health service that is appropriately provided to a transgender individual. Nothing in the rule would, for example, require a covered entity to provide a traditional prostate exam to an individual who does not have a prostate, regardless of that individual's gender identity. But for health services that are appropriately provided to an individual, the covered entity must provide coverage for those health services on the same terms regardless of an individual's sex assigned at birth, gender identity, or recorded gender. Second, we are deleting the phrase ''in a medical record'' to address concerns that ''medical records'' could be understood as referring only to clinical notes of a health care provider.

The comments and our responses regarding § 92.206 are set forth below:

Comment: A majority of commenters strongly supported the requirement that covered entities provide equal access to health programs and activities without discrimination on the basis of sex and treat individuals consistent with their gender identity. Several commenters noted that discrimination in access to gender-specific facilities remains one of the most common and harmful forms of sex-based discrimination against transgender people, singling them out for humiliation and causing them to avoid the use of such facilities and the associated medical care. Numerous commenters strongly encouraged OCR to strengthen § 92.206 with explicit protections for individuals with non-binary gender identities who need access to gender-specific programs and facilities, and to affirm that individuals with non-binary gender identities should be permitted to determine which facilities are appropriate for them.

Response: OCR recognizes the difficulty that individuals with non-binary gender identities may face in accessing gender-specific programs and facilities. The rule makes clear that in order to meet their obligations under § 92.206, covered entities must treat all individuals consistent with their gender identity, including with regard to access to facilities. OCR has revised the definition of ''gender identity'' to clarify individuals with non-binary gender identities are protected under the rule from all forms of discrimination based on their gender identity. Thus, OCR does not believe that it is necessary to reiterate protections for non-binary individuals in this context.

Comment: Commenters noted that because pregnant women have experienced considerable discrimination in accessing certain health care services such as mental health care and drug treatment services, the final rule should state that equal access without discrimination on the basis of sex includes equal access without discrimination on the basis of pregnancy.

Response: OCR recognizes the difficulty many pregnant people experience in accessing certain health care services. In response to this concern, OCR is clarifying here that the equal program access provision under § 92.206 is simply a specific application of the more general prohibition of discrimination under § 92.101(a). Under both provisions, denial of program access on any of the prohibited bases, including pregnancy or related medical conditions, is prohibited.

Summary of Regulatory Changes

For the reasons set forth in the proposed rule and considering the comments received, we are finalizing the provision as proposed in § 92.206 with technical revisions to clarify our intent and ensure consistency with other parts of the final rule.

Nondiscrimination in Health-Related Insurance and Other Health-Related Coverage (§ 92.207)

In § 92.207 of the proposed rule, we provided specific details regarding the prohibition of discrimination on the basis of race, color, national origin, sex, age, or disability in the provision and administration of health-related insurance or other health-related coverage. We proposed that this prohibition applies to all covered entities that provide or administer health-related insurance or other health-related coverage, including health insurance issuers and group health plans that are recipients of Federal financial assistance and the Department in the administration of its health-related coverage programs. We noted that this section is independent of, but complements, the nondiscrimination provisions that apply to the Health Insurance Marketplaces [223] and to issuers of qualified health plans [224] under other Departmental regulations, and that entities covered under those provisions and Section 1557 are obligated to comply with both sets of requirements.

Based on the longstanding civil rights principles discussed in connection with the definition of ''health program or activity'' in § 92.4, we proposed to apply this part to all of the coverage and services of issuers that receive Federal financial assistance, whether those issuers' coverage is offered through the Marketplace℠, outside the Marketplace℠, in the individual or group health insurance markets, or as an employee health benefit program through an employer-sponsored group health plan.[225] We provided an example illustrating that an issuer participating in the Marketplace℠, and thereby receiving Federal financial assistance, that also offers plans outside the Marketplace℠ would be covered by the regulation for all of its health plans, as well as when it acts as a third party administrator for an employer-sponsored group health plan.[226]

Paragraph (a) proposed a general nondiscrimination requirement, and paragraph (b) provided specific examples of prohibited actions. Paragraphs (b)(1) and (2) proposed to address the prohibition on denying, cancelling, limiting, or refusing to issue or renew a health-related insurance plan or policy or other health-related coverage, denying or limiting coverage of a claim, or imposing additional cost sharing or other limitations or

[223] 45 CFR 155.120(c).

[224] 45 CFR 156.200(e); 45 CFR 147.104(e); Public Health Service Act section 2705 (codified at 42 U.S.C. 300gg–4).

[225] Like the proposed rule, the final rule separately addresses employer liability for discrimination in employee health benefit programs at § 92.208.

[226] Where an entity that acts as a third party administrator for an employer's employee health benefit plan is legally separate from an issuer that receives Federal financial assistance for its insurance plans, we proposed to engage in a case-by-case inquiry to evaluate whether that entity is appropriately subject to Section 1557. The final rule addresses this further in the discussions under § 92.2 and § 92.208.

restrictions, on the basis of an enrollee's or prospective enrollee's race, color, national origin, sex, age, or disability, and the use of marketing practices or benefit designs that discriminate on these bases.

In the proposed rule, we did not propose to require plans to cover any particular benefit or service, but we provided that a covered entity cannot have coverage that operates in a discriminatory manner. For example, the preamble stated that a plan that covers inpatient treatment for eating disorders in men but not women would not be in compliance with the prohibition of discrimination based on sex. Similarly, a plan that covers bariatric surgery in adults but excludes such coverage for adults with particular developmental disabilities would not be in compliance with the prohibition on discrimination based on disability.

In paragraphs (b)(3) through (5) of the proposed rule, we proposed to address discrimination faced by transgender individuals in accessing coverage of health services. We proposed in paragraph (b)(3) that to deny or limit coverage, deny a claim, or impose additional cost sharing or other limitations or restrictions on coverage of any health service is impermissible discrimination when the denial or limitation is due to the fact that the individual's sex assigned at birth, gender identity, or gender otherwise recorded by the plan or issuer is different from the one to which such services are ordinarily or exclusively available.[227] Under the proposed rule, coverage for medically appropriate health services must be made available on the same terms and conditions under the plan or coverage for all individuals, regardless of sex assigned at birth, gender identity, or recorded gender.

In addition, we noted that many health-related insurance plans or other health-related coverage, including Medicaid programs, currently have explicit exclusions of coverage for all care related to gender dysphoria or associated with gender transition. Historically, covered entities have justified these blanket exclusions by categorizing all transition-related treatment as cosmetic or experimental.[228] However, such across-the-board categorization is now recognized as outdated and not based on current standards of care.[229]

OCR proposed to apply basic nondiscrimination principles in evaluating whether a covered entity's denial of a claim for coverage for transition-related care is the product of discrimination. We noted that based on these principles, an explicit, categorical (or automatic) exclusion or limitation of coverage for all health services related to gender transition is unlawful on its face under paragraph (b)(4); in singling out the entire category of gender transition services, such an exclusion or limitation systematically denies services and treatments for transgender individuals and is prohibited discrimination on the basis of sex.

Moreover, we proposed in § 92.207(b)(5) to bar a covered entity from denying or limiting coverage, or denying a claim for coverage, for specific health services related to gender transition where such a denial or limitation results in discrimination against a transgender individual. In evaluating whether it is discriminatory to deny or limit a request for coverage for a particular service for an individual seeking the service as part of transition-related care, we provided that OCR will start by inquiring whether and to what extent coverage is available when the same service is not related to gender transition. If, for example, an issuer or State Medicaid agency denies a claim for coverage for a hysterectomy that a patient's provider says is medically necessary to treat gender dysphoria, OCR will evaluate the extent of the covered entity's coverage policy for hysterectomies under other circumstances. We noted that OCR will also carefully scrutinize whether the covered entity's explanation for the denial or limitation of coverage for transition-related care is legitimate and not a pretext for discrimination.

We noted that these provisions do not, however, affirmatively require covered entities to cover any particular procedure or treatment for transition-related care; nor do they preclude a covered entity from applying neutral standards that govern the circumstances in which it will offer coverage to all its enrollees in a nondiscriminatory manner.

We invited comment as to whether the approach of § 92.207(b)(1)–(5) is over- or underinclusive of the types of potentially discriminatory claims denials experienced by transgender individuals in their attempts to access coverage and care, as well as on how nondiscrimination principles apply in this context.

Paragraph (c) of § 92.207 of the proposed rule provided that the enumeration of specific forms of discrimination in paragraph (b) does not limit the general applicability of the prohibition in paragraph (a) of this section. Paragraph (d) of the proposed rule provided that nothing in § 92.207 is intended to determine, or restrict a covered entity from determining, whether a particular health care service is medically necessary or otherwise meets applicable coverage requirements in any individual case.

The comments and our responses regarding § 92.207 are set forth below.

Comment: Numerous commenters requested clarification regarding the rule's applicability to various health programs or activities that are regulated under other Federal requirements and recommended that OCR deem health programs and activities that comply with existing Federal regulations as in compliance with, or exempt from, Section 1557. For example, commenters requested that compliance with CMS regulations pertaining to qualified health plans or insurance benefit design, such as prescription drug formularies designed by a pharmacy and therapeutics committee,[230] be deemed compliance with the final rule. Numerous commenters also requested that OCR harmonize its language access requirements with existing CMS regulations. This is addressed in the discussion of § 92.201.

In addition, other commenters sought clarification as to the applicability of the rule to wellness programs [231] and value-based insurance designs [232] that are regulated by other Federal departments and agencies, and similarly requested that compliance with other Federal laws regarding these programs be deemed compliance with this final rule. Conversely, regarding employer

[227] We note that under § 92.207(a), a covered entity would be barred from denying coverage of any claim (not just sex-specific surgeries) on the basis that the enrollee is a transgender individual.

[228] Liza Khan, *Transgender Health at the Crossroads,* 11 Yale J. Health Pol'y L. & Ethics 375, 393 (2011).

[229] *See infra* note 263. *See also* discussion in the proposed rule at 80 FR at 54189–90.

[230] 45 CFR 156.122(a)(3) (for plan years beginning on or after Jan. 1, 2017).

[231] U.S. Dep't of the Treasury, U.S. Dep't of Labor, and U.S. Dep't of Health & Human Servs., Incentives for Nondiscriminatory Wellness Programs in Group Health Plans (Final Rule), 78 FR 33158 (June 3, 2013).

[232] For a discussion of Value-Based Insurance Design, see Affordable Care Act Implementation FAQs Set 5, Q1, *http://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs5.html* (last visited May 4, 2016); U.S. Dep't of the Treasury, Dep't of Labor, and U.S. Dep't of Health & Human Servs., Coverage of Certain Preventive Services Under the Affordable Care Act, Final Rule, 80 FR 41318, 41321 (July 1, 2015); and U.S. Dep't of Health & Human Servs., Center for Medicare & Medicaid Servs., Medicare Advantage Value-Based Insurance Design Model (Sept. 1, 2015), *https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2015-Fact-sheets-items/2015-09-01.html.*

wellness programs, one commenter wanted OCR to expressly prohibit covered entities from implementing outcomes-based employee wellness programs that base financial rewards or penalties on outcome standards that are coextensive with or directly related to a disability, such as an outcome standard related to high glucose levels, which are directly related to diabetes.

Response: For the same reasons discussed in connection with the General Comments above,[233] we reject the recommendation to deem health programs or activities that comply with other Federal regulations as automatically in compliance with, or exempt from, the final rule. As a general matter, OCR does not view a covered entity's compliance with other Federal regulations, adopted with different requirements and for different purposes, as determinative of a covered entity's compliance with Section 1557 or other Federal civil rights laws that we enforce. Moreover, deeming compliance in this context must be considered in light of the potential harmful consequences to consumers' health that may occur if covered entities do not adhere to civil rights obligations.

While we reject deeming, OCR will consider a covered entity's compliance with other applicable Federal laws in evaluating a covered entity's compliance with this final rule, and will continue to coordinate with other Federal agencies to promote consistency and avoid duplication in enforcement efforts.

Further, we clarify that evidence-based insurance designs and wellness programs offered through covered entities, such as a health insurance issuer or a group health plan that receives Federal financial assistance, are health programs or activities that are subject to the final rule. We decline to expressly prohibit a particular type of practice by wellness programs in the final rule, as complaints will be reviewed on a case-by-case basis. We note that CMS has made clear that covered entities are responsible for ensuring compliance with other applicable Federal and State laws, including nondiscrimination obligations under Federal laws.[234] We remind covered entities that employer-sponsored wellness programs are considered an employee health benefit program and that employers will be subject to liability for discrimination in such programs under the circumstances identified in § 92.208.

Comment: Several commenters expressed concern that covered entities would not be able to revise their health insurance coverage or other health coverage to comply with the regulation within 60 days after publication, and requested that the effective date of the final rule, in particular § 92.207, be delayed until January 1, 2017 or 2018.[235] These commenters explained that health insurance plans are filed for review with CMS and State insurance regulators during the year before the calendar year in which the plan is offered for sale. Thus, depending on the publication date of the final rule, the commenters suggested that delaying the effective date to plan years (in the individual market, policy years) beginning in 2017 or 2018 would be necessary for issuers to avoid the administrative challenges associated with applying the final rule's requirements in the middle of a plan year or policy year, including amending benefit designs, revising premium rates if applicable, and refiling the products for review with CMS and State insurance regulators. In addition, the commenters noted that issuers are not permitted to adjust rates mid-year for some insurance products.

By contrast, one commenter supported maintaining the proposed effective date, arguing that the benefits of more immediate implementation of the final rule outweigh any expenses or confusion associated with mid-year policy revisions.

Response: We appreciate the concerns expressed by the commenters but we are maintaining the effective date as 60 days after the date of publication of the final rule, except in the limited circumstances described below. Section 1557 has been in effect since its passage as part of the ACA in March 2010, and covered entities have been subject to its requirements since that time. To delay implementation of the final rule would delay the existing and ongoing protections that Section 1557 currently provides and has provided since enactment.[236]

That said, we recognize that some covered entities will have to make changes to their health insurance coverage or other health coverage to bring that coverage into compliance with this final rule. We are sensitive to the difficulties that making changes in the middle of a plan year could pose for some covered entities and are committed to working with covered entities to ensure that they can comply with the final rule without causing excessive disruption for the current plan year.

Consequently, to the extent that provisions of this rule require changes to health insurance or group health plan benefit design (including covered benefits, benefits limitations or restrictions, and cost-sharing mechanisms, such as coinsurance, copayments, and deductibles), such provisions, as they apply to health insurance or group health plan benefit design, have an applicability date of the first day of the first plan year (in the individual market, policy year) beginning on or after January 1, 2017.

Comment: Several commenters representing issuers and large employers recommended that the rule exempt from Section 1557 benefits that constitute excepted benefits under section 2791(c) of the Public Health Service Act (codified at 42 U.S.C. 300gg–91(c)), which generally are exempt from market reforms under the ACA and HIPAA portability requirements. Excepted benefits include, but are not limited to: limited scope dental and vision plans; coverage only for a specified disease or illness; and Medicare supplemental health insurance (also known as Medigap).[237] Commenters suggested that being excepted from the ACA market reforms and HIPAA portability requirements should result in exemption from Section 1557. Others stated that covering excepted benefits under the rule would serve as a disincentive to employers to provide these benefits due to increased litigation risk.

Response: We are not exempting benefits excepted from ACA market reforms and HIPAA portability requirements from the final rule. If an issuer providing these benefits receives Federal financial assistance and is principally engaged in providing health benefits, all of its operations will be covered by the rule; if it is not principally engaged, we will apply the rule to its federally funded health

[233] *See supra* discussion on deeming compliance with other laws in the General Comments section.

[234] 78 FR at 33168; U.S. Dep't of Health & Human Servs., Center for Medicare & Medicaid Servs., Affordable Care Act Implementation FAQs Set 2, Q5, *https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs2.html* (last visited May 4, 2016).

[235] The comments addressed in this section pertain to comments related to the implementation date of § 92.207. OCR also received comments requesting a delayed effective date for the rule in general, which are discussed *supra* under § 92.1 of this preamble.

[236] We note that issuers have been provided notice that they are subject to Section 1557 in other Departmental regulations (HHS's Notice of Benefit and Payment Parameters for 2017, Final Rule, 80 FR 12204, 12312 (Mar. 8, 2016); HHS's Notice of Benefit and Payment Parameters for 2017, Proposed Rule, 80 FR 75488, 75553 (Dec. 2, 2015); HHS's Notice of Benefit and Payment Parameters for 2016, Final Rule, 80 FR 10750, 10823 (Feb. 27, 2015)).

[237] 42 U.S.C. 300gg–91(c).

programs and activities. Many of the benefits excepted from the ACA market reforms and HIPAA portability rules will meet the definition of ''health program and activity.'' [238]

Nothing in the text of Section 1557 limits its coverage only to health programs and activities created or regulated by other provisions of the ACA. Indeed, Section 1557's incorporation of the four civil rights laws to which it refers, as those laws were amended by the CRRA, conclusively suggests otherwise. Moreover, Title VI, Section 504, and the Age Act independently apply to these benefits,[239] and other civil rights laws, such as Title VII, apply to these benefits when they are provided as a fringe benefit of employment by employers covered by that law.

There are several statutorily-defined categories of excepted benefits that are exempt from the ACA market reforms and HIPAA portability requirements if certain conditions are satisfied, such as when medical benefits are incidental or secondary to other insurance benefits, when the benefits are limited in scope or supplemental, or when the benefits are provided as independent, non-coordinated benefits.[240] Excepted benefits do not provide comprehensive medical coverage and do not satisfy the individual or employer responsibility provisions under the ACA. But these characteristics do not justify an exemption from the requirements of Section 1557, which reflects the fundamental policy that entities that operate health programs and activities, any part of which receives Federal funds, cannot use those funds to discriminate—however broad or narrow the scope of those health programs and activities may be.

Comment: Some commenters requested that OCR address a number of issues that are not within the purview of OCR or Section 1557, including the scope of essential health benefit coverage and establishing minimum network adequacy requirements.

Response: OCR appreciates the commenters' suggestions, but the commenters' requests are beyond the scope of this regulation. CMS is statutorily responsible for establishing and regulating the scope of essential health benefits and network adequacy requirements for health insurance issuers. Absent any allegation that a covered entity has discriminated on a basis prohibited by Section 1557, OCR lacks authority to address the terms of these CMS regulations.

Comment: Several commenters asked that OCR exercise more stringent and consistent oversight over consumer access to a wide range of specialists and subspecialists. Commenters pointed out that many qualified health plans in the Marketplace℠ offer network-based plans, and enrollee cost-sharing can be substantially lower when care is delivered by an in-network provider. The commenters expressed concern that some issuers appear to systematically exclude from their provider networks high-cost providers or those in certain high-cost specialties. The commenters suggested that narrow networks could potentially be discriminatory if they deprive patients of reasonable access to a specialty provider or if they discourage enrollment by individuals with specific health needs.

Response: OCR agrees that provider networks with a wide range of specialists and subspecialists are beneficial for consumers and appreciates the concerns expressed about the effect of the exclusion of certain specialists from an issuer's network. We clarify, however, that it is beyond the scope of this regulation to establish uniform or minimum network adequacy standards. Qualified health plan issuers are subject to network adequacy requirements under CMS regulations.[241]

Comment: Some commenters asked OCR to clarify that issuers cannot discriminate against providers based on a provider's protected status. That is, these commenters recommended that OCR make clear that Section 1557's prohibition of discrimination is not limited in scope to the health care consumer and extends to other entities that may be engaged in health programs and activities.

Response: OCR clarifies that covered entities providing or administering health-related insurance or other health-related coverage may not discriminate against or exclude health care providers they contract with on the basis of the provider's race, color, national origin, sex, age, or disability. OCR reminds covered entities that they may have obligations under other Federal laws prohibiting discrimination against providers [242] or against employees.[243]

Comment: A few commenters asked OCR to amend § 92.207(a) so that it more clearly describes the various activities that a covered entity may perform that are considered ''administering'' health-related insurance or other health-related coverage. Specifically, these commenters asked that OCR add language to § 92.207(a) explaining that administering health-related insurance or other health-related coverage may include claims processing, rental of a provider network, designing plan benefits or policies, drafting plan documents, processing or adjudicating appeals, administering disease management services, and pharmacy benefit management.

Response: We appreciate the commenters' suggestion, but we believe the regulatory text is clear as written and does not require further clarification. The term ''administering'' is broad enough to encapsulate a variety of activities related to the administration of health-related insurance or other health-related coverage.

Comment: We received a number of comments related to the proper handling of claims alleging discrimination in employee health benefit plans that are covered by both this rule and other Federal laws and regulations. For example, several commenters recommended that the rule not apply to the services of third party administrators providing administrative services to self-insured group health plans. These commenters asserted that Congress did not intend for third party administrators to be covered by Section 1557 and asserted that third party administrators do not design plans, are not responsible for determining the benefits covered under the plan, and are required by ERISA [244] to administer plans as they are written. Commenters also asserted that coverage of third party administrators would indirectly subject self-insured group health plans to Section 1557 and create an unlevel playing field between third party administrators operated by issuers that receive Federal financial assistance and those that do not, thereby creating a disincentive for self-insured group health plans to contract with third party administrators that participate as issuers in the Marketplace℠ and a resulting

[238] We note that non-health-related excepted benefits would be covered under the rule if offered by a covered entity that is principally engaged in providing health care or health coverage.

[239] Title IX applies to these benefits to the extent they are provided in connection with federally funded educational programs or activities.

[240] 42 U.S.C. 300gg–91(c).

[241] 45 CFR 156.230.

[242] *See, e.g.,* 42 U.S.C. 300gg–5(a); 42 CFR 422.205(a).

[243] *See, e.g.,* Title VII of the Civil Rights Act of 1964 (42 U.S.C. 2000e–2000e–17), the ADA (42 U.S.C. 12101 *et seq.*), the Age Discrimination in Employment Act (29 U.S.C. 621–634); Executive Order 11246 (30 FR 12319, 12935, 3 CFR, 1964–1965, as amended), Section 503 of the Rehabilitation Act of 1973 (29 U.S.C. Sec. 793), and the Vietnam Veterans' Readjustment Assistance Act of 1974 (38 U.S.C. Sec. 4212).

[244] 29 U.S.C. 1001 *et seq.*

disincentive for issuers to offer qualified health plans on the Marketplace[SM]. These commenters also emphasized that self-insured group health plans are already subject to extensive Federal regulation under ERISA.

Some commenters representing issuers and larger employers also objected to language in footnote 73 [245] in the preamble of the proposed rule stating that when an entity that acts as a third party administrator is legally separate from the issuer that receives Federal financial assistance, we will engage in a case-by-case analysis to determine whether the third party administrator is subject to the rule. These commenters stated that the rule should never extend beyond the legal entity that receives the Federal financial assistance.

Response: We are not excluding third party administrator services from the final rule; however, we are adopting specific procedures to govern the processing of complaints against third party administrators.

Third party administrator services are undeniably a health program or activity, as they involve the administration of health services. Under the final rule, if an entity that receives Federal financial assistance is principally engaged in providing or administering health services, health insurance coverage, or other health coverage, then, consistent with the approach taken under the civil rights laws referenced in Section 1557 and under the CRRA, as discussed *supra,*[246] all of its operations are covered. Thus, if an issuer that receives Federal financial assistance is principally engaged in providing health insurance and also provides third party administrator services, there is no principled basis on which to exclude the law's application to the third party administrator services or to treat them differently from other entities and services covered by the rule.

Commenters' assertion that employers or group health plans may have an incentive to contract with third party administrators that are operated by entities that do not receive Federal financial assistance does not justify exempting third party administrator services from the rule. Commenters' rationale would undermine the application of all of the civil rights laws that attach obligations to the receipt of Federal financial assistance; if any competitive disparity exists here, it is no different than in other types of businesses in which some entities receive Federal financial assistance and others do not.

Moreover, the fact that third party administrators are governed by other Federal laws such as ERISA is not a reason to exempt them from Section 1557. ERISA itself explicitly preserves the independent operation of civil rights laws, by providing that nothing in ERISA ''shall be construed to alter, amend, modify, invalidate, impair, or supersede any law of the United States . . . or any rule or regulation issued under any such law.'' [247] And in any event, the fact that entities are subject to regulation under other Federal statutory schemes adopted for other purposes does not justify insulating them from the obligation to comply with civil rights requirements.[248]

Commenters expressed a number of concerns related to the relationship between third party administrators and the employers whose self-insured group health plans they administer. OCR clarifies here that, contrary to the understanding of some commenters, Section 1557's coverage of a third party administrator under the rule does *not* extend to the coverage of an employer providing a group health plan that is being administered by the third party administrator. The rule addresses employer liability separately from that of issuers that receive Federal financial assistance; [249] under Section 1557, an employer is liable for discrimination in its employee health benefit programs only if the employer is principally engaged in health services, health insurance coverage, or other health coverage, or otherwise satisfies one of the criteria set forth in § 92.208. Whether an employer's group health plan is administered by a third party administrator that is a covered entity is not relevant in this analysis.

In response to commenters' arguments on this point, however, OCR recognizes that third party administrators are generally not responsible for the benefit design of the self-insured plans they administer and that ERISA (and likely the contracts into which third party administrators enter with the plan sponsors) requires plans to be administered consistent with their terms.[250] Thus, if a plan has a discriminatory benefit design under Section 1557, a third party administrator could be held responsible for plan features over which it has no control.

Based on these comments, OCR is adjusting the way in which it will process claims that involve alleged discrimination in self-insured group health plans administered by third party administrators that are covered entities. Fundamentally, OCR will determine whether responsibility for the decision or other action alleged to be discriminatory rests with the employer or with the third party administrator. Thus, where the alleged discrimination is related to the administration of the plan by a third party administrator that is a covered entity, OCR will process the complaint against the third party administrator because it is that entity that is responsible for the decision or other action being challenged in the complaint. Where, for example, a third party administrator denies a claim because the individual's last name suggests that she is of a certain national origin or threatens to expose an employee's transgender or disability status to the employee's employer, OCR will proceed against the third party administrator as the decision-making entity. Where, by contrast, the alleged discrimination relates to the benefit design of a self-insured plan—for example, where a plan excludes coverage for all health services related to gender transition—and where OCR has jurisdiction over a claim against an employer under Section 1557 because the employer falls under one of the categories in § 92.208, OCR will typically address the complaint against that employer.

As part of its enforcement authority, OCR may refer matters to other Federal agencies with jurisdiction over the entity. Where, for example, OCR lacks jurisdiction over an employer responsible for benefit design, OCR typically will refer or transfer the matter to the EEOC and allow that agency to address the matter. The EEOC has informed OCR that, provided the filing meets the requirements for an EEOC charge, the date a complaint was filed with OCR will be deemed the date it was filed with the EEOC (although any subsequent denial of a renewed coverage request could be separately challenged by a timely complaint).

This approach is consistent with our efforts to ensure coordination with other Federal agencies that can also exercise jurisdiction over the subject of a particular complaint. Thus, we will also coordinate with the Office of Personnel Management (OPM) in the handling of claims alleging discrimination in the Federal Employees Health Benefits (FEHB) Program. OPM is charged by

[245] 80 FR at 54189 n.73.

[246] *See supra* discussion of the CRRA under the discussion of ''health program or activity'' under § 92.4.

[247] 29 U.S.C. 1144(d).

[248] *See supra* discussion on deeming compliance with other laws in the General Comments section.

[249] *See* § 92.208 and discussion of § 92.208 *infra.*

[250] *See* 29 U.S.C. 1104(a)(1)(D).

Federal statute[251] with offering FEHB plans as a fringe benefit of Federal employment and, in that role, approves benefit designs and premium rates, sets rules generally applicable to FEHB carriers, adjudicates and orders payment of disputed health claims, and adjusts policies as necessary to ensure compliance with nondiscrimination standards. As a result, OCR will refer to OPM complaints that allege discrimination in the FEHB Program where OPM is the entity with decision-making authority over the challenged action; OPM will treat these claims as complaints filed against OPM and will seek relief comparable to that available were these claims to be processed by OCR under Section 1557.

In response to the comments requesting additional clarification on footnote 73 in the proposed rule, we reiterate that we will engage in a case-by-case inquiry to evaluate whether a third party administrator is appropriately subject to Section 1557 as a recipient in situations in which the third party administrator is legally separate from an issuer that receives Federal financial assistance for its insurance plans. This analysis will rely on principles developed in longstanding civil rights case law, such as the degree of common ownership and control between the two entities,[252] and will also examine whether the purpose of the legal separation is a subterfuge for discrimination—that is, intended to allow the entity to continue to administer discriminatory health-related insurance or other health-related coverage.[253] But we note that a third party administrator is unlikely to be covered by this final rule where it is a legal entity that is truly independent of an issuer's other, federally funded, activities.

Comment: Commenters requested clarification on OCR's approach when evaluating whether a prohibited discriminatory action occurred under § 92.207(b).

Response: We clarify that OCR's approach in applying basic nondiscrimination principles, as discussed in the proposed rule under § 92.207(b)(5)[254] relating to coverage for specific health services related to gender transition, is the same general approach that OCR will take when evaluating denials or limitations of coverage for other types of health services. In other words, OCR will evaluate whether a covered entity utilized, in a nondiscriminatory manner, a neutral rule or principle when deciding to adopt the design feature or take the challenged action or whether the reason for its coverage decision is a pretext for discrimination. For example, if a plan limits or denies coverage for certain services or treatment for a specific condition, OCR will evaluate whether coverage for the same or a similar service or treatment is available to individuals outside of that protected class or those with different health conditions and will evaluate the reasons for any differences in coverage. Covered entities will be expected to provide a neutral, nondiscriminatory reason for the denial or limitation that is not a pretext for discrimination.

Comment: One commenter asked OCR to clarify that targeted marketing practices designed to reach certain populations to increase enrollment, such as specific segments of those who are uninsured or underserved, are not considered discriminatory. This commenter pointed out that some issuers sometimes launch targeted campaigns to reach a high number of uninsured in their service areas. In so doing, issuers may study the profile of uninsured populations, and based on the results of that study, may concentrate their marketing efforts on certain demographic groups that are disproportionately uninsured or underserved. The commenter cited a Gallup Poll that indicated that roughly one-third of Hispanics remain uninsured, which the commenter stated creates a particular need for issuers to help educate and expand coverage for this community. The commenter sought reassurance that OCR will not consider it discriminatory to target enrollment efforts where they will make the most difference.

Response: Congress intended the ACA to help uninsured and underserved populations gain access to care. Nothing in this regulation is intended to limit targeted outreach efforts to reach underserved racial or ethnic populations or other underserved populations. Indeed, it is OCR's intention that this regulation will increase access for uninsured and underserved populations, much as other Departmental regulations implementing the ACA have strived to do.[255]

Comment: Several commenters recommended that we define ''marketing practices'' in the regulatory text of § 92.207(b)(2). These commenters suggested that the inclusion of a precise definition for ''marketing practices'' would serve to clarify the scope of § 92.207(b)(2).

Response: We decline to define ''marketing practices'' in the final rule because to do so would be overly prescriptive. We emphasize, however, that we intend to interpret the term ''marketing practices'' broadly; such practices would include, for example, any activity of a covered entity that is designed to encourage individuals to participate or enroll in the covered entity's programs or services or to discourage them from doing so, and activities that steer or attempt to steer individuals towards or away from a particular plan or certain types of plans. We remind covered entities that other Departmental regulations address marketing practices,[256] and covered entities are obligated to comply with all applicable Federal and State laws regarding such practices.

Comment: Many commenters recommended that we define ''benefit design'' in the regulatory text of the final rule. These commenters suggested that the inclusion of a precise definition of ''benefit design'' would serve to clarify the scope of § 92.207(b)(2). In addition, numerous commenters requested that we codify or provide examples of benefit designs that discriminate on the basis of race, color, national origin, sex, age, or disability. A number of commenters urged OCR to consider specific types of benefit designs as constituting per se discrimination under § 92.207(b)(2) of the final rule.

Response: We appreciate commenters' requests for guidance and clarification regarding potentially discriminatory benefit designs and suggestions for scenarios that constitute per se discrimination. However, we decline to

[251] 5 U.S.C. 8901 *et seq.*

[252] *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).

[253] *Papa* v. *Katy Indus., Inc.,* 166 F.3d at 941.

[254] 80 FR at 54190.

[255] *See, e.g.,* 45 CFR 155.210(b)(2)(i) (requiring Exchanges to develop and publically disseminate Navigator training standards that ensures expertise in the needs of underserved and vulnerable populations); 81 FR 12204, 12338 (Mar. 8, 2016) (establishing new requirement at 45 CFR 155.210(e)(8) to require Navigators to provide targeted assistance to serve underserved or vulnerable populations).

[256] 45 CFR 156.225(b) (prohibiting qualified health plans from employing marketing practices or benefit designs that will have the effect of discouraging the enrollment of individuals with significant health needs); 45 CFR 147.104(e) (prohibiting a health insurance issuer from employing marketing practices or benefit designs that 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, gender identity, sexual orientation, expected length of life, degree of medical dependency, quality of life, or other health conditions); 42 CFR 422.2260–422.2615 (establishing Part D marketing requirements).

define ''benefit design'' in the final rule because to do so would be overly prescriptive.[257] We also decline to codify examples of discriminatory benefit designs because determining whether a particular benefit design results in discrimination will be a fact-specific inquiry that OCR will conduct through its enforcement of Section 1557. For the same reason, we avoid characterizing specific benefit design practices as per se discriminatory in the final rule.[258]

OCR will analyze whether a design feature is discriminatory on a case-by-case basis using the framework discussed above. We reiterate that our determination of whether a practice constitutes discrimination will depend on our careful analysis of the facts and circumstances of a given scenario. OCR recognizes that covered entities have discretion in developing benefit designs and determining what specific health services will be covered in their health insurance coverage or other health coverage. The final rule does not prevent covered entities from utilizing reasonable medical management techniques; nor does it require covered entities to cover any particular procedure or treatment. It also does not preclude a covered entity from applying neutral, nondiscriminatory standards that govern the circumstances in which it will offer coverage to all its enrollees in a nondiscriminatory manner. The rule prohibits a covered entity from employing benefit design or program administration practices that operate in a discriminatory manner.

Comment: We received a number of comments requesting that OCR add language to § 92.207(b) clarifying that categorical exclusions of certain conditions, such as coverage related to developmental disabilities or maternity care, are prohibited.

Response: While categorical exclusions of all coverage related to certain conditions could raise significant compliance concerns under Section 1557, OCR believes that existing regulatory language is sufficient to address this scenario. For example, the law has long recognized that discrimination based on pregnancy is a form of sex discrimination,[259] and OCR has interpreted Section 1557 in the same manner by defining the term ''on the basis of sex'' in this regulation to include ''discrimination on the basis of pregnancy, false pregnancy, termination of pregnancy, or recovery therefrom, childbirth or related medical conditions.'' As a result, it is unnecessary to add language in response to commenters' concerns.

We note that some products known as excepted benefits, which are subject to this final rule as discussed *supra,* provide limited scope benefits or coverage only for a specified disease or illness.[260] It would not be discriminatory for such products to include exclusions of coverage for conditions that are outside the scope of the benefits provided in those products. Accordingly, the purpose and scope of the coverage provided under health-related insurance or health-related coverage are factors that OCR will consider in determining whether an exclusion of all coverage for a certain condition is discriminatory under this final rule.

Comment: In light of OCR's statement in the preamble to the proposed rule that ''[t]he proposed rule does not require plans to cover any particular benefit or service, but a covered entity cannot have a coverage policy that operates in a discriminatory manner,'' [261] a few commenters asked OCR to clarify that the solution to a potentially discriminatory benefit design could be addition of coverage for a benefit or service.

Response: OCR agrees that the solution to a potentially discriminatory benefit design could be coverage, or added coverage, of a benefit or service.

Comment: The proposed rule invited comment as to whether the approach of § 92.207(b)(1)–(5) is over- or under-inclusive of the types of potentially discriminatory claim denials experienced by transgender individuals in their attempts to access coverage and care, as well as on how nondiscrimination principles apply in this context.[262] Many commenters supported OCR's approach in prohibiting a range of practices that discriminate against transgender individuals by denying or limiting coverage for medically necessary and medically appropriate health services. Numerous commenters asserted that the protections at § 92.207(b)(3)–(5) are vital to ensuring that transgender individuals are able to access the health coverage and care they need and urged OCR to preserve these provisions in the final rule.

For instance, many commenters strongly supported the proposed rule's prohibition against categorical or automatic exclusions of coverage for all health services related to gender transition. These commenters further supported the proposed rule's prohibition against otherwise denying or limiting coverage, or denying a claim, for health services related to gender transition if such a denial or limitation results in discrimination against a transgender individual. These commenters expressed hope that these prohibitions will serve to eliminate the significant barriers that transgender individuals have faced in accessing coverage for transition-related care, such as counseling, hormone therapy, and surgical procedures that they said had previously been denied to them because they have been viewed as cosmetic or experimental. Many commenters also favored the prohibition against denying, limiting, or otherwise restricting coverage for health services that are ordinarily or exclusively available to individuals of one sex based on an individual's gender identity. Commenters indicated that the proposed rule's protections will help to resolve various health care disparities suffered by transgender individuals.

Several commenters, however, opposed the protections that the proposed rule affords to transgender individuals. Some commenters suggested that covered entities should

[257] We note that ''benefit design'' is a term of art used in other Departmental and Federal regulations governing the private health insurance industry. *See e.g.,* 42 CFR 422.100(f)(3); 45 CFR 156.225(b); 45 CFR 147.104(e); 29 CFR 2510.3–40(c)(1)(iv)(A).

[258] CMS has identified benefit design features that might be discriminatory. For example, placing most or all prescription medications that are used to treat a specific condition on the highest cost formulary tiers (U.S. Dep't of Health & Human Servs., Centers for Medicare & Medicare Servs., Patient Protection and Affordable Care Act: HHS Notice of Benefit and Payment Parameters Rule, (Final Rule), 80 FR 10750, 10822 (Feb. 27, 2015); U.S. Dep't of Health & Human Servs., Centers for Medicare and Medicaid Servs., Final 2016 Letter to Issuers in the Federally-facilitated Marketplace, 37 (Feb. 20, 2015)); applying age limits to services that have been found clinically effective at all ages (80 FR at 10822 (Feb. 27, 2015); Final 2016 Letter to Issuers in the Federally-facilitated Marketplace, 36–37 (Feb. 20, 2015)); and requiring prior authorization and/or step therapy for most or all medications in drug classes such as anti-HIV protease inhibitors, and/or immune suppressants regardless of medical evidence (Centers for Medicare and Medicaid Servs., Qualified Health Plan Master Review Tool, Non-Discrimination in Benefit Design (2017), *https://www.cms.gov/CCIIO/Programs-and-Initiatives/Health-Insurance-Marketplaces/Downloads/Master-Review-Tool_v1-1_03302016.zip* (open ''Master Review Tool_2017v1.0.xlsm'' document; then open ''Non-Discrimination Guidance'' tab)).

[259] Title VII prohibits discrimination in employment practices ''because of sex,'' 42 U.S.C. 2000e–2(a), which is defined to include ''because of or on the basis of pregnancy, childbirth, or related medical conditions. . . .'' 42 U.S.C. 2000e(k); *Newport News Shipbuilding & Dry Dock Co.* v. *EEOC,* 462 U.S. 669, 684 (1983) (''discrimination based on a woman's pregnancy is, on its face, discrimination because of her sex.'').

[260] 42 U.S.C. 300gg–91(c).

[261] 80 FR at 54189.

[262] 80 FR at 54191.

be permitted to categorically exclude coverage for transition-related health services based on moral or religious convictions that an individual's biological sex, or sex assigned at birth, should not be altered. Other commenters suggested that OCR is exceeding its legal authority by addressing covered entities' provision of coverage to transgender individuals because discrimination based on gender identity should not be recognized as a form of sex discrimination.

Response: We agree with the commenters who expressed their general support of the protections for transgender individuals afforded by the provisions at § 92.207(b)(3)–(5), and therefore we are keeping the provisions as proposed. We believe that it is important to ensure that civil rights protections are extended to transgender individuals to afford them equal access to health coverage, including for health services related to gender transition. As we stated in the preamble to the proposed rule, the across-the-board categorization of all transition-related treatment, for example as experimental, is outdated and not based on current standards of care.[263]

Further, we disagree with commenters who asserted that sex-based discrimination does not include discrimination based on gender identity. As discussed previously,[264] OCR's definition of discrimination ''on the basis of sex'' is consistent with the well-accepted interpretations of other Federal agencies and courts. Further, as previously noted in this preamble,[265] we decline to adopt a blanket religious exemption in the final rule as any religious concerns are appropriately addressed pursuant to pre-existing laws such as RFRA and provider conscience laws.

Comment: A significant number of commenters recommended that OCR revise the language in § 92.207(b)(4) that prohibits categorical exclusions or limitations of ''all health services related to gender transition'' to remove the word ''all,'' and proposed modifications to § 92.207(b)(3)–(5) relating to the medical necessity or medical appropriateness of coverage for health services related to gender transition and sex-specific services. Other commenters, concerned that the rule may be too broadly interpreted, requested clarification as to when gender transition services or sex-specific services must be provided and recommended that the rule specify that such health services are to be provided only when medically necessary or medically appropriate. These commenters also requested that OCR clarify that the rule's intent is not to require covered entities to cover elective services or mandate that it cover certain services. Conversely, other commenters specifically requested that the rule clarify that covered entities cannot deny medically necessary services for gender transition-related care because such treatment is medically necessary for transgender individuals. Further, some commenters suggested that covered entities must provide coverage for procedures or services to treat gender dysphoria or associated with gender transition when substantially similar procedures or services are covered for other conditions. For example, commenters observed that a hysterectomy to treat gender dysphoria is substantially similar to a hysterectomy performed for cancer treatment or prevention in a cisgender woman (*i.e.,* a woman whose gender identity is consistent with her sex assigned at birth).

Response: OCR appreciates the array of comments provided but does not believe it is necessary to revise the regulatory text. As noted in the preamble to the proposed rule, we will evaluate whether a particular exclusion is discriminatory based on the application of longstanding nondiscrimination principles to the facts of the particular plan or coverage. Under these principles, issuers are not required to cover all medically necessary services. Moreover, we do not affirmatively require covered entities to cover any particular treatment, as long as the basis for exclusion is evidence-based and nondiscriminatory.

Thus, we reject commenters' suggestion that the rule require covered entities to provide coverage for all medically necessary health services related to gender transition regardless of the scope of their coverage for other conditions.

At the same time, the rule does require that a covered entity apply the same neutral, nondiscriminatory criteria that it uses for other conditions when the coverage determination is related to gender transition. Thus, if a covered entity covers certain types of elective procedures that are beyond those strictly identified as medically necessary or appropriate, it must apply the same standards to its coverage of comparable procedures related to gender transition. As a result, we decline to limit application of the rule by specifying that coverage for the health services addressed in § 92.207(b)(3)–(5) must be provided *only* when the services are medically necessary or medically appropriate.

With regard to § 92.207(b)(3), we recognize that not every health service that is typically or exclusively provided to individuals of one sex will be a health service that is appropriately provided to a transgender individual. Nothing in the rule would, for example, require an issuer to cover a traditional prostate exam for an individual who does not have a prostate, regardless of that individual's gender identity. However, the issuer must cover the health services that are appropriately provided to an individual by applying the same terms and conditions, regardless of an individual's sex assigned at birth, gender identity, or recorded gender.

We also clarify that the prohibition in § 92.207(b)(4) on categorically limiting coverage for all health services related to gender transition is intended to prevent issuers from placing categorical, arbitrary limitations or restrictions on coverage for all gender transition-related services, such as by singling out services related to gender transition for higher co-pays; it is not intended to prevent issuers from placing nondiscriminatory limitations or restrictions on coverage under the plan. We have revised the language of the provision to clarify that intent.

Comment: Some commenters requested that the final rule define ''health services related to gender transition.''

Response: We decline to include a definition of ''health services related to gender transition.'' OCR intends to interpret these services broadly and recognizes that health services related to gender transition may change as standards of medical care continue to evolve.

The range of transition-related services, which includes treatment for gender dysphoria, is not limited to surgical treatments and may include, but is not limited to, services such as

[263] 80 FR at 54189 *See e.g.,* World Professional Association for Transgender Health (WPATH), *Standards of Care for the Health of Transsexual, Transgender, and Gender-Nonconforming People* (7th ed. 2011), *http://www.wpath.org/uploaded_files/140/files/* Standards Of Care, V7 Full Book.pdf; Institute of Medicine of the National Academies, *The Health of Lesbian, Gay, Bisexual and Transgender People: Building a Foundation for Better Understanding (2011); www.nationalacademies.org/hmd/Reports/2011/The-Health-of-Lesbian-Gay-Bisexual-and-Transgender-People.aspx. See also* U.S. Dep't of Health & Human Servs., Departmental Appeals Bd., Appellate Division NCD 140.3, Docket No. A–13–87, Decision No. 2576, 22–24 (May 30, 2014), *http://www.hhs.gov/dab/decisions/dabdecisions/dab2576.pdf.*

[264] *See supra* discussion of the definition ''on the basis of sex'' under § 92.4.

[265] *See supra* discussion on including a religious exemption under § 92.2.

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hormone therapy and psychotherapy, which may occur over the lifetime of the individual. We believe the flexibility of the general language in the final rule best serves transgender individuals and covered entities.

Comment: Several commenters expressed concern that some issuers do not yet have the technological capability to avoid initial denials of coverage for sex-specific services for transgender individuals due to their computer systems flagging a mismatch between the gender of the individual identified at enrollment and the billing code associated with the biological sex that typically receives the health service. The commenters explained that issuers' computer systems accommodate only binary gender billing codes (*e.g.,* ''male'' or ''female'') and cannot accommodate descriptions of an enrollee's gender identity. Further, commenters observed that the Health Insurance Marketplace℠ enrollment application available through *HealthCare.gov* permits applicants to identify themselves only as male or female and does not currently allow applicants to denote their gender identity. These commenters noted that, as a result, qualified health plan issuers receive incomplete information about an enrollee's gender identity and biological sex. Moreover, these commenters requested that OCR clarify that an initial denial of a transgender enrollee's claim due to the discrepancy between the enrollee's recorded gender and the sex with which the health service is generally associated does not constitute discrimination if the enrollee is able to reverse the denial through an internal appeals process.

Response: As we indicated in the proposed rule,[266] we recognize that some issuers use computer systems that accommodate only binary gender billing codes that flag a gender mismatch for coverage of certain sex-specific services. We noted that such flagging, by itself, would not be impermissible if it does not result in a delay or denial of services or a claim for services. We reject, however, the commenters' suggestion that an initial denial of a transgender enrollee's claim should never be considered discriminatory as long as the enrollee is able to correct the denial through the internal appeals process. Requiring transgender enrollees to repeatedly go through the internal appeals process to obtain coverage for certain services would subject these enrollees to a burdensome process that is likely to delay their receipt of coverage.

Moreover, there are available interim methods for correcting initial coverage denials due to computer systems flagging a gender mismatch that issuers can use as their computer systems are updated. For instance, we understand that current billing code practices include general billing code modifiers that are used to identify situations in which issuers need to evaluate further claims that might otherwise be automatically rejected. As a result, issuers could advise health care providers to submit an existing billing code modifier along with a claim for sex-specific services for a transgender patient to flag the billing for the issuer's further review.[267] Issuers are free to develop another method of processing claims for sex-specific services by transgender individuals as long as the process is not overly burdensome and provides timely access to care. We note that commenters have raised concerns about the Health Insurance Marketplace℠ enrollment application and will address these concerns as appropriate.

Comment: One commenter recommended that we extend a safe harbor protection to issuers who demonstrate their good faith compliance with § 92.207(b)(3) for the time period during which they update their computer systems and operations to prevent inappropriate denials of coverage for sex-specific services for transgender enrollees.

Response: While we reject the commenter's recommendation of a safe harbor protection, OCR is willing to work with issuers to help identify potential interim solutions and to come into compliance.

Comment: One commenter requested clarification regarding whether an issuer may require transgender enrollees to provide additional information related to their biological sex to enable the issuer to override inappropriate denials of coverage for sex-specific health services. Another commenter inquired as to whether an issuer is permitted to request information about an applicant's biological sex on an insurance application form.

Response: We understand that, in some instances, a covered entity may need to ask transgender enrollees for additional information, including information related to their biological sex or sex assigned at birth, to facilitate overriding denials of coverage for sex-specific health services due to gender billing code mismatches in their computer systems. We clarify in this preamble that a covered entity is permitted to ask transgender enrollees to provide such additional information, as long as the covered entity does not unduly burden enrollees or make unreasonable inquiries that serve to delay their receipt of coverage. In addition, we clarify that it is permissible for a covered entity to request information about the biological sex of the applicant on an insurance application form to assist the covered entity in identifying the medical appropriateness of sex-specific health services, as long as the information requested is not used in a discriminatory manner, and the collection and use of the information is otherwise lawful and complies with applicable HIPAA privacy requirements.

Comment: Many commenters recommended revisions to § 92.207(d), which provides that nothing in this section is intended to determine, or restrict a covered entity from determining, whether a particular health service is medically necessary or otherwise meets applicable coverage requirements in any individual case. Some commenters requested that we revise this provision to ensure that a covered entity does not use criteria that lead to a discriminatory result in its medical necessity or coverage determinations. For example, some commenters suggested that we require covered entities to use certain treatment guidelines when determining medical necessity or coverage for transgender-related health services, such as those published by the WPATH. Conversely, other commenters expressed concern that Section 1557 may unduly restrict a covered entity's ability to evaluate medical necessity in its coverage determinations and requested clarification that covered entities are permitted to require certain treatment, such as mental health services for gender dysphoria, as part of their medical necessity or coverage determinations.

Response: We appreciate the concerns raised by commenters, but we are maintaining the language in § 92.207(d) without revision. OCR will not second-guess a covered entity's neutral

[266] 80 FR at 54189 n.75.

[267] The Medicare program already directs providers to use this approach. *See* Dep't of Health & Human Servs., Centers for Medicare & Medicaid Servs., Medicare Claims Processing Manual, Chapter 32, Transmittal 240: Special Instructions for Certain Claims with a Gender/Procedure Conflict *(last revised Jan. 20, 2015),* (directing providers to use an approved national billing code for sex-specific services for transgender patients to alert the contractor that it is not an error and to allow the claim to continue with normal processing), *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c32.pdf.*

nondiscriminatory application of evidence-based criteria used to make medical necessity or coverage determinations. Therefore, we refrain from adding any regulatory text that establishes or limits the criteria that covered entities may utilize when determining whether a health service is medically necessary or otherwise meets applicable coverage requirements. Nevertheless, we caution covered entities that, although § 92.207(d) does not dictate the criteria that a covered entity must use, a covered entity must use a nondiscriminatory process to determine whether a particular health service is medically necessary or otherwise meets applicable coverage requirements.

Summary of Regulatory Changes

For the reasons set forth in the proposed rule and considering the comments received, we are finalizing the provisions proposed in § 92.207 with minor technical revisions for clarity, to make our intent clear, and to ensure consistency with other parts of the final rule. We are making technical corrections to paragraphs (b)(1), (b)(3) and (b)(5) to add the word ''coverage'' where appropriate to reconcile with other parts of the rule. In (b)(1), we are making two modifications to the language. We are reconciling the usage of ''health-related insurance'' and ''other health-related coverage'' by adding ''related'' to those terms in (b)(1). We are also removing reference to ''enrollees'' as it unintentionally limited application of the paragraph. In (b)(2), we are replacing text that prohibited employing discriminatory marketing practices or benefit designs with text that prohibits having or implementing discriminatory marketing practices or benefit designs to clarify our intent that both having and applying discriminatory marketing practices and benefit design are prohibited. This clarification does not substantively modify the prohibition set forth in the proposed rule. In (b)(3), we are adding the words ''to a transgender individual'' for clarity, and are deleting the words ''by the plan or issuer'' for consistency with other parts of the rule. In (b)(4), we are revising the language to be clear that our intent was to prohibit categorical exclusions or limitations in both benefit design and administration; thus, we are replacing language prohibiting categorical or automatic exclusions or limitations of coverage with language that prohibits having or implementing a categorical exclusion or limitation of coverage. This clarification does not substantively modify the prohibition set forth in the proposed rule. In (b)(5), we also are revising the description of the prohibited actions to reconcile the language with other paragraphs in § 92.207(b).

Employer Liability for Discrimination in Employee Health Benefit Programs (§ 92.208)

In § 92.208, we proposed to address the application of Section 1557 to employers that offer health benefit programs to their employees. Under our proposed approach, where an entity that receives Federal financial assistance provides an employee health benefit program to its employees, it will be liable for discrimination in that employee health benefit program under this part only in three defined circumstances.[268] In paragraph (a), we proposed that where an employer is principally engaged in providing or administering health services or health coverage and receives Federal financial assistance, the employer would be subject to Section 1557 in its provision or administration of employee health benefit programs to its employees. Thus, if a hospital provides health benefits to its employees, it will be covered by Section 1557 not only for the services it offers to its patients or other beneficiaries but also for the health benefits it provides to its employees.[269]

In paragraph (b), we proposed that where an entity receives Federal financial assistance the primary objective of which is to fund an employee health benefit program, that entity's provision or administration of the health benefit program will be covered by Section 1557 regardless of the business in which the entity is engaged.

In paragraph (c), we proposed that an employer that is not principally engaged in providing or administering health services or health insurance coverage, but that operates a health program or activity (that is not an employee health benefit program) that receives Federal financial assistance, will be covered for its provision or administration of an employee health benefit program, but only with regard to employees in the health program or activity. Thus, we noted that when a State receives Federal financial assistance for its Medicaid program, the State will be governed by Section 1557 in the provision of employee health benefits for its Medicaid employees, but not for its transportation department employees, assuming no part of the State transportation department operates a health program or activity.

In summary, unless the primary purpose of the Federal financial assistance is to fund employee health benefits, we proposed that Section 1557 would not apply to an employer's provision of employee health benefits where the provision of those benefits is the only health program or activity operated by the employer.

We explained that absent the limitations in § 92.208, employers that receive Federal financial assistance for any purpose could be held liable for discrimination in the employee health benefit programs they provide or administer, even where those employers are not otherwise engaged in a health program or activity and where the use of Federal funds for employee health benefits is merely incidental to the purpose of the assistance. We noted that claims of discrimination in such benefits, brought against employers that do not operate other health programs or activities, could be better addressed under other applicable laws. For example, Title VII of the Civil Rights Act of 1964,[270] the ADA,[271] and the Age Discrimination in Employment Act[272] address claims that an employer has discriminated in the provision of benefits, including health benefits, to its employees.

We proposed to apply the same analysis of employer liability under Section 1557 whether the employee health benefit program is self-insured or fully-insured by the employer. We provided that where an employer that would otherwise be covered under this section creates a separate legal entity to administer its employee health benefit plan, the employer would continue to be liable for the nondiscriminatory provision of employee health benefits to its employees; the employer, as a recipient, may not, through contractual or other arrangements, discriminate on

[268] As reflected in § 92.101(a)(2) and as discussed in the preamble of the proposed rule, 80 FR at 54180, except as provided here, the proposed rule does not generally apply to discrimination by a covered entity against its own employees. Thus, the rule does not generally extend to hiring, firing, promotions, or terms and conditions of employment outside of those identified in § 92.208; such claims would continue to be brought under other laws, including Title VII, Title IX, Section 504, the ADA and the Age Discrimination in Employment Act, as appropriate.

[269] This approach is consistent with the basic principle underlying the rule and derived from longstanding civil rights interpretations: Where an entity that receives Federal financial assistance is principally engaged in providing or administering health services, health insurance coverage, or other health coverage, all of its operations are covered by Section 1557. *See* discussion *supra* of § 92.2.

[270] 42 U.S.C. 2000e–2000e–17.

[271] 42 U.S.C. 12101 *et seq.*

[272] 29 U.S.C. 621–634.

a prohibited basis against its employees.[273]

The comments and our responses regarding § 92.208 are set forth below.

Comment: One commenter expressed the view that while most churches or church boards providing employee health benefits through a church plan would not be covered under § 92.208, some might be covered under § 92.208(c). The commenter expressed the concern that churches that sponsor plans on behalf of numerous employers would not know whether any of those employers operated a health program or activity and received Federal financial assistance and thus would be required to either comply with Section 1557 requirements, even though most or all of the participating employers do not receive Federal financial assistance, or exclude the employer that receives Federal financial assistance from the plan.

Response: The comment reflects a misunderstanding about the application of § 92.208. This section of the regulation applies to employers, not to plan sponsors. In a church plan with multiple participating employers, the plan sponsor will be an entity other than the employer.[274] In this scenario, when an employer is covered under § 92.208(c) and the plan sponsor is a different entity that does not receive Federal financial assistance, it is the employer's obligation, not the plan sponsor's, to ensure that the benefits it provides to employees of its health program or activity do not violate Section 1557. We note that a plan sponsor will be separately covered under Section 1557 if it receives Federal financial assistance and is considered a covered entity under this rule.

Comment: One commenter expressed the view that treating a group health plan as an entity principally engaged in health coverage—and thereby subjecting all of its operations to Section 1557—undermines the limitations on employer liability under § 92.208. The commenter expressed concern that any employer that offers a self-insured group health plan to its employees would be accountable under Section 1557 for any discrimination by that group health plan.

Response: The commenter has misunderstood the relationship between the obligations of an employer and the application of the rule to a separate group health plan providing the employer's employee health benefit program. The fact that a group health plan is principally engaged in providing health services, health insurance coverage, or other health coverage, and therefore must comply with Section 1557 in all of its operations does not necessarily mean that an employer offering an employee health benefit program will be liable for a Section 1557 violation by the group health plan.[275] Employers will be liable under Section 1557 only under the circumstances set forth in 92.208.

Comment: Two commenters requested clarification of whether tax credits claimed by an employer that purchases health insurance coverage through the Small Business Health Options Program (SHOP) Marketplace[SM] and the health insurance plan purchased through a SHOP are covered by the rule.

Response: The tax credit to a small employer participating in the SHOP Marketplace[SM] is not considered Federal financial assistance from the Department under this rule because the tax credit is not administered by the Department.

Comment: Some comments suggested eliminating or drastically revising § 92.208 to make clear that all covered entities are covered in their provision of employee health benefits. One commenter suggested adding ''employee health benefits plan'' to the definition of ''health program or activity.'' Another asserted that § 92.208 is unnecessary because all group health plans are health programs or activities. One commenter recommended that OCR include in the regulatory text the substance of footnote 93 from the preamble of the proposed rule,[276] which clarifies that, regardless of whether an employer is liable for a discriminatory employee health benefit plan, an issuer that is a covered entity will be liable for discrimination in the health insurance coverage it offers to employers.

Response: We decline to eliminate or revise § 92.208 in the manner proposed by these commenters. As we explained in the preamble to the proposed rule,[277] absent the limitations in § 92.208, employers that receive Federal financial assistance for any purpose could be held liable for discrimination in the employee health benefits they provide or administer, even where those employers are not otherwise engaged in a health program or activity and where the use of Federal funds for employee health benefits is merely incidental to the purpose of the Federal assistance. We do not believe that Congress intended for Section 1557 to apply in such circumstances. We reiterate that issuers that receive Federal financial assistance and are principally engaged in providing or administering health services, health insurance coverage, or other health coverage are liable for the health insurance coverage offered to employers in connection with a group health plan.

Comment: Some commenters asked us to make clear that employer-provided benefits are covered by the rule even if the employer does not contribute to the cost of these benefits and the entire cost is borne by the employee or other beneficiary.

Response: The rule does not limit employer liability for discrimination in employee health benefit programs to those benefits for which the employer pays for part or all of the cost. Thus, if an employer would otherwise be liable for discrimination in an employee health benefit program, the fact that the employer did not pay for part of the cost of these benefits does not remove it from the reach of 92.208.

Summary of Regulatory Changes

For the reasons set forth in the proposed rule and considering the comments received, we are finalizing the provisions proposed in § 92.208 with minor technical revisions to ensure consistency with other parts of the final rule by adding the words ''or other health coverage.''

Nondiscrimination on the Basis of Association (§ 92.209)

In § 92.209 of the proposed rule, we specifically addressed discrimination

[273] By contrast, with regard to the liability of the legal entity that an employer creates to administer its employee health benefit plan, *i.e.,* a group health plan, we proposed to analyze questions related to the application of Section 1557 on a case-by-case basis consistent with longstanding principles of nondiscrimination law. We will ask, for example, whether the group health plan itself receives Federal financial assistance, such as through receipt of Medicare Part D payments. If it does not, we will evaluate the group health plan's relationship with the employer in assessing whether Section 1557 applies to the group health plan. 80 FR at 54191 n. 94. We noted that a group health plan may be a covered entity under this rule if the group health plan receives Federal financial assistance, as it operates a health program or activity by virtue of its provision or administration of the employee health benefit program. 80 FR at 54191 n. 93.

[274] Under ERISA, when a group health plan is established or maintained by a single employer, the plan sponsor is the employer, but when a group health plan is established or maintained by two or more employers, the plan sponsor is the association, committee, joint board of trustees, or other similar group of representatives of the parties who establishes or maintains the plan. In the case of a plan established or maintained by an employee organization, the plan sponsor is the employee organization. 29 U.S.C. 1002(16)(B).

[275] However, under employment discrimination laws like TItle VII, the employer may be liable for the health plan's discrimination. *See, e.g., Los Angeles Dept. of Water and Power* v. *Manhart*, 435 U.S. 702 (1978).

[276] 80 FR at 54191 n. 93.

[277] *Id.*

faced by an individual or an entity on the basis of the race, color, national origin, age, disability, or sex of an individual with whom the individual or entity is known or is believed to have a relationship or association. We explained that the language of Section 1557 makes clear that individuals may not be subject to any form of discrimination ''on the grounds prohibited by'' Title VI and other civil rights laws; the statute does not restrict that prohibition to discrimination based on the individual's own race, color, national origin, age, disability or sex. Further, we noted that a prohibition on associational discrimination is consistent with longstanding interpretations of existing anti-discrimination laws, whether the basis of discrimination is a characteristic of the harmed individual or an individual who is associated with the harmed individual.[278] A prohibition on associational discrimination is also consistent with the approach taken in the ADA, which includes a specific prohibition of discrimination based on association with an individual with a disability.[279]

The comments and our responses regarding § 92.209 are set forth below.

Comment: A few commenters recommended that OCR add the words ''or deter'' to the prohibition on associational discrimination, so that § 92.209 would read as follows: ''A covered entity shall not exclude or deter from participation in, deny the benefits of, or otherwise discriminate against an individual or entity in its health programs or activities on the basis of the race, color, national origin, age, disability, or sex of an individual with whom the individual or entity is known or believed to have a relationship or association.''

Response: We believe the regulatory text, as it is currently written, encompasses this approach. It is well established in civil rights law that deterrence is a form of exclusion.[280]

Comment: Several comments recommended that the rule state that unlawful discrimination based on association occurs when a provider is subject to adverse treatment because the provider is known or believed to furnish, refer or support services that are medically appropriate for, ordinarily available to, or otherwise associated with a patient population protected by Section 1557.

Response: To clarify, the rule prohibits covered entities from discriminating against any individual or entity on the basis of a relationship or association with a member of a protected class. The term ''individual or entity'' includes providers. Thus, for example, an issuer covered by the rule may not use the fact that a provider's clientele is primarily composed of individuals with limited English proficiency to disqualify an otherwise eligible and qualified provider from participation in the issuer's network; such a decision would discriminate against the provider on the basis of the provider's association with a national origin group. We believe that the regulatory text encompasses this approach.

Comment: Commenters asked OCR to clarify whether § 92.209's prohibition of discrimination on the basis of association prohibits discrimination against individuals in same sex relationships.

Response: We will interpret the language of § 92.209 consistent with our interpretation of the term ''on the basis of sex,'' as described in § 92.4 above.

Summary of Regulatory Changes

For the reasons set forth in the proposed rule and considering the comments received, we are finalizing the provisions proposed in § 92.209 as proposed without modification.

Subpart D—Procedures

Enforcement Mechanisms (§ 92.301)

In proposed § 92.301, we restated the language of Section 1557 regarding enforcement, which provides that the enforcement mechanisms under Title VI, Title IX, the Age Act, or Section 504 apply for violations of Section 1557. We noted that these existing enforcement mechanisms include requiring covered entities to keep records and submit compliance reports to OCR, conducting compliance reviews and complaint investigations, and providing technical assistance and guidance. We further noted that where noncompliance or threatened noncompliance cannot be corrected by informal means, the enforcement mechanisms provided for and available under the civil rights laws referenced in Section 1557 include suspension of, termination of, or refusal to grant or continue Federal financial assistance; referral to the Department of Justice with a recommendation to bring proceedings to enforce any rights of the United States; and any other means authorized by law.[281] In addition, we provided that based on the statutory language, a private right of action and damages for violations of Section 1557 are available to the same extent that such enforcement mechanisms are provided for and available under Title VI, Title IX, Section 504, or the Age Act with respect to recipients of Federal financial assistance. We further provided that a private right of action and damages are available for violations of Section 1557 by Title I entities. We invited comment on these positions.

The comments and our responses regarding § 92.301 are set forth below.

Comment: Many commenters requested that OCR clarify that all enforcement mechanisms available under the statutes listed in Section 1557 are available to each Section 1557 plaintiff, regardless of the plaintiff's protected class. Thus, for example, an individual could bring a race claim under the Age Act procedure and an age claim under the Title VI procedure.

Under this approach, given that the Age Act authorizes a private right of action for disparate impact claims, a private right of action would exist for disparate impact claims of discrimination on the basis of race, color, or national origin.

The commenters primarily rely on reasoning in *Rumble* v. *Fairview Health Services,*[282] in which the U.S. District Court for the District of Minnesota discussed the standards to be applied to Section 1557 private right of action claims and stated: ''It appears Congress intended to create a new, health-specific, anti-discrimination cause of action that is subject to a singular standard, regardless of plaintiff's protected class status. Reading Section 1557 otherwise would lead to an illogical result, as different enforcement

[278] *See, e.g., McGinest* v. *GTE Service Corp.,* 360 F. 3d 1103, 1118 (9th Cir. 2004), cert. denied, 552 U.S. 1180 2008) (holding that harassment of white employee who associated with African American employees was discrimination under Title VII); *Tetro* v. *Elliot Popham Pontiac,Oldsmobile, Buick & GMC Trucks Inc.,* 173 F.3d 988, 993–96 (6th Cir. 1999) (holding that white plaintiff with biracial child stated a claim under Title VII based on his own race because Title VII protects victims of discriminatory animus towards third persons with whom one associates); *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.'')

[279] 42 U.S.C. 12182(b)(1)(E)(Title III); 28 CFR 35.130(g) (Title II). *See generally http://www.eeoc.gov/facts/association_ada.html. Cf. Loeffler* v. *Staten Island Univ. Hosp.,* 582 F.3d 268, 277 (2d Cir. 2009) (permitting associational discrimination claim under Section 504); *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). *Cf.* Questions and Answers About the Americans with Disabilities Act's Association Provision.

[280] *See* discussion of § 92.101(a) *supra.*

[281] See 45 CFR 80.8(a).

[282] No. 14–CV–2037 2015 WL 1197415 (D. Minn. Mar. 16, 2015).

mechanisms and standards would apply to a Section 1557 plaintiff depending on whether plaintiff's claim is based on her race, sex, age, or disability. For example, it would not make sense for a Section 1557 plaintiff claiming race discrimination to be barred from bringing a claim using a disparate impact theory but then allow a Section 1557 plaintiff alleging disability discrimination to do so.'' [283]

Similarly, many commenters requested that the regulation clarify that a private right of action exists for disparate impact claims, arguing, like commenters discussed above, that all enforcement mechanisms should be available to all Section 1557 complainants. A few commenters requested that the availability of a private right of action be addressed in the final rule itself, rather than in the preamble.

Response: OCR interprets Section 1557 as authorizing a private right of action for claims of disparate impact discrimination on the basis of any of the criteria enumerated in the legislation. At the same time, OCR is incorporating its existing procedures for its administrative processing of complaints; thus, we will use our current processes to address age discrimination on the one hand and race, color, national origin, sex, or disability on the other hand. This approach will enable us to be consistent in our processing of complaints under OCR's other authorities in instances where we have concurrent jurisdiction under Section 1557 and the other civil rights laws it references. This approach is not intended to limit the availability of judicial enforcement mechanisms. We note as well that both the proposed and the final rule specify that a private right of action is available under Section 1557.

Comment: A few commenters suggested that the text of the regulation specifically mention the availability of compensatory damages. Although OCR discussed the availability of compensatory damages in the preamble of the NPRM, commenters recommended that explicit authorization for compensatory damages in the regulation would strengthen the enforcement of Section 1557.

Response: OCR has added a provision to § 92.301 to make clear in the regulation that compensatory damages are available. Our interpretation of Section 1557 as authorizing compensatory damages is consistent with our interpretations of Title VI, Section 504, and Title IX.

[283] *Id.* at *11.

Comment: Many commenters requested that OCR involve the Department of Justice (DOJ) in all Section 1557 investigations and compliance reviews where DOJ has concurrent jurisdiction, and that OCR refer cases to DOJ for litigation, where appropriate.

Response: Although OCR recognizes the importance of working with DOJ and other agencies, it would not be a productive use of resources to include DOJ in every case in which it has concurrent jurisdiction. OCR has been enforcing Section 1557 since it became effective in 2010 and continues to investigate and resolve Section 1557 cases over which it has jurisdiction. OCR involves DOJ in investigations where appropriate and will continue to do so. And, as § 92.209 makes clear, OCR has the authority to refer cases to DOJ for litigation where efforts at compliance have been unsuccessful.

Comment: Some commenters recommended that HHS agreements with State agencies and State contracts with Medicaid managed care organizations include nondiscrimination provisions that obligate the State agencies to ensure compliance with nondiscrimination requirements.

Response: OCR agrees that nondiscrimination provisions in contracts help covered entities to ensure that contractors do not discriminate against program beneficiaries. Although this rule does not require such provisions in contracts, OCR has worked with HHS entities to include such language in their contracts in the past, and OCR will continue to look for opportunities to promote compliance with civil rights laws through nondiscrimination provisions in contracting in the future.

Comment: Several commenters recommended that the regulatory text specifically provide that OCR will conduct compliance reviews and perform outreach. These commenters expressed concern that individual complaint resolution, as an enforcement mechanism, will be inadequate to achieve widespread compliance with the Section 1557 final rule.

Response: We recognize the need for OCR to employ the full range of enforcement tools in order to ensure compliance with the law, and we intend to continue in our robust enforcement of Section 1557. We do not believe that any changes to regulatory text are necessary, since the rule contemplates and authorizes the suite of enforcement mechanisms that OCR has long employed.

Comment: Some commenters recommended that HHS, and not States, should be the primary enforcement agency for benefit design issues. These commenters asserted that State enforcement would lead to inconsistent results.

Response: OCR is responsible for enforcement with respect to benefit design issues under Section 1557. States have an important role in ensuring compliance with nondiscrimination requirements respecting insurance, including benefit design, under CMS regulations and applicable State laws. It is beyond the scope of this rulemaking to change State obligations under those laws.

Comment: Some commenters recommended that OCR be required to publish the outcomes of all resolved Section 1557 complaints and statistics regarding Section 1557 complaints received by OCR.

Response: We decline to accept this recommendation, but OCR will continue to include information and corrective action plans and resolution agreements on the OCR Web site.

Comment: Some commenters recommended that OCR allow at least a one-year period with no administrative sanctions if a covered entity can demonstrate good faith compliance. These commenters suggested that this approach will promote compliance while covered entities, OCR, and consumers become familiar with the requirements of the regulation.

Response: We appreciate the commenters' recommendation, but we decline to accept it because, while good faith is relevant under certain CMS regulations with which covered entities may be familiar, courts have not treated good faith as a consideration in assessing whether a covered entity is in compliance with the civil rights laws referenced in Section 1557. We are retaining this principle in interpreting whether a covered entity is in compliance with Section 1557. That said, OCR has the authority and discretion to consider a range of factors when reviewing cases and determining appropriate remedies, including consideration of steps taken by covered entities to ensure compliance with the law, compliance with other Federal regulations regarding the issue, timeframes for implementation of corrective action and resources to facilitate compliance.

Comment: Some commenters suggested that the final rule mandate training for employees of entities required to comply with the requirements of Section 1557.

Response: Although OCR encourages covered entities to train employees on compliance with Section 1557 periodically, OCR does not believe it is necessary for the final rule to mandate training. However, to facilitate training that covered entities choose to provide, we are preparing and will make available a training curriculum for their use in advance of the effective date of the rule. We also expect to engage in outreach and technical assistance to promote understanding of and compliance with the final rule.

Comment: Several commenters stated that the final rule should require OCR to perform unannounced, onsite reviews of covered entities to ensure compliance with Section 1557.

Response: While OCR may consider performing unannounced, onsite reviews where appropriate, OCR does not believe it is necessary to include a requirement to do so in the final rule.

Comment: Some commenters recommended that the regulation permit class actions and third party complaints in court. Other commenters recommended that the regulation provide for the availability of attorneys' fees in successful private suits. These commenters pointed out that many individuals who are subject to discrimination will be unable to afford a retainer for an attorney. Some commenters recommended that suits be allowed only in the State where the Marketplace℠ is located, not any Federal district court in a district in which a complainant resides.

Response: Although these issues are outside the scope of this regulation, nothing in Section 1557 changes the laws that otherwise would govern eligibility for attorneys' fees, including the Civil Rights Attorney's Fees Award Act of 1976,[284] laws that otherwise would govern venue,[285] or laws that otherwise would govern initiation of class action lawsuits.[286]

Comment: Some commenters suggested that the regulation prohibit issuers from including clauses requiring mandatory binding arbitration of Section 1557 complaints. These commenters asserted that such arbitration is unfair to consumers.

Response: We decline to accept the commenters' suggestion because it is outside the scope of this regulation.

Summary of Regulatory Changes

For the reasons set forth above and in the proposed rule and considering the comments received, we have revised § 92.301 to re-designate existing text as § 92.301(a) and add a new subsection (b) stating that compensatory damages for violations of Section 1557 are available in administrative and judicial actions, as they are under authorities referenced in Section 1557.

Procedures for Health Programs and Activities Conducted by Recipients and State-Based Marketplaces (§ 92.302)

In § 92.302, we proposed the procedures that will apply to enforcement of Section 1557 in health programs and activities conducted by recipients and State-based Marketplaces. We noted that the administrative procedures provided for and available under Title VI are found in the regulation implementing Title VI.[287] We explained that these administrative procedures are incorporated into the regulation implementing Title IX[288] and Section 504 with respect to recipients.[289] In paragraph (a), we proposed to incorporate these procedures into Section 1557 with respect to race, color, national origin, sex, and disability discrimination.

We also explained that the administrative procedures provided for and available under the Age Act are found in the regulation implementing the Age Act.[290] In paragraph (b), we proposed to incorporate these procedures into Section 1557 with respect to age discrimination.

In paragraph (c), we provided that an individual may bring a civil action in a United States District Court in which a recipient or State-based Marketplace℠ is located or does business, as provided for and available under Section 1557.

The comments and our responses regarding § 92.302 are set forth below.

Comment: A few commenters asserted that any enforcement provisions that apply to Health Insurance Marketplaces should apply whether the Marketplace℠ is operated by the State or Federal government.

Response: OCR declines to incorporate the commenter's request that Marketplaces operated by the Federal government be subject to the same enforcement provisions as Marketplaces operated by State governments. Under the regulations implementing Section 504, federally assisted programs, including federally assisted programs operated by States, and federally conducted programs are subject to separate enforcement procedures.[291] OCR believes that this approach has worked successfully in the past and has decided to retain separate procedures for federally conducted health programs and activities, including Health Insurance Marketplaces operated by HHS, and other health programs and activities, including Health Insurance Marketplaces operated by States.

Comment: Some commenters suggested that OCR use the enforcement scheme of Title VI for all discrimination under Section 1557. By contrast, some commenters recommended that the final rule should require mediation for all Section 1557 complaints. A few commenters requested that OCR require exhaustion of administrative remedies before individuals could pursue a private right of action.

Response: OCR declines to adopt these recommendations. OCR has decided to retain administrative procedures and application of the procedures consistent with OCR's existing procedures for complaints. Mediation and exhaustion of administrative remedies will still be required for age discrimination allegations in complaints, but not for allegations of other covered types of discrimination.

Summary of Regulatory Changes

For the reasons set forth in the proposed rule and considering the comments received, we are finalizing the provisions proposed in § 92.302 with two modifications. As addressed previously in the discussion of the comments on § 92.5 (Assurances), the text that was previously found at § 92.302(c) has been moved to § 92.302(d), and § 92.302(c) now clarifies OCR's ability to initiate enforcement procedures where a recipient or State-based Marketplace℠ fails to provide OCR with requested information.

Procedures for Health Programs and Activities Administered by the Department (§ 92.303)

In the proposed rule, we noted that Section 1557 expressly states that the enforcement mechanisms provided for and available under Title VI, Title IX, Section 504, or the Age Act shall apply for purposes of violations of Section 1557. We also noted that the administrative procedures provided for and available under Section 504—the only one of these statutes that applies to federally conducted, as well as federally assisted, programs—for programs and activities administered by the

[284] 42 U.S.C. 1988.

[285] *See, e.g.,* 28 U.S.C. 1391.

[286] *See, e.g.,* 28 U.S.C. 1332.

[287] 45 CFR 80.6–.11; 45 CFR pt. 81.

[288] 45 CFR 86.71.

[289] 45 CFR 84.61.

[290] 45 CFR 91.41–.50.

[291] *Compare* 45 CFR 84.61 *with* 45 CFR 85.61–.62.

Department are found in the regulation implementing Section 504.[292] We provided that these procedures shall apply with respect to complaints and compliance reviews of health programs or activities administered by the Department, including the Federally-facilitated Marketplaces, concerning discrimination on the basis of race, color, national origin, sex, age, or disability.

In the proposed rule, we proposed to add two provisions that are not found in Section 504 enforcement procedures for programs conducted by the Department. We proposed that the first provision, which reflects OCR's practice under Section 504 and mirrors similar requirements under the Title VI regulation with regard to access to information, is designed to ensure that OCR has the ability to obtain all of the relevant information needed to investigate a complaint or determine compliance in a particular health program or activity administered by the Department.

We further proposed language prohibiting the Department, including Federally-facilitated Marketplaces, from retaliating against any individual for the purpose of interfering with any right or privilege under Section 1557 or the proposed rule or because the individual has made a complaint, testified, assisted, or participated in any manner in an investigation, proceeding, or hearing under Section 1557 or this proposed rule. We explained that Section 504 of the Rehabilitation Act, to which the Department is already subject, provides that the procedures, rights, and remedies under Title VI are available to any individual aggrieved by an act or failure to act by any recipient of Federal financial assistance or Federal provider of such financial assistance under Section 504. Thus, we noted that the prohibition on retaliation under Title VI[293] would apply to the Department under Section 504. We noted that the retaliation provision in the proposed rule is simply an extension of this existing prohibition. We further noted that this provision is also in accordance with a similar requirement for recipients under the Title VI regulations. The Department should hold itself to the same standards to which it holds recipients of Federal financial assistance.[294]

Summary of Regulatory Changes

We did not receive any significant comments regarding § 92.303. For the reasons set forth in the proposed rule, we are finalizing the provisions proposed in § 92.303 without modification.

Information Collection Requirements

The notice of proposed rulemaking called for new collections of information under the Paperwork Reduction Act of 1995.[295] As defined in implementing regulations,[296] ''collection of information'' comprises reporting, recordkeeping, monitoring, posting, labeling and other similar actions. In this section, we first identify and describe the entities that must collect the information, and then we provide an estimate of the total annual burden. The estimate covers the employees' time for reviewing and posting the collections required.

The final rule calls for the same collections of information as the notice of proposed rulemaking, with one addition: The cost estimates for covered entities to develop and implement a language access plan, should the covered entities choose to do so, given that development and implementation of a language access plan is one of the factors that the Director will consider, if relevant, in assessing whether a covered entity has met its obligation to take reasonable steps to provide meaningful access to each individual with limited English proficiency.

Title: Nondiscrimination in Health Programs and Activities.

OMB Control Number: XXXX–XXXX.

Summary of the Collection of Information: The final rule estimates four categories of information collection: (1) Submission of an assurance of compliance form, per § 92.5; (2) posting of a nondiscrimination notice and posting of taglines, under § 92.8; (3) development and implementation of a language access plan, anticipated per § 92.201; and (4) designation of a compliance coordinator and adoption of grievance procedures for covered entities with 15 or more employees, per § 92.7. Each category is described in the following analysis.

Under the final rule, each entity applying for Federal financial assistance, each health insurance issuer seeking certification to participate in a Marketplace℠, and each entity seeking approval to operate a Title I entity is required to submit an assurance that its health programs and activities will be operated in compliance with Section 1557.

In addition, each covered entity subject to the final rule is required to post a notice of individuals' civil rights and covered entities' obligations, including acknowledging that the covered entity provides auxiliary aids and services, free of charge, in a timely manner, to individuals with disabilities, when such aids and services are necessary to provide an individual with a disability an equal opportunity to benefit from the entity's health programs or activities; and language assistance services, free of charge, in a timely manner, to individuals with limited English proficiency, when those services are necessary to provide an individual with limited English proficiency meaningful access to a covered entity's health programs or activities. Furthermore, each covered entity is required to post taglines in the top 15 languages spoken by individuals with limited English proficiency by relevant State or States, informing individuals with limited English proficiency that language assistance services are available.

Although the final rule does not require covered entities to develop a language access plan, the development and implementation of a language access plan is one factor that the Director will consider when evaluating a covered entity's compliance with this rule. We anticipate that some proportion of covered entities will develop and implement a language access plan following issuance of the rule.

Additionally, each covered entity that employs 15 or more persons is required to adopt grievance procedures that incorporate appropriate due process standards and that provide for the prompt and equitable resolution of grievances alleging any action that would be prohibited by Section 1557. Each covered entity is also required to designate at least one individual to coordinate its efforts to comply with and carry out its responsibilities under Section 1557, including the investigation of any grievance communicated to it alleging noncompliance with Section 1557.

Need for Information: The requirement that every entity applying for Federal financial assistance, seeking certification to participate in a Health Insurance Marketplace℠, or seeking approval to operate a Title I entity, submit an assurance of compliance, is similar to the current regulatory

[292] 45 CFR 85.61–.62.

[293] 45 CFR 80.7(e).

[294] Further, as the U.S. Supreme Court observed in *Jackson* v. *Birmingham Bd. of Educ.,* 544 U.S. 167, 180 (2005), protecting individuals from discrimination under Title IX ''would be difficult, if not impossible, to achieve if persons who complain about sex discrimination did not have effective protection against retaliation.'' (citing to the brief of the United States as Amicus Curiae). The same principle is true for discrimination under Section 1557.

[295] 44 U.S.C. 3501–3520.

[296] 5 CFR 1320.3(c).

requirements under Title VI,[297] Section 504,[298] and the Age Act.[299] These requirements protect individuals by assuring that covered entities will comply with all applicable nondiscrimination statutes and their implementing regulations.

The posting of a notice of individuals' rights and covered entities' obligations and the posting of taglines in the top 15 languages spoken by individuals with limited English proficiency by relevant State or States are necessary to ensure that individuals are aware of their protections under the law, and are grounded in OCR's experience that failures of communication based on the absence of auxiliary aids and services and language assistance services raise particularly significant compliance concerns under Section 1557, as well as Section 504 and Title VI.

The development and implementation of a language access plan helps ensure meaningful access to persons with limited English proficiency to a covered entity's health programs and activities. While Title VI has long required covered entities to take reasonable steps to provide persons with limited English proficiency meaningful access, the addition of a language access plan brings specificity and increased probability of implementation of the requirement. Although the final rule does not require development and implementation of a language access plan, covered entities may choose to develop and implement a language access plan because the Director will consider, if relevant, the language access plan as one factor when assessing a covered entity's compliance with this rule.

The requirements that every covered entity that employs 15 or more persons adopt grievance procedures and designate at least one individual to coordinate its efforts to comply with and carry out its responsibilities under Section 1557 are similar to requirements included in the Title IX and Section 504 implementing regulations. Through its case investigation experience, OCR has observed that the presence of a coordinator and grievance procedures helps to bring concerns to prompt resolution within an entity, leading to lower compliance costs and more efficient outcomes.

Use of Information: OCR will use this information to ensure covered entities' adherence to the statutory requirements imposed under Section 1557 and this final rule. OCR will enforce the requirements by verifying during investigations of covered entities that an entity has submitted an assurance of compliance and posted the notice and taglines and, for each covered entity that employs 15 or more persons, that an individual has been designated to coordinate its compliance efforts and that appropriate grievance procedures have been adopted, as required.

Description of the Respondents: The respondents are: the Department, each entity that operates a health program or activity, any part of which receives Federal financial assistance, and each entity established under Title I of the ACA that administers a health program or activity. These include such entities as hospitals, home health agencies, community mental health centers, skilled nursing facilities, and health insurance issuers.

Number of Respondents: The number of respondents is estimated to include the 275,002 covered entities affected by the final rule.

Burden of Response: Because the Department provides the assurance of compliance and the final rule provides a sample Notice, sample taglines in 64 languages, and sample grievance procedures, the burden on respondents is minimal. Additionally, because all recipients of Federal financial assistance with 15 or more employees are already expected under other laws to have in place grievance procedures and a designated individual to coordinate their compliance responsibilities, the burden to comply with this requirement will be minimal for most respondents.

The requirement to sign and submit an assurance of compliance exists under other civil rights regulations (Title VI, Section 504, Title IX, the Age Act), and since the Department provides a copy of the Assurance of Compliance form to covered entities, OCR believes this requirement adds no extra burden. OCR believes that the time, effort, and financial resources necessary to comply with this requirement are considered part of the usual and customary business practice and would be incurred by covered entities during their ordinary course of business.

OCR estimates that the burden for responding to the proposed notice requirement is an average of 17 minutes to download and post the notice and that the burden to download and post taglines in the top 15 languages by relevant State or States is also an average of 17 minutes, for a burden total of 34 minutes on average at each of the 405,534 affected establishments (associated with the affected covered entities) in the first year following publication of the final rule. (See Regulatory Impact Analysis, II. Costs, B.2.for a more detailed explanation of the differences between ''firm'' and ''establishment.'') We estimate that administrative or clerical support personnel would perform these functions. Based on the wage rate for a Clerical Support Worker ($15.52) we estimate the annual burden for these two requirements to be approximately $7.1 million after adjusting for overhead and benefits by adjusting the wage rate upward by 100%.

OCR estimates that the burden for developing a language access plan is approximately three hours of medical and health service manager staff time in the first year, and an average of one hour of medical and health service manager staff time per year to update the plan in subsequent years. The value of an hour of time for people in this occupation category, after adjusting for overhead and benefits, is estimated to be $89.24 based on Bureau of Labor Statistics (BLS) data. As discussed later in this analysis, we estimate that approximately 135,000 entities will develop and implement language access plans, as part of the requirement to take reasonable steps to provide meaningful communication with persons with limited English proficiency. These assumptions imply that the total cost of the development of language access plans will be approximately $36.0 million (269,141 entities × 50% of entities × 3 hours per entity × $89.24 per hour) in the first year and approximately $12.0 million (269,141 entities × 50% of entities × 1 hour per entity × $89.24 per hour) per year in subsequent years.

Regarding the requirement that every covered entity that employs 15 or more persons adopt grievance procedures and designate at least one individual to coordinate its efforts to comply with and carry out its responsibilities under Section 1557, based on OCR's complaint workload increase since the enactment of Section 1557, we anticipate that within the first five years following the rule's enactment, complaints will increase approximately 0.5% in the first year, 0.75% in the second year, and 1% in years three through five, but eventually will drop off as covered entities modify their policies and practices in response to this final rule. We estimate that medical and health service managers will handle the grievances, and that a 1% increase in complaints will require 1% of an FTE at each covered entity. Using the annual wage rate for medical and health service managers ($103,680), adjusting for fringe benefits and overhead, and multiplying by the 41,250 entities

[297] 45 CFR 80.4(a).

[298] 45 CFR 80.5.

[299] 45 CFR 91.33.

affected by this requirement, we estimate the annual burden for this requirement to be approximately $42.8 million in year one, $64.2 million in year two, and $85.5 million for each year in years three, four, and five following publication.

Thus, the total estimated annual burden cost for the proposed information collection requirements will be approximately $86.0 million in the first year, $76.2 million in the second year, and $97.5 million per year in years three through five following publication of the final rule.

We asked for public comment on the proposed information collection to help us determine:

1. Whether the proposed collection of information is necessary for the proper performance of the functions of OCR, including whether the information will have practical utility;

2. The accuracy of the estimated burden associated with the proposed collection of information;

3. How the quality, utility, and clarity of the information to be collected may be enhanced; and

4. How the burden of complying with the proposed collection of information may be minimized, including through the application of automated collection techniques or other forms of information technology.

We received no comments with specific data in response to numbers one, two, or three above. With regard to question four, we received comments asking that the proposed collection of information be minimized and stating that it is burdensome for covered entities to develop notices to put in several locations in all their facilities. OCR responded by proposing that OCR develop a model notice of important information and model taglines, to minimize the burden on covered entities. The new cost analysis is included above, in this Information Collection section, as well as in the Regulatory Impact Analysis.

Regulatory Impact Analysis

I. Introduction

A. Executive Orders 12866 and 13563

Executive Order 12866 [300] directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects; distributive impacts; and equity). Executive Order 13563 [301] is supplemental to and reaffirms the principles, structures, and definitions governing regulatory review as established in Executive Order 12866. OMB has determined that this final rule is a ''significant regulatory action'' under Executive Order 12866. Accordingly, OMB reviewed this final rule.

In general, we received few comments with regard to the Regulatory Impact Analysis (RIA), and thus the analysis in the final rule remains fairly similar to the proposed rule, although there are some changes. The comments will be addressed in each section below, as appropriate.

B. The Need for a Regulation

Section 1557 of the ACA 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.[302] The Secretary of the Department is authorized to promulgate regulations to implement Section 1557 under the statute and 5 U.S.C. 301. The purpose of this regulatory action is to implement Section 1557 of the ACA.[303]

One of the central aims of the ACA is to expand access to health care and health coverage for all individuals. Equal access for all individuals without discrimination is essential to achieving this goal. Discrimination in the health care context can often lead to poor and inadequate health care or health insurance or other coverage for individuals and exacerbate existing health disparities in underserved communities. Individuals who have experienced discrimination in the health care context often postpone or do not seek needed health care; individuals who are subject to discrimination are denied opportunities to obtain health care services provided to others, with resulting adverse effects on their health status. Moreover, discrimination in health care can lead to poor and ineffective distribution of health care resources, as needed resources fail to reach many who need them. The result is a marketplace comprised of higher medical costs due to delayed treatment, lost wages, lost productivity, and the misuse of people's talent and energy.[304]

We received comments suggesting that we consider either writing a more informative than prescriptive regulation or delaying the regulation. The Department's current experience, however, points to the importance of a regulation that is prescriptive in the sense that it provides concrete guidance. The Department continues to receive many complaints of discrimination and continues to provide technical assistance and outreach in order to promote compliance. In addition, the majority of the comments from the public in response to the proposed rule favored speedy issuance of a strong regulation.

To help address the issues of nondiscrimination in health programs and activities, this regulation seeks to clarify the application of the nondiscrimination provision in the ACA to any health program or activity receiving Federal financial assistance from or administered by HHS or any entity established under Title I. Such clarity will promote understanding of and compliance with Section 1557 by covered entities and the ability of individuals to assert and protect their rights under the law.

In addition, Executive Order 13563 directs Federal agencies to improve regulations and regulatory review by promoting the simplification and harmonization of regulations and to ensure that regulations are accessible, consistent, and easy to understand. Regulations implementing the civil rights laws referenced in Section 1557 contain certain inconsistencies across common areas and subject matters, reflecting, among other things, differences in time and experience when the regulations were issued. The regulation attempts to harmonize these variations where possible.

We received comments asking that the regulation be written in plain language. The approach we adopt in the final rule is to simplify and make uniform, consistent, and easy to understand the various nondiscrimination requirements

[300] Exec. Order No. 12866, 58 FR 51735 (1993).

[301] Exec. Order No. 13563, 76 FR 3821 (2011).

[302] Patient Protection and Affordable Care Act, Public Law 111–148, 1557, 124 Stat. 119, 260, (2010) (codified at 42 U.S.C. 18116).

[303] 42 U.S.C. 18116(c).

[304] Kristen Suthers, American Public Health Association: Issue Brief: Evaluating the Economic Causes and Consequences of Racial and Health Disparities (2008), *http://hospitals.unm.edu/dei/documents/eval_cause_conse_apha.pdf;* Timothy Waldmann, Urban Institute, Estimating the Cost of Racial and Ethnic Health Disparities (2009), *http://www.urban.org/sites/default/files/alfresco/publication-pdfs/411962-Estimating-the-Cost-of-Racial-and-Ethnic-Health-Disparities.PDF;* LaVera M. Crawley, David K. Ahn, and Marilyn A. Winkleby, Perceived Medical Discrimination and Cancer Screening Behaviors of Racial and Ethnic Minority Adults, 17(8), Cancer Epidemiol Biomarkers Prev., 1937–1944 (2008), *http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2526181/.*

and rights available under Section 1557, as appropriate.

The analysis that follows is similar to the analysis set forth in the proposed rule, except as specified in each of the sections that follow.

C. Examples of Covered Entities and Health Programs or Activities Under the Final Regulation

This final rule applies to any entity that has a health program or activity, any part of which receives Federal financial assistance from the Department, any health program or activity administered by the Department, or any health program or activity administered by an entity created under Title I of the ACA. The following are examples of covered entities as well as health programs or activities under the final rule.

1. Examples of Covered Entities With a Health Program or Activity, Any Part of Which Receives Federal Financial Assistance From the Department

This Department, through agencies such as the Health Resources and Services Administration (HRSA), the Substance Abuse and Mental Health Services Administration (SAMHSA), the Centers for Disease Control and Prevention (CDC), and the Centers for Medicare and Medicaid Services (CMS), provides Federal financial assistance through various mechanisms to health programs and activities of local governments, State governments, and the private sector. An entity may receive Federal financial assistance from more than one component in the Department. For instance, federally qualified health centers receive Federal financial assistance from CMS by participating in the Medicare or Medicaid programs and also receive Federal financial assistance from HRSA through grant awards. Because more than one funding stream may provide Federal financial assistance to an entity, the examples we provide may not uniquely receive Federal financial assistance from only one HHS component.

(1) Entities receiving Federal financial assistance through their participation in Medicare (excluding Medicare Part B) or Medicaid (about 133,343 facilities).[305] Examples of these entities include:

Hospitals (includes short-term, rehabilitation, psychiatric, and long-term)
Skilled nursing facilities/nursing facilities—facility-based
Skilled nursing facilities/nursing facilities—freestanding
Home health agencies
Physical therapy/speech pathology programs
End stage renal disease dialysis centers
Intermediate care facilities for individuals with intellectual disabilities
Rural health clinics
Physical therapy—independent practice
Comprehensive outpatient rehabilitation facilities
Ambulatory surgical centers
Hospices
Organ procurement organizations
Community mental health centers
Federally qualified health centers

(2) Laboratories that are hospital-based, office-based, or freestanding that receive Federal financial assistance through Medicaid payments for covered laboratory tests (about 445,657 laboratories with Clinical Laboratory Improvement Act certification).

(3) Community health centers receiving Federal financial assistance through grant awards from HRSA (1,300 community health centers).[306]

(4) Health-related schools in the United States and other health education entities receiving Federal financial assistance through grant awards to support 40 health professional training programs that include oral health, behavioral health, medicine, geriatric, and physician's assistant programs.[307]

(5) State Medicaid agencies receiving Federal financial assistance from CMS to operate CHIP (includes every State, the District of Columbia, Puerto Rico, Guam, the Northern Marianas, U.S. Virgin Islands, and American Samoa).

(6) State public health agencies receiving Federal financial assistance from CDC, SAMHSA, and other HHS components (includes each State, the District of Columbia, Puerto Rico, Guam, the Northern Marianas, U.S. Virgin Islands, and American Samoa).

(7) Qualified health plan issuers receiving Federal financial assistance through advance payments of premium tax credits and cost-sharing reductions (which include at least the 169 health insurance issuers in the Federally-facilitated Marketplaces receiving Federal financial assistance through advance payments of premium tax credits and cost sharing reductions and at least 11 issuers operating in the State-Based Marketplaces that we were able to identify).[308]

(8) Physicians receiving Federal financial assistance through Medicaid payments, ''meaningful use'' payments, and other sources, but not Medicare Part B payments, as the Department does not consider Medicare Part B payments to physicians to be Federal financial assistance. The Medicare Access and CHIP Reauthorization Act amended Section 1848 of the Act to sunset ''meaningful use'' payment adjustments for Medicare physicians after the 2018 payment adjustment.

In the proposed rule, we estimated that the regulation would likely cover almost all licensed physicians because they accept Federal financial assistance from sources other than Medicare Part B. We noted that most physicians participate in more than one Federal, State, or local health program that receives Federal financial assistance, and many practice in several different settings, *e.g.,* they may practice in a hospital but also practice privately and develop nursing home plans of care at the local nursing home. We noted 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.[309]

In the proposed rule, we provided our best estimate of the number of physicians receiving Federal financial assistance by analyzing and comparing different data sources and drawing conclusions from this analysis. We noted that, based on 2010 Medicaid Statistical Information System data, about 614,000 physicians accept Medicaid payments and are covered under Section 1557 as a result.[310] This figure represents about 72% of licensed physicians in the United States when compared to the 850,000 in 2010.[311] In addition, we noted that physicians receiving Federal payments from non-Part B Medicare sources would also come under Section 1557.[312]

Earlier, before issuing the proposed rule, we identified several grant programs from various Department

[305] U.S. Dep't of Health & Human Servs., Center for Medicare & Medicaid Servs., CMS Provider of Service file, June 2014, *https://www.cms.gov/Research-Statistics-Data-and-Systems/Files-for-Order/NonIdentifiableDataFiles/ProviderofServicesFile.html.*

[306] U.S. Dep't of Health & Human Servs., Health Res. & Servs. Admin., Justification of Estimates for Appropriation Committee For Fiscal Year 2016, 53, *http://www.hrsa.gov/about/budget/budgetjustification2016.pdf.*

[307] *Id.* at 69.

[308] Qualified Health Plans Landscape Individual Market Medical, Data.HealthCare.gov (2015), *https://data.healthcare.gov/dataset/2015-QHP-Landscape-Individual-Market-Medical/mp8z-jtg7* (last visited May 3, 2016).

[309] 80 FR at 54195.

[310] John Holahan and Irene Headen, Kaiser Commission on Medicaid and the Uninsured, Medicaid Coverage and Spending in Health Reform: National and State-by-State Results for Adults at or Below 133% FPL (2010), *http://kff.org/health-reform/report/report-and-briefing-on-medicaid-coverage-and/.* Estimates are based on data from FY 2010 Medicaid Statistical Information System.

[311] Aaron Young, Humayun J. Chaudhry, Jon V. Thomas, & Michael Dugan, *A Census of Actively Licensed Physicians in the United States, 2012,* 99 no.2 J. Med. Reg. 11 (2013), *https://www.fsmb.org/Media/Default/PDF/Census/census.pdf.*

[312] 80 FR at 54195.

agencies that fund a variety of health programs in which physicians participate and thus come under Section 1557, such as the National Health Service Corps, HRSA-funded community health centers, programs receiving National Institutes of Health (NIH) research grants, and SAMHSA-funded programs. In the proposed rule, we noted that physicians participating in a CMS gain-sharing demonstration project who receive gain-sharing payments would be covered under Section 1557 even if they did not participate in Medicare and Medicaid or any other health program or activity that receives Federal financial assistance. We also noted that there will be duplication and overlap with physicians who accept Medicaid or Medicare meaningful use payments, or other payments apart from Medicare Part B payments. Nevertheless, we noted that at least some of these physicians add to the total number of physicians reached under Section 1557 because some of them are not duplicates and do not accept Medicaid or Medicare meaningful use payments. We noted that although we do not have an exact number, adding these physicians may bring the total participating in Federal programs other than Medicare Part B to over 900,000.

In the proposed rule, when we compared the upper bound estimated number of physicians participating in Federal programs other than Medicare Part B (over 900,000) to the number of licensed physicians counted in HRSA's Area Health Resource File (approximately 890,000), we concluded that almost all practicing physicians in the United States are reached by Section 1557 because they accept some form of Federal remuneration or reimbursement apart from Medicare Part B.[313]

We invited the public to submit information regarding physician participation in health programs and activities that receive Federal financial assistance. We received no comments that would change the estimates that we provided; thus, the analysis in this final rule includes the same numbers of physicians as in the proposed rule.

2. Examples of Health Programs or Activities Conducted by the Department

This final rule applies to the Department's health programs and activities, such as those administered by CMS, HRSA, CDC, Indian Health Service (IHS), and SAMHSA. Examples include the IHS tribal hospitals and clinics operated by the Department and the National Health Service Corps.

3. Examples of Entities Established Under Title I of the ACA

This final rule applies to entities established under Title I of the ACA. According to the CMS Center for Consumer Information and Insurance Oversight (CCIIO), there are Health Insurance Marketplaces covering 51 jurisdictions: (17 State-based-Marketplaces and 34 Federally-facilitated Marketplaces). The final rule covers these Health Insurance Marketplaces.

II. Costs

It is important to recognize that this final rule, except in the area of sex discrimination, applies pre-existing requirements in Federal civil rights laws to various entities, the great majority of which have been covered by these requirements for years. Because Section 1557 restates existing requirements, we do not anticipate that covered entities will undertake new actions or bear any additional costs in response to the issuance of the regulation with respect to the prohibition of race, color, national origin, age, or disability discrimination, except with respect to the voluntary development of a language access plan. However, we also note that the prohibition of sex discrimination is new for many covered entities, and we anticipate that the enactment of the regulation will result in changes in action and behavior by covered entities to comply with this new prohibition. We note that some of these actions will impose costs and others will not.

Section 1557 applies to the Health Insurance Marketplaces. We note that these entities, along with the qualified health plan issuers participating in the Health Insurance Marketplaces, are already covered by regulations issued by CMS that prohibit discrimination on the basis of race, color, national origin, sex, gender identity, sexual orientation, age, or disability. Thus, we note that the impact of Section 1557 on these entities is limited.

We received a few comments that indicated that the costs of compliance may be more than anticipated in the proposed rule. We have revised the analysis in this final rule based upon the comments and upon an updated statistical review of the health programs and activities.

The following regulatory analysis examines the costs and benefits that are attributable to this regulation only.

We first analyze the costs we expect the final rule to create for covered entities. We anticipate that the final rule will place costs on the covered entities in the areas of: (1) Training and familiarization, (2) enforcement, (3) posting of the nondiscrimination notice and taglines, and (4) revisions in policies and procedures, and may place costs on covered entities in the voluntary area of development of a language access plan. Then we examine the potential benefits the rule is likely to produce. In the subsequent analyses of costs in this RIA and the Regulatory Flexibility Act (RFA), we use data sets from the Census Bureau[314] and BLS[315] for estimating burdens.

A. Assumptions

In the proposed rule, we made the following cost assessment based on certain key assumptions, which include: (1) We assume that promulgation of this regulation will trigger voluntary activity on the part of covered entities that would not have occurred absent the promulgation of the regulation—which generates both costs and corresponding benefits; (2) to the extent that certain actions are required under the final rule where the same actions are already required by prior existing civil rights regulations, we assume that the actions are already taking place and thus that they are not a burden imposed by the rule; (3) although the regulation does not require training at any specific time, we assume that covered entities may voluntarily provide one-time training to some employees on the requirements of the regulation at the time that the regulation is published; and (4) we assume that employers are most likely to train employees who interact with the public and will therefore likely train between 40% and 60% of their employees, as the percentage of employees that interact with patients and the public varies by covered entity. For purposes of the analysis, we assume that 50% of the covered entity's staff will receive one-time training on the requirements of the regulation. We use the 50% estimate as a proxy, given the lack of certain information as described below. For the purposes of the analysis, we do not distinguish between employees whom covered entities will train and those who obtain training independently of a covered entity.

B. Training and Familiarization

In the proposed rule, we counted the cost of training on all aspects of the

[313] The Area Health Resource File itself double counts physicians who are licensed in more than one state. *See infra* discussion below at II.C.1.a.

[314] U.S. Census Bureau, Statistics of U.S. Businesses, *http://www.census.gov/econ/susb/* (last visited May 3, 2016).

[315] U.S. Dep't of Labor, Bureau of Labor Statistics, May 2015 National Occupational Employment and Wage Estimates, *http://www.bls.gov/oes/2014/may/oes_nat.htm (last visited May 3, 2016).*

regulation, not only on the new responsibilities under the regulation, as we believe covered entities will want to offer comprehensive training to employees, recognizing that refresher training can provide value. We invited comment on whether we should count only the cost of training on new responsibilities under the regulation. The comments we received supported our assumption regarding training on all aspects of the regulation, and therefore the final rule keeps this assumption.

In the proposed rule, we also assumed that covered entities will provide some workers (not all workers) a one-time awareness or familiarization training regarding the requirements in the regulation at the time of its issuance. We noted that many employees may work ''behind the scenes'' at large entities, and may not have contact with patients or the general public or otherwise have duties impacted by the final rule's requirements and therefore may have little need for training. However, we noted that we are uncertain which employees those are. Furthermore, we noted that we do not know whether an entity rotates employees into different positions that may have patient contact or relevant duties, or whether, over time, an employee will switch to a position that places him or her in such a position, which may create a need for training. Although we received one comment suggesting that we include all employees in the training, the comment did not provide evidence or data to support including all employees. Otherwise, we received no comments to the contrary; therefore, the final rule makes the same assumption that the proposed rule did, that covered entities will provide some (not all) workers a one-time familiarization training.

In the proposed rule, we also noted that we lack information on State and local regulations that may require employees to receive training on civil rights provisions and whether those provisions are more or less rigorous than the ones we propose. Thus, workers in covered entities in State and local jurisdictions with civil rights provisions more robust than the ones we propose may need only minimal training. In State and local jurisdictions where civil rights provisions are not more robust, workers may need more training. As stated above, because we lack data on covered entities' training practices, we are assuming that covered entities will voluntarily provide training on the final rule for between 40% and 60% of their staffs. Further analysis of state requirements revealed that the states do vary in the robustness of their civil rights requirements, as we assumed in the proposed rule. Therefore, we chose 50% of the employees, the average between 40% and 60%.

Based on comments we received, we added a category of training, for a one-time familiarization by a manager, after the final rule has been published. The manager will need to study and understand the regulation well enough to make assessments of how the entity will promote compliance with the rule, including assessing the training needs of the staff and the costs associated with the training.

In the following section, we identify the pool of workers and staff that we anticipate may need education about the final rule. Next, we identify the covered entities that may choose to train their staffs to provide this knowledge. Last, we estimate the costs of the training materials and the worker time that will be spent in training.

1. Number of Individuals Who Will Receive Training

a. Health Care Staffs and Managers

The first category of health care staff that may receive training is comprised of 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 BLS occupational code for this grouping is 29–1000 and the 2014 reported count for this occupational group is approximately 4.8 million.

The second category of health care staff that we assume will receive training is comprised of degreed technical staff (Occupation code 29–2000) and accounts for 2.9 million workers. Technicians work in almost every area of health care: From x-ray to physical, speech, psychiatric, dietetic, laboratory, nursing, and records technicians, to name but a few areas.

The third category of health care staff that we assume will receive training is comprised of non-degreed medical assistants (Occupation code 31–0000), and includes psychiatric and home health aides, orderlies, dental assistants, and phlebotomists. Health care support staffs (technical assistants) operate in the same medical disciplines as technicians, but often lack professional degrees or certificates. We refer to this workforce as non-degreed compared to medical technicians who generally have degrees or certificates. There are approximately 3.9 million individuals employed in these occupations.

The fourth category of health care staff that we assume will receive training is health care managers (approximately 0.3 million based on BLS data for occupation code 11–9111). Because we assess costs of familiarization with the regulation for one manager at each entity, we assume that those managers will have already become familiar with the regulation and will not need additional training.

The fifth category of health care staff that we assume will receive training is office and administrative assistants—Office and Administrative Support Occupation (Occupation code 43–0000). 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. Approximately 2.7 million individuals were employed in these occupations in health facilities in 2014.[316]

One comment asked that outreach workers be explicitly included as a category to be trained. We assume that outreach workers are included in the five categories listed above, especially in the manager category.

Below is a summary table of individuals employed in the health care sector.

TABLE 1—HEALTH CARE EMPLOYEES WHO MAY NEED TRAINING

Health diagnosing and treating practitioners	4,833,840
Degreed technicians	2,876,000
Non-degreed technicians	3,940,500
Medical and health services managers	310,320
Office and administrative support staff	2,747,330
Total	14,707,990

b. Employees Working for the Federally-Facilitated Marketplaces and State-Based Marketplaces and Issuers in Those Marketplaces

We have data from CMS/CCIIO on the number of issuers offering qualified health plans in the Federally-facilitated Marketplaces.[317] We assume that many issuers that operate in the Federally-facilitated Marketplaces also operate in the State-based Marketplaces. However, to the extent there are issuers who operate in a State-based Marketplace[SM]

[316] U.S. Dep't of Labor, Bureau of Labor Statistics, Occupational Employment Statistics, May 2014 National Occupational Employment and Wage Estimates, United States, *http://www.bls.gov/oes/2014/may/oes_nat.htm* (last visited May 3, 2016). This code includes health care sector data for health care and social assistance (including private, State and local government hospitals).

[317] Qualified Health Plans Landscape Individual Market Medical (2015), *supra* note 308.

only, an estimate of their employees will not be included in our count of issuers (derived from the CCIIO tables of issuers participating only in the 34 jurisdictions with Federally-facilitated Marketplaces). We are basing our calculations on the number of employees working for those issuers participating in the Federally-facilitated Marketplaces and we assume, as noted above, that some of the same issuers and employees serve the State-based Marketplaces. Determining the number of employees working for issuers participating in the Health Insurance Marketplaces is challenging because we have no data directly linking the number of employees to our data on participating issuers in the Federally-facilitated Marketplaces. Consequently, we must impute the number of employees working for issuers participating in the Federally-facilitated Marketplaces and, by extension, employees working for issuers in State-based Marketplaces.

We performed this imputation by first identifying the number of issuers offering qualified health plans in the Federally-facilitated Marketplaces. To determine the number of issuers offering qualified health plans in the Federally-facilitated Marketplaces, we looked at the 2015 Qualified Health Plan Landscape Individual and Small Business Health Options Program Market Medical files.[318] The Qualified Health Plan Landscape Individual Market Medical file contains over 100,000 line items, and the Small Business Health Options Program Market Medical file contains over 50,000 line items listing each Federally-facilitated Marketplace℠ plan for each county by metal level (bronze, silver, gold, and platinum) and catastrophic plans provided by each issuer. To determine the number of issuers in the individual and Small Business Health Options Program Marketplaces, we removed all plan line items to reduce the count to an unduplicated count of the issuers in the Federally-facilitated Marketplaces. We identified 155 individual plan issuers and 14 issuers in the Small Business Health Options Program that only issued group plans to employees of employers participating in the Small Business Health Options Program. Our total count of 169 issuers differs from the CCIIO sources, which counted issuers in each State in which they operated. For example, a national issuer such as Aetna that offers coverage through Federally-facilitated Marketplaces operating in several States was counted separately by CCIIO for each State in which it was qualified, whereas we counted it only once.[319]

In addition to 169 issuers participating in Federally-facilitated Marketplaces, we are aware of 11 issuers participating only in the State-based Marketplaces. Thus, we calculated that the total number of issuers included in the analysis of covered issuers equals 180.

We next analyzed the number of employees working in the health insurance industry in the following way. Using Census Bureau 2011 payroll and employment data (the latest data available) for North American Industry Classification System 524114—Direct Health Insurance,[320] we attempted to match the number of employees to the health insurance entities. The Census data permitted us to divide all health insurance issuers into ''large'' (500 or more employees) and ''small'' (fewer than 500 employees) issuers, and from that we were able to estimate the number of employees for large and small issuers.

The Census data shows 805 small issuers and 180 large issuers. The ratio of small to large issuers is about 4.5 small issuers for every large issuer. We assume the ratio of small to large issuers in the Health Insurance Marketplaces is approximately the same as the ratio in the Census table. We asked for public comment on this assumption, and we received no comments to the contrary.

Applying this ratio to the issuers in the Federally-facilitated Marketplaces, we get 131 small issuers and 38 large issuers. We assume that the 11 issuers (for which we have data and have thus identified) operating in the State-based Marketplaces are likely to be classified as small, based on Census workforce data. Therefore, we are adding them to the 131 small issuers identified above, bringing the total number of small issuers to 142.

Based on the Census data, the average number of employees in a small issuer is 34 and the average number of employees in a large issuer is 2,300. If we multiply the number of issuers by the number of employees, there are 4,828 employees of the 142 small issuers and 87,400 employees of the 38 large issuers. The combined total number of employees for small and large issuers in the Marketplaces is estimated to be 92,228 employees.

With respect to the majority of issuers operating in a State-based Marketplace℠ that we have not been able to identify but would also be subject to the regulation, we do not have any direct data. However, the workforce data we have from the Census tables covers employees regardless of their work site. If any of the 169 issuers identified above operating in the Federally-facilitated Marketplaces also operate in the State-based Marketplaces, then some portion of the nearly 92,000 employees imputed to be working for the issuers in the Federally-facilitated Marketplaces may also be working for issuers operating in the State-based Marketplaces. Thus, in effect, we are including employees working for issuers that operate in both the State-based Marketplaces and the Federally-facilitated Marketplaces in our count of employees who likely will receive training on the regulation.

At the same time that we include employees who work for issuers operating in both the Federally-facilitated Marketplaces and State-based Marketplaces, we lack direct data on issuers participating only in State-based Marketplaces. We are not able to include employees that work for insurance issuers that operate only in State-based Marketplaces, such as New York or California, which would be subject to the proposed rule. We invited public comment on ways we could identify issuers that participate only in State-based Marketplaces and the number of employees they employ. We did not receive any comments that identified ways we can better identify these issuers.

A third category of workers who may need to be trained are navigators receiving Federal financial assistance to support the functions they perform in Federally-facilitated Marketplaces, such as assisting applicants to enroll in qualified health plans through the Marketplace℠. CMS has awarded grant funding to 100 Navigator entities.[321] In the proposed rule, we estimated that 2,797 navigators worked for 92 Navigator entities, which implies 30.4 employees per entity. We lacked data on the number of employees of these Navigator entities, and we thus applied the previous estimate of 30.4 employees per Navigator entity to estimate in the

[318] *Id.*

[319] We count the issuer only once because we assume the same enterprise will minimize training costs by preparing the same training materials for all its employees nationally.

[320] U.S. Census Bureau, Statistics of U.S. Businesses (SUSB) (2011), *http://www.census.gov/econ/susb/*.

[321] CMS awards $67 million in Affordable Care Act funding to help consumers sign-up for affordable Health Insurance Marketplace℠ coverage in 2016, *https://www.cms.gov/Newsroom/MediaReleaseDatabase/Press-releases/2015-Press-releases-items/2015-09-02.html* (last visited May 3, 2016).

final rule that 3,040 employees work for these entities.

We invited public comment on our approach to estimating the number of employees per issuer based on the Census data and sought any public information on issuers who operate only in State-based Marketplaces. We did not receive comments that changed our assumptions regarding types and numbers of employees working for Marketplaces. Thus, the final rule applies the estimate of the number of navigators per Navigator entity to the most recent number of Navigator grantees.

c. Medicaid and State and Local Health Department Employees

The Census Bureau State government payroll and employment data for 2012 shows the number of full-time employees working in State hospitals and departments of health as 531,251.[322] The State Medicaid Operations Survey: Fourth Annual Survey of Medicaid Directors reports that State Medicaid agencies employed between 27 and 3,853 full-time employees with a median workforce level of 455 employees.[323] Multiplying the median level of workers by 56 Medicaid agencies adds 25,480 workers to the number of State health and hospital workers in health departments, bringing the total to 556,731 employees. (Although a more appropriate method of calculating the total would be to use the mean as the multiplier, OCR used the median because the mean was unavailable.) However, this number double counts medical personnel that were previously counted as discussed in part I.C.1.a (regarding health care staffs and managers who will receive training) in this RIA.

To address this problem, we looked at the BLS industry data for North American Industry Classification System code 999201: State government, including schools and hospitals, we identified 442,680 personnel employed by State governments.[324] Subtracting this number from the 556,731 employees we identified employed in State government health services and Medicaid programs, results in 114,051 additional State employees who may obtain training on the provisions of the regulation.

d. Non-Health Care Personnel in Pharmacies

The 2012 Census data for all U.S. industries identifies 43,343 pharmacy establishments. The number of employees presented in the Census data includes both pharmacists and non-pharmacist personnel. At this point, we must refer back to the BLS data on the number of health care workers reported for 2014 because the BLS data divides the pharmacy workforce by occupation. The number of employees that BLS reports were employed in pharmacies for 2014 is 708,660. The number of health care workers discussed in subsection II.C.1.a. above includes 348,190 individuals counted above in occupation codes 11–9111, 29–0000 and 31–0000 reported to be working in pharmacies.[325] Because we already counted the costs of health care workers employed in pharmacies in the analysis of health care staff, to achieve a more accurate estimate of the number of non-health care pharmacy workers, we must subtract the 348,190 health care staff from the total workforce BLS reports. Removing health care staff from the BLS data yields a net of 360,470 non-health care pharmacy workers in pharmacies who may receive training on the final rule.

The following table shows the total number of employees whom we estimate will receive training; that is, the table shows the 50% of total workers whom we estimate may receive training. The table does not include HHS employees conducting HHS health programs or activities because there are roughly 65,000 HHS total employees and many of these employees do not work in health programs or activities administered by HHS. For those employees who do work in health programs or activities administered by HHS, many may not have direct beneficiary contact. Given these limitations, we estimate the number of employees added would be small and have little impact on overall cost.

TABLE 2—WORKERS WHO MAY RECEIVE TRAINING ON THE REGULATION

Medical health staffs and managers	7,216,494
Employees working for 180 issuers in the Health Insurance Marketplaces	46,114
State health employees	55,442
Navigators	1,520
Pharmacy workers (excluding health care personnel)	180,235
Total	7,637,306

2. Number of Covered Entities That May Train Workers

Just as there are a number of data sources for counting workforce, there are various sources for counting the number of health care entities. Many covered entities are controlled or owned by a single corporate entity, and one can count each individual entity separately or count only the single corporate enterprise. For example, a multi-campus facility or vertically integrated entity that owns a hospital, a nursing home, and a home health agency and also operates an accountable care organization could count each of these entities separately—as does Medicare—or count them only once, with each entity treated as part of the corporate entity. At this point, we make two assumptions: (1) Albeit not required to do so by the regulation, each covered entity will provide some training to its staff on the requirements of the regulation; and (2) when entities are controlled or owned by a corporate entity, the corporate entity will supplement or make any desired modification to the OCR training materials and distribute the training materials. We believe this last point to be especially true because rather than have each entity prepare its own training materials, the corporate entity is more likely to prepare one set of training materials and distribute the materials to its individual entities. This is because the corporate entity saves money by preparing a limited set of training materials and assures uniform quality and consistency in its policies across all its entities. It is also possible that some local health centers in a State may be managed from a central location that handles logistics and training materials. Therefore, we propose using the 2012 Census table that presents the number of entities, referred to as firms in the Census tables, to count the number of health care entities. In the Census data, a corporate entity is referred to as a ''firm'' and the corporation's facilities are ''establishments.'' When a firm has one

[322] U.S. Census Bureau, Government Employment & Payroll (2013), *http://www.census.gov/govs/apes/*.

[323] Nat'l Ass'n of State Medicaid Dirs, State Medicaid Operations Survey: Fourth Annual Survey of Medicaid Directors, at 5 (Nov. 2015) *http://medicaiddirectors.org/wp-content/uploads/2015/11/namd_4th_annual_operations_survey_report_-_november_2_2015.pdf*.

[324] U.S. Dep't of Labor, Bureau of Labor Statistics, May 2015 National Occupational Employment and Wage Estimates by ownership, *http://www.bls.gov/oes/2014/may/oes_nat.htm* (last visited May 3, 2016).

[325] U.S. Dep't of Health & Human Servs., Health Res. & Servs. Admin., Area Health Resource Files, *http://ahrf.hrsa.gov/* (last visited May 3, 2016). The Area Health Resource File reports 272,022 pharmacists licensed in 2014.

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establishment, the establishment is the firm.

Another difficulty we face in using these data sources is that the Census data captures all entity types that fit the definition of a health care service entity, including entities such as private retirement communities that are unlikely to receive Federal financial assistance and thus would not be covered by Section 1557. In our use of the Census data, we attempted to exclude types of entities that are not likely to receive Federal financial assistance by excluding retirement communities and other similar type entities in the file, but we have included entities that may receive Federal financial assistance, such as community health centers and residential centers for individuals with intellectual disabilities.

To test our success in producing a list of covered entities from the Census data, we compared the number of entities we selected from the Census data and the number of entities included in the CMS Provider of Service file. However, to make the lists comparable, we had to remove the count of Clinical Laboratory Improvement Act laboratories from the CMS Provider of Service data files. There are close to 450,000 Clinical Laboratory Improvement Act laboratories located in hospitals, clinics, outpatient centers, and doctors' offices. Only a few thousand of these laboratories serve the public. The majority of laboratories serve the facility in which they are housed—including them in our comparison would grossly distort this comparison.

If we add the entities in the Provider of Service file (excluding Clinical Laboratory Improvement Act laboratories) and the number of community health centers to our list of affected entities that are not included in the Provider of Service file, we get a total of 134,543 entities. Using the Census data, minus the categories for medical laboratories, we obtain a total of 139,164 covered entities. It is evident that these numbers are very similar. However, as discussed earlier, we propose using only the number of firms for the analysis of the number of entities possibly conducting training, that is, 70,384 firms. As noted, we believe firms and not establishments will modify or supplement materials and train employees.

In addition to the firms we include from the Census file, we must add physicians' office firms and pharmacy firms because they may also need to train some workers. Physicians' office firms and pharmacy firms are generally referred to as physician group practices and pharmacy chains.

Below we present the types and number of firms that we estimate will take part in the training for the regulation.

TABLE 3—NUMBER OF HEALTH CARE ENTITY FIRMS EXPECTED TO TAKE PART IN TRAINING

NAIC	Entity type	Number of firms
62142	Outpatient mental health and substance abuse centers	4,987
621491	HMO medical centers	104
621492	Kidney dialysis centers	492
621493	Freestanding ambulatory surgical and emergency centers	4,121
621498	All other outpatient care centers	5,399
6215	Medical and diagnostic laboratories	7,958
6216	Home health care services	21,668
6219	All other ambulatory health care services	6,956
62321	Residential intellectual and developmental disability facilities	6,225
6221	General medical and surgical hospitals	2,904
6222	Psychiatric and substance abuse hospitals	411
6223	Specialty (except psychiatric and substance abuse) hospitals	373
6231	Nursing care facilities (skilled nursing facilities)	8,623
44611	Pharmacies and drug stores	18,852
6211	Offices of physicians	185,649
524114	Insurance Issuers	180
	Navigator grantees	100
Total Entities		275,002

3. Training and Familiarization Costs

a. Cost of Training Materials and Presentations

There are two components to the cost of training the workers we identified in the previous section: (1) The cost of training materials that is based on the number of covered entities identified in the previous section; and (2) the cost of employee time spent in training.

OCR estimates, based on its experience of training employees on other regulations it enforces, that training employees on this regulation will take about one hour of an employee's time. Based on discussions with firms that develop training materials, we estimate that developing or presenting materials for a one-hour course would cost about $500. However, before the effective date of the rule, OCR will provide covered entities with training materials that will cover the key provisions of the regulation that can be used by entities in conjunction with their own training materials. We estimate that OCR preparing the training materials on the regulation will substantially reduce the material preparation burden to covered entities and reduce the cost by about three quarters, or about $375 per entity. Therefore, the costs to entities will equal $125 multiplied by the number of entities that will prepare and present training materials. Based on its experience in preparing training materials for other civil rights and HIPAA regulations, OCR expects to spend $10,000 to develop training materials that will prepare health care workers and managers to effectively implement the Section 1557 regulation.

Training materials can be presented in a number of ways. A common method for offering training materials is through e-courses that are distributed over an entity's computer network. Another method is to offer lectures to selected employees/staff and then have attendees present the materials to their co-workers as part of train-the-trainer programs. For small entities, one lecture session may be given to all employees. Regardless of presentation mode, we estimate that the cost of training via an e-course will be

the same as the cost of training through a lecturer for a train-the-training approach: $125 per entity.

Applying the $125 per course materials to the number of firms ($125 × 275,002)—including the 169 health insurance issuers—equals $34.4 million for the cost of developing training materials.

b. Cost of Employee Time

The next step is to compute the cost of employee time for training and familiarization. This involves taking the hourly wage rate times the amount of time that a new activity will require, times the number of employees expected to undertake the activity as a result of the rule. We use data from the BLS on median wage rates by occupation to estimate wages throughout this analysis. We are uncertain about how many employees identified in the workforce above will actually seek and obtain training and how many firms in the health sector will offer training. However, for the purposes of this analysis we assume that all firms may offer some training to their staffs, but because the training is voluntary, and because only a portion of employees who have direct patient contact or otherwise have duties impacted by the regulation may require or take training, we assume that 50% of employees will receive training. We assume that training will require an average of one hour of time for each participating employee.

The occupation code 29–1000 (health care practitioners) applies to the 4.8 million professional staff and degreed technical staffs we discussed above. The BLS reports the median hourly wage for this code as $36.26. We estimate one hour of a worker's time would be required for training. To this amount we must add 100% for fringe benefits and overhead, which yields an adjusted hourly wage per employee of $72.52. Assuming that half of the 4.8 million health care practitioners identified earlier receive or obtain training (2.4 million workers), and multiplying this number by the hourly employee wage plus fringe benefits and overhead for one hour equals slightly more than $175.3 million in training costs for practitioners.

We note that one commenter suggested that we use a factor higher than 100% to adjust wages for overhead and benefits. However, the commenter's argument is based on Federal overhead rates for contracts, and not evidence of the resource costs associated with reallocating employee time. As a result, we do not adopt the commenter's recommendation, and we continue to use the Department's standard of 100% for overhead and fringe benefits.

For the degreed health care work force in occupation 29–2000, the median hourly wage is $19.92. Adding 100% for fringe benefits and overhead equals $39.84. The total training cost for one hour of training for half of the 2.9 million degreed technical staff (1.44 million workers) is about $57.3 million. In addition, we must add the cost of training non-degreed staff (reported in occupation 31–0000) who earn a median hourly wage of $12.71. Adding 100% for fringe benefits and overhead to the $12.71 median hourly wage rate yields an adjusted wage of $25.42. Multiplying this amount by half of the 3.9 million workforce yields a cost of $50.1 million.

To these amounts we must add the cost associated with familiarization and training for the medical and health service managerial staff, of which there are 300,320 individuals with a median hourly pay rate of $44.62. Adding 100% for fringe benefits and overhead gives us an adjusted hourly wage of $89.24. We assume that an average of one person in this occupation will spend an average of two hours becoming familiar with the final rule's requirements upon its publication at each of the 275,002 entities covered by the rule. These assumptions imply familiarization costs of $49.1 million. We assume that half of the remaining managers receive training. This implies that 12,659 managerial staff will receive an hour of training, which results in a cost of $1.1 million. This implies that total costs for training and familiarization for this occupation category comes to $50.2 million.

The cost of training occupation code 43–0000, office and administrative support workers employed in covered health care entities, is the product of the median hourly rate of $15.52 adjusted for fringe benefits and overhead multiplied by the 2.7 million workers reported for North American Industry Classification System code 62: Health Care and Social Assistance (including private, State, and local government hospitals). Adding 100% for fringe benefits and overhead to the $15.52 equals $31.04. Multiplying the pay rate by half the number of support and administrative personnel equals $42.6 million.

The 2013 BLS data for North American Industry Classification System pharmacies and drugstores reports a total workforce of 708,660 workers. As with the analysis for State employees, we must remove the 348,190 health care workers who are already counted in our training costs analysis of the health care workforce. To avoid double counting training costs for these occupations, we removed them from the count of the pharmacy workforce. (The entities that employ these workers will still bear the cost for training them.) Their median weighted wage is $17.22, which is derived from BLS data for medical pharmacy personnel, and the cost associated with an hour of their time is $34.44 after adjusting for overhead and benefits. We estimate $6.0 million in costs for training half of these medical pharmacy personnel.[326]

For the 360,470 non-medical pharmacy personnel, their weighted median hourly rate for pharmacy employees is $11.87, which is derived from BLS data for non-medical pharmacy personnel. After adjusting for overhead and benefits, the cost of one hour of time in this category is $23.74. We estimate $4.3 million in costs for training half of these non-medical pharmacy personnel.

For the 3,040 navigators, we lack data to determine their wages. As a proxy, we use the wage rate for medical and health service managerial staff, with a median hourly pay rate of $44.62. Adding 100% for fringe benefits and overhead gives us an adjusted hourly wage of $89.24. We estimate $0.1 million in costs for training half of these navigators.

For the remaining entities for which we cannot use BLS data, we must use the industry payroll and employment Census data. To arrive at an estimate of the cost of time for training employees of health insurance issuers and State health and Medicaid agencies, we must divide the total annual payroll reported for these entities by the total number of employees and divide that number by the annual hours paid (2,080 hours), adjusted for fringe benefits and overhead.

For workers employed by the issuers participating in the Health Insurance Marketplaces, it was necessary to determine the hourly wage rate for workers employed in small and large issuers as we have described them above. The total number of workers in small entities (fewer than 500 workers) is 27,269 and the annual payroll is $1.68 billion. The average wage per employee is $61,895. Using the 2,080 hours for the annual number of work hours, we obtain an hourly rate of $29.76.

[326] Determining the cost to train employees other than pharmacists and medical staff who work in pharmacies requires use of the Bureau of Labor Statistics industry data for North American Industry Classification System. These data show that for 2013, 348,380 medical practitioners, technologists and medical support staff were employed in pharmacies and drug stores. U.S. Dep't of Labor, Bureau of Statistics, Occupational Employment Statistics, *supra* note 316.

Assuming that the payroll amounts reported in the Census data do not include fringe benefits and overhead, we add 100% to the hourly rate to yield $59.51 per hour. Multiplying this amount by half of the 4,454 employees in small issuers equals $132,540 in training costs.

The total number of employees employed by large issuers (500 or more) is 415,017 and the annual payroll is $30.8 billion. The average annual wage is $74,219. Dividing this figure by 2,080 hours yields an hourly wage rate of $35.68. Multiplying by 100% for fringe benefits and overhead yields $71.36. Multiplying this amount by 50% of the 87,400 workers equals slightly more than $3.12 million in training costs.

For State government workers employed in welfare, health, and hospital services, we divided the total number of workers the 2012 Annual Census Bureau reported (873,289 employees) into the monthly payroll reported for the period ($3,774,775,691).[327] On an annual basis, the average salary per employee equals $51,870. The hourly rate equals $24.94 and multiplied by 100% for fringe benefits and overhead yields $49.87 per worker for training costs.

In the State Medicaid Operations Survey: Second Annual Survey of Medicaid Directors, States reported the median number of full-time Medicaid employees is 421. Using this number multiplied by the 53 Medicaid agencies in the 50 States, the District of Columbia, Puerto Rico, Guam, and the other territories, we added 22,313 workers to the total of health and hospital workers reported in the Census data, bringing the total number of workers in covered State government entities to 553,564. We then subtracted the 442,680 medical personnel we accounted for in the training costs for all health care personnel and therefore were considered to be duplicative of the medical personnel previously counted in our analysis of medical staff workforce (occupations 29–1000, 29–2000 and 31–0000). This left a net of 110,884 State employees receiving training. Taking half of this number and multiplying it by $49.87 equals a training cost of slightly more than $2.76 million.

Although we removed the cost of training the 442,680 medical personnel from the State training cost analysis to avoid double counting training costs, the cost of training half the medical staff may still fall to the States where they are employed. We estimate the cost to train State medical personnel to be approximately $11.1 million.[328]

As noted above, total familiarization costs are estimated to be $49.1 million. The following table summarizes the training costs we estimate for this rule.

TABLE 4—TOTAL TRAINING COSTS

	Number of entities/workers	Cost (millions)
Training preparation costs ($125/entity)/entity	* 275,002	$34.4
Health care staff and managers training	* 7,214,862	326.9
Small Issuers in the Health Insurance Marketplace℠ training	2,414	0.1
Large issuers in the Health Insurance Marketplace℠ training	43,700	3.1
Navigators	1,399	0.1
State health, hospital and Medicaid worker training	55,442	2.8
Pharmacy worker training	180,235	4.3
Total	7,498,052	371.7

* Not included in column total.

C. Notification and Other Procedural Requirements

1. Designation of Responsible Employee and Adoption of Grievance Procedures

Pursuant to the regulations implementing Section 504, recipients of Federal financial assistance with 15 or more employees are required to designate a responsible employee to coordinate compliance with respect to nondiscrimination requirements and to have grievance procedures to address complaints of discrimination under this law. Of the 275,002 covered entities, approximately 15% 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. Thus, all recipients of Federal financial assistance with 15 or more employees are already expected to have in place grievance procedures and a designated employee to coordinate their compliance responsibilities. The rule standardizes the requirement to designate a responsible employee and adopt grievance procedures across all bases of discrimination prohibited under Section 1557.

To implement the rule, a recipient of Federal financial assistance could increase the responsibilities of an already-designated employee to handle compliance with the rule's nondiscrimination requirements. In addition, a recipient of Federal financial assistance could increase the scope of existing grievance procedures to accommodate complaints of discrimination under all bases prohibited under Section 1557. The costs associated with these requirements are the costs of training the designated employee on the employee's increased responsibilities and the costs associated with modifying the existing grievance procedures to reflect the additional bases of race, color, national origin, sex, and age. Here we are referring to employee training to perform their specific enforcement responsibilities, not one-time training in the provisions of the final rule described in the training section above. We also note that grievance officials will probably receive specific training on their new responsibilities and that covered entities will probably provide this additional training and absorb the costs, which are expected to be de minimis. Many covered entities already may be using their existing grievance procedures to address the additional cases covered under Section 1557.

State-based Marketplaces are required to designate an employee to handle compliance responsibilities and to adopt grievance procedures under the ADA. The duties of the employee and

[327] U.S. Census Bureau, Government Employment & Payroll, *http://www.census.gov/govs/apes/* (last visited May 3, 2016).

[328] We calculated the cost of training the medical personal using the weighted median hourly rate, $47.22, multiplied by the 446,210 medical staff identified as employed in State governments.

the grievance procedures could be modified to reflect all the bases covered under Section 1557.

We have not estimated the additional costs of training grievance officials on their individual enforcement responsibilities, but we believe such cost would be absorbed in general training costs of all employees on their job responsibilities. Costs associated with modifying existing grievance procedures are covered in the section of the analysis on enforcement.

2. Notice Requirement

The implementing regulations of Title VI, Section 504, Title IX, and the Age Act require recipients of Federal financial assistance and, in the case of Section 504, the Department, to notify individuals that recipients (and, under Section 504, the Department) do not discriminate. The content of the nondiscrimination notices varies based on the applicable civil rights law.

The final rule harmonizes notification requirements under Title VI, Section 504, Title IX and the Age Act, and standardizes the minimum information for a notice. The final rule also requires initial and continuing notification of individuals. OCR drafted a sample notice (located in Appendix A to Part 92) in English that meets the requirements and will translate that notice into 64 additional languages, in advance of the effective date of this rule. Covered entities have discretion to use the OCR sample notice or their own notice, if preferred, and to post the notice in non-English languages.

As all Section 1557 covered entities will need to create or update an existing notice of nondiscrimination, all covered entities can discharge their responsibilities under § 92.8(a) by replacing their current notices with the sample notice developed by OCR (found in Appendix A), available to all covered entities pursuant to § 92.8(c). Using the sample OCR notice means that covered entities will not have to compose their own notices; we expect nearly all covered entities will use the sample OCR notice.

All covered entities will incur costs, however, to implement § 92.8(a) of the final rule, which requires ''initial and continuing'' notification. Such notification is expected to involve:

- Downloading the notice from the OCR Web site;
- Printing copies of the notice for posting;
- Posting hard copies of the notice in public spaces of the office or facility; and
- Posting the notice on the entity's Web site, if it has one.

While many costs to comply with this rule are incurred at the entity level, the costs of downloading, printing, and posting the notice are incurred at the establishment level. There are approximately 275,000 covered entities covered by this final rule. According to 2012 Census data, these covered entities are associated with 405,534 establishments. We estimate that a clerical worker at each establishment would spend an average of one minute downloading the notice from the OCR Web site, an average of one minute printing copies of the notice for posting, an average of five minutes posting hard copies of the notice in public areas, and an average of ten minutes total between preparing the OCR notice for posting on the facility's Web site and posting the notice on the Web site. This implies that the estimated cost associated with posting is $8.79 ($31.04 per hour × 17 minutes × 1 hour per 60 minutes) per establishment, which implies that the total estimated cost associated with this requirement is $3.6 million ($8.79 per establishment × 405,534 establishments).

Covered entities will need to update their significant publications and significant communications to include the new notice. However, as noted above, OCR is allowing entities to exhaust their current publications, rather than do a special printing of the publications to include the new notice. When covered entities restock their printed materials, they will be expected to include in those printed materials the notice that OCR will provide with this final rule.

Because we are permitting covered entities to exhaust their existing stock of publications with the current notices before using the new notice, we conclude that the notice requirement imposes no resource costs related to including updated notices in the publications.

Section 92.8 provides covered entities discretion to post the OCR sample notice of nondiscrimination in non-English languages, which can include languages that differ from OCR's list. In addition, covered entities can draft and translate their own notice in however many languages they choose, if they prefer.

We examined CMS contractual cost for translating a one page notice into 13 languages. It was $1,000 per page. Based on this figure, we expect total costs to the government to be limited to $64,000 to translate the notice into 64 languages and place the translated notices on OCR's Web site. The sample notice is one page long. In addition, we expect total costs to the government for translating the statement of nondiscrimination for small-size publications to be $50 for each of the 64 languages. We count the nondiscrimination statement as .05 pages long.

Although not required, we expect that many covered entities would choose to post the OCR-provided notice in one or more non-English languages on their Web sites, in their physical office space, and in certain publications they may have. We do not know how many covered entities would take this action or how many non-English language versions of the notice they would choose to post, or where they would make the non-English versions of the notice available.

Section 92.8 requires covered entities to publish taglines indicating the availability of language assistance services in the top 15 languages of the relevant State or States. Before the effective date of the rule, OCR will make these taglines available electronically in 64 languages; therefore, there will be no burden to the covered entity other than the cost of printing and posting these taglines, as described above with respect to the notice. We are uncertain of the exact volume of taglines that will be printed or posted, but we estimate that covered entities will print and post the same number of taglines as notices and therefore the costs would be comparable to the costs for printing and disseminating the notice, or $3.6 million. The costs to the Federal government for translating the taglines will be approximately $50, based on counting each tagline as being .05 pages long. We estimate that the combined costs of printing and distributing notices, nondiscrimination statements, and taglines will be $7.1 million for entities and $70,400 for the Federal government.

D. Meaningful Access for Individuals With Limited English Proficiency

In the proposed rule, we said that § 92.201, which effectuates Section 1557's prohibition of national origin discrimination as it affects individuals with limited English proficiency, does not pose any new burden on covered entities. This is because, with regard to recipients of Federal financial assistance, the proposed rule adopted recipients' existing obligations under Title VI to take reasonable steps to provide meaningful access to individuals with limited English proficiency and codified the standards consistent with long-standing principles from the HHS LEP Guidance regarding the provision of oral interpretation and written translation services. However,

we anticipate that, as a result of issuance of the final rule, covered entities may choose to take one extra step: To develop and implement a language access plan, in order to ensure that they provide meaningful access to individuals with limited English proficiency. We have thus revised our cost estimates, for the final rule, as shown below, to reflect our assumption that 50% of the covered entities will choose to develop a language access plan.

Although Title VI does not apply to the Department, Executive Order 13166 ''Improving Access to Services for Persons with Limited English Proficiency'' has applied to HHS for nearly 15 years.[329] This Executive Order requires Federal departments to develop and implement a plan, consistent with the HHS LEP Guidance, to ensure that persons with limited English proficiency can meaningfully access the Department's programs and activities. HHS adopted a Language Access Plan in 2000, and updated it in 2013, to provide individuals with limited English proficiency meaningful access to HHS-conducted programs and activities, including Federally-facilitated Health Insurance Marketplaces.[330] Because the final rule does not impose duties beyond the Department's existing obligation under the Executive Order, the rule imposes no new burden on the Department.

In order to estimate the costs of developing a language access plan for recipients of Federal financial assistance, we assume that developing a plan requires approximately three hours of medical and health service managers staff time for the first year, and then an average of one hour of medical and health service managers staff time per year to update the plan in subsequent years. We based our assumption of three hours on feedback from covered entities included in our pre-award compliance review program. This program reviews civil rights compliance of 2,000 to 3,000 health care provider applicants for Medicare Part A per year.

The health care providers that receive Medicare Part A funds already have to develop a written language access plan as a requirement of participation in the Medicare Part A program. Thus, we can reduce the number of covered entities from having a new burden of developing a language access plan. CMS reports data on Medicare hospital spending per claim which identifies 3,209 unique hospitals, which suggests that at least 3,209 hospitals participate in Medicare Part A. As discussed previously, Census data reports that there are a total of 3,688 hospital firms in the United States. Census data reports that there are 6,741 establishments associated with these firms, which in turn suggests that at least 47.6% (3,209/6,741) participate in Medicare Part A. Census data also reports that there are 8,623 nursing care facility entities in the United States. For the purpose of this analysis, we assume that 47.6% of hospitals and nursing care facilities participate in Medicare Part A. Applying 47.6% to all hospitals and nursing care facilities, we estimate that 5,861 entities (47.6% × 3,688 hospital entities (firms) + 47.6% × 8,623 nursing care facility entities) covered by this rule participate in Medicare Part A. This implies that 269,141 entities (firms) will potentially make changes and develop a language access plan as a response to the rule. We arrived at the 269,141 number by subtracting the number of entities participating in Medicare Part A (5,861) from the total number of entities (275,002). We estimate that 50% of these entities will make these changes. Taken together, these assumptions imply that the total cost of the development of language access plans will be approximately $36.0 million (269,141 entities × 50% of entities × 3 hours per entity × $89.24 per hour) in the first year and approximately $12.0 million (269,141 entities × 50% of entities × 1 hour per entity × $89.24 per hour) per year in subsequent years.

We received a number of comments stating that developing a language access plan imposes a cost burden on covered entities. We revised the proposed rule to include cost estimates, in this final rule, for the development of language access plans, as outlined in the paragraph above. We also received comments that providing interpreters imposes a heavy burden on covered entities. The obligation to provide interpreters as part of taking reasonable steps to provide meaningful communication with individuals with limited English proficiency has been a requirement under Title VI for many years. As a result of developing a language access plan, a covered entity might find increased efficiencies in providing language assistance services. Another covered entity might incur extra costs for the provision of language assistance services on more occasions. We are unable to estimate at this point how many covered entities will incur extra costs or the extent of such costs or the savings realized in increased efficiencies. We anticipate that the potential increased efficiencies and increased costs may offset each other to some degree. Thus, we do not believe this rule will impose a greater burden regarding the costs of language assistance services than exist under Title VI.

E. Nondiscrimination on the Basis of Sex

Section 1557 prohibits discrimination on the basis of sex in certain health programs and activities. When providing services, including access to facilities, covered entities must provide individuals with equal program access on the basis of sex, and covered entities are required to treat individuals in a manner consistent with their gender identity.

Title IX applies to educational institutions. Therefore, medical schools, nursing programs, and other health education programs were already prohibited from discriminating on the basis of sex prior to the enactment of Section 1557. Under Section 1557 and this regulation, health insurance issuers receiving Federal financial assistance, hospitals, clinics and other health facilities, HHS health programs and activities, and Title I entities, along with the staff and practitioners working in these health programs, are now similarly prohibited from discriminating on the basis of sex.[331] This section discusses the costs associated with the prohibition of discrimination on the basis of sex in the rule, taking into account the existing environment, including legal authorities, that addresses equal access on the basis of sex.

Covered entities that provide or administer health services or health insurance coverage are covered by the prohibition of discrimination on the basis of sex. The costs that we anticipate that covered entities would incur relate to: (1) Training; (2) enforcement; (3) the posting of the notice; (4) the revision of policies and procedures; and (5) some costs associated with changes in discriminatory practices. This section discusses costs related to changes in policy and procedures and potential changes in discriminatory practices.

[329] Exec. Order No. 13166, 65 FR 50121 (2000).

[330] U.S. Dep't of Health & Human Servs., Language Access Plan, *supra* note 186.

[331] Consistent with OCR's enforcement of other civil rights authorities, the proposed definition of ''Federal financial assistance'' under the regulation does not include Medicare Part B, which means that physicians receiving only Medicare Part B payments are not covered under the regulation. However, because almost all physicians receive payments from other Department programs such as Medicaid or Medicare meaningful use payments, we believe that there are very few physicians excluded from these provisions. *See supra* pt. I. C. 1.

1. Costs for Entities Providing or Administering Health Services

The rule would not invalidate specialties that focus on men or women, *e.g.,* gynecology, urology, etc. Nor would providers have to fundamentally change the nature of their operations to comply with the regulation. For example, the rule would not require a provider that operates a gynecological practice to add to or change the types of services offered in the practice.

Under the sex discrimination prohibition, however, providers of health services may no longer deny or limit services based on an individual's sex, without a legitimate nondiscriminatory reason. Although a large number of providers may already be subject to state laws or institutional policies that prohibit discrimination on the basis of sex in the provision of health services, the clarification of the prohibition of sex discrimination in this regulation, particularly as it relates to discrimination on the basis of sex stereotyping and gender identity, may be new. We anticipate that a large number of providers may need to develop or revise policies or procedures to incorporate this prohibition. For example, if a hospital or other provider has specific protocols in place for domestic violence victims, but engages that protocol only for women, the provider would have to revise its procedures to require that protocol for all domestic violence victims regardless of sex. A provider specializing in gynecological services that previously declined to provide a medically necessary hysterectomy for a transgender man would have to revise its policy to provide the procedure for transgender individuals in the same manner it provides the procedure for other individuals.

a. Developing or Revising Policies and Procedures

We assume that it will take, on average, three to five hours for a provider to develop or modify policies and procedures concerning sex discrimination. We are selecting four hours, or the midpoint of this range, for our analysis. We further assume that an average of three of the hours will be spent by a mid-level manager equivalent to a front-line supervisor (Occupation code 43–1011), at a cost of $48.84 per hour after adjusting for overhead and benefits, and an average of one hour will be spent by executive staff equivalent to a general and operations manager (Occupation code 11–1021), at a cost of $93.54 per hour after adjusting for overhead and benefits. We further assume that 75% of covered entities will need to develop or modify policies and procedures, given that some proportion of health care providers already prohibit sex discrimination based on State law or institutional policies prohibiting discrimination generally. The total cost for the estimated 206,252 covered entities to make their policies and procedures consistent with the regulatory prohibition on discrimination on the basis of sex is estimated to be approximately $49.5 million, which we assume is divided evenly between the first two years of compliance.

The above estimates of time and number of entities that would have to revise their policies under the regulation is an approximate estimate based on general BLS data. Due to the wide range of types and sizes of covered entities, from complex multi-divisional hospitals to small neighborhood clinics and physician offices, the above estimates of time and number of entities that would have to revise their policies under the regulation is difficult to calculate.

b. Ending Discriminatory Practices

For providers that discriminate on the basis of sex in violation of the rule, some changes in behavior or action would be necessary to come into compliance. We anticipate some change in the patient population for which a particular provider provides care or the extent of services provided. However, the infrastructure and protocols for providing services or treatment are already in place; providers would simply have to start providing those existing services in a nondiscriminatory manner to individuals regardless of sex. For example, a provider could not refuse to treat a patient for a cold or a broken arm based on the patient's gender identity. Similarly, if the provider is accepting new patients, it must accept a new patient request from a transgender individual and cannot decline to accept a transgender individual in favor of a person who is not transgender.

However, the rule does not impose a burden on covered entities with respect to the number of patients treated. The rule does not require a covered entity to change the total number of patients it sees or to treat more patients than it currently accepts. Providers may continue to treat the same number of patients that were accepted prior to the issuance of this final rule, but they must do so in a nondiscriminatory manner. Thus, for example, if a provider is not accepting new patients, the provider does not have to accept a new patient request from a transgender individual. We anticipate that the costs associated with these types of changes would be de minimis.

Moreover, costs associated with administering care or treating a new patient generally would be offset by the reimbursement received by the provider for providing the care, in the same way the provider gets paid for existing care or treatment of patients. Thus, for example, for the hospital or other provider that needs to revise its protocol for domestic violence to require that protocol for all domestic violence victims regardless of sex, rather than just women, there would be little to no net increase in costs for treating men because the hospital or provider would be paid for its services in the same way it is paid to treat women.

2. Costs for Entities Providing or Administering Health Insurance Coverage

The ACA, including Section 1557, changed the health care landscape for millions of people by instituting protections against sex discrimination in the provision of health care and health insurance coverage. Prior to the ACA, it was standard health insurance practice to treat women differently in premium pricing and coverage of benefits,[332] while transgender individuals frequently experienced discrimination when seeking coverage for treatment.[333]

The ACA addresses inequitable treatment by health plans based on sex in multiple ways. The regulations from CMS implementing the ACA prohibit Title I entities [334] and most health insurance issuers [335] from

[332] *See* Adelle Simmons, Katherine Warren, & Kellyann McClain, U.S. Dep't of Health & Human Servs., Office of the Assistant Sec'y for Planning and Eval., ASPE Issue Brief, The Affordable Care Act: Advancing the Health of Women and Children (Jan. 2015), *https://aspe.hhs.gov/pdf-report/affordable-care-act-advancing-health-women-and-children;* U.S. Dep't of Health & Human Servs., Women and The Affordable Care Act, *http://www.hhs.gov/healthcare/facts-and-features/fact-sheets/women-and-aca/index.html* (last visited May 3, 2016).

[333] *See* Lambda Legal, When Health Care Isn't Caring: Lambda Legal's Survey on Discrimination Against LGBT People and People Living with HIV (2010), *http://www.lambdalegal.org/publications/when-health-care-isnt-caring.*

[334] 45 CFR 155.120(c)(1)(ii) prohibits a Health Insurance Marketplace℠ from discriminating based on race, color, national origin, disability, age, sex, gender identity, or sexual orientation.

[335] 45 CFR 147.104(e) prohibits health insurance issuers in non-grandfathered individual, small and large group markets from employing 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, gender

Continued

discriminating based on sex, sexual orientation, and gender identity, in addition to other bases. These market-wide provisions are applicable to health insurance issuers both on and off the Health Insurance Marketplace SM, which includes qualified health plan issuers [336] and health insurance issuers providing non-grandfathered coverage in the individual and group markets outside of the Health Insurance Marketplace SM.[337]

In addition, the ACA prohibits many health insurance issuers from charging higher premiums based on sex; [338] failing to provide essential health benefits that greatly impact women, such as maternity care; [339] failing to cover preventive services that are necessary for women's health, such as mammograms; [340] and denying benefits based on pre-existing conditions [341] or health factors,[342] many of which affect women's health, such as a history of a Caesarian section or a history of domestic violence.[343] Thus, health insurance issuers and the Health Insurance Marketplaces have already had to expand access to women and lesbian, gay, bisexual and transgender (LGBT) individuals under these health insurance market reforms, independent of Section 1557. The existence of these other provisions circumscribes cost burdens on Health Insurance Marketplaces and issuers in the ACA-compliant individual and small group markets that are recipients of Federal financial assistance that are imposed by the prohibition of sex discrimination in the rule.

Section 92.207 (Nondiscrimination in health insurance and other health coverage) of the rule prohibits discrimination on the basis of sex by a covered entity providing or administering health insurance or other health coverage. As noted, many of the same covered entities subject to Section 1557, including Health Insurance Marketplaces and health insurance issuers in the individual and small group markets that are recipients of Federal financial assistance, are also subject to existing nondiscrimination provisions in CMS regulations. Although the CMS regulations complement and do not replace Section 1557 or this part, the existing nondiscrimination requirements applicable to health insurance issuers and Health Insurance Marketplaces have made these entities aware that they are not permitted to discriminate on the basis of sex, sexual orientation, or gender identity, and thus they are familiar with their nondiscrimination obligations under the law. We assume that these covered entities have already taken steps to comply with CMS regulations and so instituted changes in their policies and actions. To the extent these existing obligations overlap with Section 1557 and covered entities have complied with the CMS regulations that prohibit discrimination on the basis of sex, sexual orientation, and gender identity, this rule will impose little or no burden on health insurance issuers and Title I entities to comply with Section 1557's and this part's prohibition on sex discrimination. However, the rule nonetheless imposes some costs.

a. Developing or Revising Policies and Procedures

There may be some incremental burden on issuers and Title I entities in terms of the additional guidance that this rule provides related to sex discrimination, because, in some circumstances, it provides more detail than CMS regulations or guidance. Therefore, covered entities may have an increased burden when incorporating this rule into their existing nondiscrimination policies and procedures. For example, this rule specifies that a categorical coverage exclusion or limitation for all health care services related to gender transition is discriminatory on its face. If a covered entity had not previously understood sex discrimination on the basis of gender identity in this way, the covered entity would have to revise its policies and procedures to provide coverage consistent with this final rule's parameters, which might include revising policies to include gender transition-related care.

However, we note that the number of major U.S. employers providing transgender-inclusive health care coverage has been increasing, from 0 in 2002, to 49 in 2009, 278 in 2013, 336 in 2014, 418 in 2015, and at least 511 in 2016.[344] This indicates that plans that offer transgender-inclusive health care are becoming readily available as models for issuers that may not offer such care, limiting their costs in developing or revising policies and procedures for compliance.

Similar to the estimate for providers of health services, we assume that it will take, on average, three to five hours for issuers of health insurance coverage to develop or modify policies and procedures concerning sex discrimination. We are selecting four hours, or the midpoint of this range, for our analysis. We further assume that three of the hours will be spent by a mid-level manager, at a salary, with fringe benefits and overhead of $57.60 per hour,[345] and one hour will be spent by executive staff, at a salary, with fringe benefits and overhead of $122.15 per hour. Based on our best estimate of industry compliance with CMS regulations, we further assume that one-third or 33% of health insurance issuers will need to develop or modify policies and procedures. Based on an unduplicated count of issuers, we previously identified 180 issuers in the Marketplaces (including Federally-facilitated Marketplaces). One third of this number equals 60 issuers that we estimate would need to revise policies to address the prohibition of sex discrimination in this regulation. The costs to issuers to revise policies and procedures to provide coverage consistent with this rule's parameters equal 60 issuers multiplied by $295 for a one-time cost of $17,700.

b. Ending Discriminatory Practices

In addition to the cost some covered health insurance providers may have for revising policies and procedures to comply with the rule, such providers may also incur a de minimis cost related to the cost of coverage. In this regard, we note that the April 2012 California

identity, sexual orientation, expected length of life, degree of medical dependency, quality of life, or other health conditions. 45 CFR 156.200(e) prohibits a qualified health plan issuer from discriminating on the basis of race, color, national origin, disability, age, sex, gender identity, or sexual orientation. 45 CFR 156.125(a) prohibits issuers that provide essential health benefits from using benefit designs that discriminate based on an individual's age, expected length of life, present or predicted disability, degree of medical dependency, quality of life, or other health conditions. 45 CFR 156.125(b) requires issuers that provide essential health benefits to comply with 45 CFR 156.200(e).

[336] 45 CFR 147.104(e), 156.200(e) and 156.125(a)–(b) are applicable to qualified health plan issuers.

[337] 45 CFR 147.104(e) is applicable to non-grandfathered coverage in the individual, small and large group markets. 45 CFR 147.150(a) incorporates essential health benefits requirements (and implementing regulations at 45 CFR 156.200(e) and 156.125(a)–(b)) for non-grandfathered coverage in the individual and small group markets.

[338] 42 U.S.C.300gg.

[339] *Id.* 18022 (b).

[340] *Id.* 300gg–13 (a)(4).

[341] *Id.* 18001.

[342] *Id.* 300gg–4.

[343] *Id.* 300gg–4(a)(7); ASPE Issue Brief, *supra* note 332.

[344] Human Rights Campaign, Corporate Equality Index, *Rating American Workplaces on Lesbian, Gay, Bisexual and Transgender Equality, http://www.hrc.org/campaigns/corporate-equality-index* (last visited May 3, 2016).

[345] U.S. Dep't of Labor, Bureau of Labor Statistics, Occupational Employment Statistics, May 2015 National Occupational Employment and Wage Estimates by ownership, *http://www.bls.gov/oes/2014/may/oes_nat.htm* (last visited May 3, 2016) (using data for First-Line Supervisors of Office and Administrative Support Workers and General and Operations Managers for the health insurance industry).

Department of Insurance Economic Impact Assessment on Gender Nondiscrimination in Health Insurance found that covering transgender individuals under California's private and public health insurance plans would have an ''insignificant and immaterial'' impact on costs.[346] 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% and 0.0173%.[347] The study revealed that, contrary to common assumptions, not all transgender individuals seek surgical intervention, and that gender-confirming health care differs according to the needs and pre-existing conditions of each individual.[348] 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.[349] Additionally, issuers in California that established premium surcharges after enactment of California's Gender Nondiscrimination in Health Insurance Law subsequently eliminated them because they found they did not spend the extra funds generated.[350]

Two other studies also support the conclusion that the cost is de minimis for entities providing or administering health insurance coverage to come into compliance with this rule's provision of nondiscrimination on the basis of sex. One is a 2013 Williams Institute study of 34 public and private employers, and the second consists of cost projections of providing transition-related health-care benefits to members of the military.

The first of these two studies, a 2013 study of 34 employers that provided nondiscriminatory health care coverage, found that providing transition-related benefits to treat gender dysphoria had ''zero to very low costs.''[351]

The second study, published in the *New England Journal of Medicine,* projected that the cost for providing transition-related health care benefits to members of the military would result in an annual increase of 0.012% of health care costs, ''little more than a rounding error in the military's $47.8 billion annual health care budget.''[352] Based on the California and two other studies discussed above, we estimate that providing transgender individuals nondiscriminatory insurance coverage and treatment will impact a very small segment of the population due to the fact that the number of transgender individuals (and particularly those who seek surgical procedures in connection with their gender transition) in the general population is small, and consequently will have de minimis impact on the overall cost of care and on health insurance premiums.[353]

F. Accessibility of Electronic and Information Technology

Although Section 1557 requires covered entities to ensure that the health programs, services, and activities provided through electronic and information technology are accessible to individuals with disabilities, all covered entities affected by Section 1557 already have these obligations under Section 508, Section 504 or the ADA.

1. HHS Health Programs and Activities, Including the Federally-Facilitated Marketplaces

Section 508 requires that electronic and information technology developed, procured, maintained, or used by Federal agencies be accessible for individuals with disabilities (both members of the public and Federal employees). Section 504 also establishes general obligations for Federal agencies to make their programs that are provided through electronic and information technology accessible to individuals with disabilities. Both Section 504 and Section 508 were in place before the passage of the ACA. There is, therefore, no additional burden under Section 1557 for HHS health programs, including the Federally-facilitated Marketplaces, as the Section 1557 requirements are consistent with the obligations these programs already have under Section 504 and Section 508.

2. Recipients of Federal Financial Assistance From HHS and Title I Entities

Section 504 also establishes general obligations for entities receiving Federal financial assistance to make their programs, services, and activities provided through electronic and information technology accessible to individuals with disabilities. The ADA imposes similar accessibility requirements on covered entities. This rule thus imposes no additional burden on recipients of Federal financial assistance from HHS because Section 1557 is consistent with existing standards these entities are already obligated to meet under the ADA and Section 504. Title I entities have no Section 1557 burden with respect to this proposed requirement, as the Title I entities must already be compliant with the ADA, which is consistent with the Section 1557 accessibility standards.

G. Enforcing the Rule

After grievances are filed with covered entities or complaints are filed with OCR, there are associated costs to investigate and resolve those grievances and complaints. We believe the following costs result from enforcement of the Section 1557 regulation:

- Costs to covered entities for modifying and implementing grievance procedures to cover grievances filed under Section 1557.
- Costs to OCR for reviewing and investigating complaints, monitoring corrective action plans, and taking other enforcement actions against covered entities.

In the analysis below, we estimate the aggregate costs of these enforcement procedures, and analyze the costs to covered entities separately from the costs to OCR.

1. Costs to Covered Entities

Federal civil rights laws that were in place before the enactment of Section 1557 apply to entities that receive Federal financial assistance. Entities subject to those laws are already required to have in place established grievance procedures to address complaints of disability discrimination and complaints of sex discrimination in education programs. We anticipated that additional costs arising from the expansion of the grievance process to cover all bases included in Section 1557, including race, color, national origin, and age, as well as sex discrimination in health care, could impose additional costs on covered entities. We assumed a slight increase in the number of grievances filed, and a

[346] State of Cal., Dep't of Ins., Economic Impact Assessment Gender Nondiscrimination in Health Insurance. (Apr. 13, 2012). *http://translaw.wpengine.com/wp-content/uploads/2013/04/Economic-Impact-Assessment-Gender-Nondiscrimination-In-Health-Insurance.pdf.*

[347] *Id.*

[348] *Id.* at 8.

[349] *Id.* at 9.

[350] *Id.* at 6–7.

[351] The Williams Inst., Cost and Benefits of Providing Transition-Related Health Care Coverage in Employee Health Benefits Plans: Findings from a Survey of Employers, at 2 (Sept. 2013), *http://williamsinstitute.law.ucla.edu/wp-content/uploads/Herman-Cost-Benefit-of-Trans-Health-Benefits-Sept-2013.pdf*

[352] A. Belkin, ''Caring for Our Transgender Troops — The Negligible Cost of Transition-Related Care,'' 373 New Eng. J. Med. 1089 (Sept. 15, 2015).

[353] State of Cal., Dep't of Ins., *supra* note 346, at 2, 5. Issuers in California that established a premium surcharge to cover the City of San Francisco's expected claim costs eventually eliminated the additional premium because they found their cost assumptions were 15 times higher than actual claims generated.

corresponding increase in time to investigate and resolve these additional grievances.

To compute the anticipated costs for covered entities to enforce the regulation, we looked to OCR data. The current number of civil rights complaints filed annually with OCR is approximately 3,000. Since the passage of Section 1557, OCR's complaint workload has increased slightly, with approximately 15 to 20 unique Section 1557 cases filed each year. If we include another ten cases per year as a result of the promulgation of the regulation, we calculate an increase of 30 cases per year or 1% of the annual caseload of 3,000. We assume the incremental workload will be similar for affected entities and thus will be approximately 1%. We anticipate that within the first five years following the promulgation of the regulation, complaints will initially increase, but then will eventually drop off as covered entities modify their policies and practices in response to the rule. Due to the likelihood that applicable changes will need to be phased in, we assume one half of the annual projected costs for investigating discrimination complaints will be incurred during the first year and three quarters of the annual projected enforcement costs will be spent in the second year and the full amounts in the third through fifth years. Although we have data on OCR's caseload, we have no data on the caseload of affected covered entities.

We assume that as a result of promulgating the regulation, the 41,250 covered entities with 15 or more employees will require an average of an additional 1% of a Full Time Equivalent (FTE) for designated grievance officials to investigate discrimination grievances in years three through five following publication of the final rule, with costs half as large in the first year and costs three quarters as large in the second year. We assume the grievance official's salary is equivalent to that of medical and health service managers (occupation code 11–9111), who have annual median wages of $103,680. These assumptions imply costs, after adjusting for fringe benefits and overhead, of $42.8 million in the first year, $64.2 million in the second year, and $85.5 million in years three through five following publication of the final rule.

One comment suggested that litigation costs may also rise as a result of issuance. We assume that the costs of litigation are included in the costs listed in the paragraph above.

The same incremental calculations apply to the workloads of State agencies and the officials working in these agencies. If we assume the same increases in workload at each State agency as discussed previously, and the average mid-level State official salary is $94,580 (including fringe benefits and overhead), we must multiply $94,580 by the number of State covered entities.[354] To arrive at the number of State covered entities we make the following assumptions:

- We assume that there are 56 Medicaid State agencies;
- We assume that there are 56 State health departments;
- We assume that there are 1,003 State and local government community hospitals;[355] and
- We assume that each of 3,143 counties has a county health department that provides direct health services (*e.g.,* immunization clinics) and is accountable to the State Health Department. We assume that each of the county health departments has a designated official for handling grievances.

The total number of State covered entities is 4,252. Multiplying $94,580 by 4,252 equals $402.2 million. One percent of this value equals $4.0 million. This implies costs of $2.0 million in the first year, $3.0 million in the second year and $4.0 million in subsequent years following the publication of the final rule.

2. Costs to OCR

We considered the various OCR enforcement costs together, based on OCR average salary data presented in its annual budgets. According to the FY 2016 President's Budget, $28,400,000 and 137 FTEs were requested for Enforcement and Regional Operations, at a cost of approximately $201,000 per FTE. Of the 137 FTEs, approximately 40 FTEs spend 100% of their investigative time enforcing the civil rights laws.[356] If we make the same assumption we did above and assume the same increase in caseload from the issuance of Section 1557 as discussed above, the anticipated increase in number of staff necessary would be approximately 0.4 of an FTE (1% of 40) and would cost approximately $40,200 in the first year, $60,300 in the second year, and $80,400 in subsequent years following the publication of the final rule.

3. Summary of Cost and Phase-In

The table below summarizes the costs attributable to the regulation that covered entities may incur following enactment of the final regulation. We assume that half of the training costs and changes to policies and procedures on the prohibition of discrimination on the basis of sex will be incurred in the first year and the second half will be expended in the second year. For covered entities that will be printing and distributing notices to their patients and policy holders, we assume that all of the estimated printing and distribution costs will be expended in the first year after the effective date of the rule. Familiarization costs, information collection requirements and paperwork burden costs would be incurred within the first year after the effective date of the final regulation. Cost of enforcement, by contrast, will increase over the course of the first five years.

TABLE 5—COST SUMMARY OF THE REGULATION FOLLOWING ENACTMENT OF THIS FINAL RULE

[Discounted 3% and 7% in millions]

	Year 1	Year 2	Year 3	Year 4	Year 5	Total/ annualized
Training and Familiarization (undiscounted)	234.9	185.8	0.0	0.0	0.0	420.8
Training and Familiarization (3%)	228.1	175.2	0.0	0.0	0.0	88.1
Training and Familiarization (7%)	219.6	162.3	0.0	0.0	0.0	93.1
Enforcement (undiscounted)	44.8	67.2	89.6	89.6	89.6	381.0
Enforcement (3%)	43.5	63.4	82.0	79.6	77.3	75.5
Enforcement (7%)	41.9	58.7	73.2	68.4	63.9	74.6
Notice Publication (undiscounted)	7.2	0.0	0.0	0.0	0.0	7.2

[354] Based on the annual salary of Executive Secretary and Executive Administrative Assistant.

[355] American Hospital Ass'n: Fast Facts on US Hospitals, (Jan. 2016), *http://www.aha.org/research/rc/stat-studies/101207fastfacts.pdf.*

[356] This is based on an informal staff estimate.

TABLE 5—COST SUMMARY OF THE REGULATION FOLLOWING ENACTMENT OF THIS FINAL RULE—Continued

[Discounted 3% and 7% in millions]

	Year 1	Year 2	Year 3	Year 4	Year 5	Total/ annualized
Notice Publication (3%)	7.0	0.0	0.0	0.0	0.0	1.5
Notice Publication (7%)	6.7	0.0	0.0	0.0	0.0	1.6
Sex discrimination	24.8	24.8	0.0	0.0	0.0	49.5
Policy and Procedure Changes (undiscounted):						
Sex discrimination	24.0	23.3	0.0	0.0	0.0	10.3
Policy and Procedure Changes (3%):						
Sex discrimination	23.1	21.6	0.0	0.0	0.0	10.9
Policy and Procedure Changes (7%):						
Language Access Plan (undiscounted)	36.0	12.0	12.0	12.0	12.0	84.1
Language Access Plan (3%)	35.0	11.3	11.0	10.7	10.4	17.1
Language Access Plan (7%)	33.7	10.5	9.8	9.2	8.6	17.5
Total (undiscounted)	347.7	289.8	101.6	101.6	101.6	942.5
Total (3%)	337.6	273.2	93.0	90.3	87.7	192.5
Total (7%)	325.0	253.2	83.0	77.5	72.5	197.8

Note: Discounted and annualized values take into account the cost of borrowing and paying back funds at hypothetical interest rates to simulate opportunity costs.

This completes our analysis of the costs of the final rule. Next, we examine the benefits that can be expected to accrue as a result of the final rule.

III. Benefits & Transfers

In enacting Section 1557 of the ACA, Congress recognized the benefits of equal access to health services and health insurance that all individuals should have, regardless of their race, color, national origin, age, or disability. Section 1557 brought together the rights to equal access that had been guaranteed under Title VI, the Age Act and Section 504. At the same time, Congress extended these protections and rights to individuals seeking access to health services and health insurance without discrimination on the basis of sex.

This rule implements the provisions of Section 1557. In most respects, the rule clarifies existing obligations under existing authorities, and we have noted in the cost analysis that we do not expect that covered entities will incur costs related to the clarification of those existing obligations in the final rule. As the HHS LEP Guidance [357] and regulation implementing Title VI [358] indicate, recipients are already required to take reasonable steps to ensure meaningful access to their programs and activities by persons with limited English proficiency. We note that the additional provisions related to serving individuals with limited English proficiency in the final rule may create some additional costs but will also create substantial benefits to patients and providers by improving access to quality care.[359]

Studies show that individuals with limited English proficiency experience barriers to receiving regular and adequate health care. However, according to the Institute of Medicine, when reliable language assistance services are utilized, patients experience treatment-related benefits, such as enhanced understanding of physician instruction, shared decision-making, provision of informed consent, adherence with medication regimes, preventive testing, appointment attendance, and follow-up compliance.[360] Additional intangible benefits may include retention of cultural information, exchange of information, greater satisfaction with care,[361] and enhanced privacy and autonomy of individuals with limited English proficiency who may have previously had to rely on family members for language assistance.[362]

Health service providers also benefit from providing language assistance services for individuals with limited English proficiency. Providers can more confidently make diagnoses, prescribe medications, reach treatment decisions, and ensure that treatment plans are understood by patients.[363] ''Language is also an important tool for clinicians to establish an empathic connection with patients[;]'' accordingly, language assistance services benefit both patients and providers alike.[364] One study states that ensuring effective communication can also help providers avoid costs associated with ''damages paid to patients, legal fees, the time lost when defending a lawsuit, the loss of reputation and patients, the fear of possible monetary loss, and the stress and distraction of litigation.'' [365] Another study of malpractice claims found that a malpractice carrier insuring in four states paid over $2 million in damages or settlements as well as over $2 million in legal fees over a four year period for claims arising from failure to use an appropriate interpreter.[366]

We have also noted that we expect that the prohibition of sex discrimination in the final rule will generate certain actions and other changes in behavior by covered entities and that these actions and changes will impose costs. These actions and other

[357] 68 FR 47311, 47313 (Aug. 8, 2003).

[358] 45 CFR 80.3.

[359] Report to Congress. Assessment of the Total Benefits and Costs of Implementing Executive Order No. 13166: Improving Access to Services for Persons with Limited English Proficiency (Mar. 2002), p. 20, *https://www.justice.gov/sites/default/files/crt/legacy/2010/12/14/omb-lepreport.pdf.*

[360] Brian D. Smedley, Adrienne Y. Stith, Alan R. Nelson, eds., Institute of Medicine, *Unequal Treatment: Confronting Racial and Ethnic Disparities in Health Care, Committee on Understanding and Eliminating Racial and Ethnic Disparities in Health Care, Board on Health Science Policy,* (2003), pp.142, 191; Report to Congress, *supra* note 359 at 20–22.

[361] *Id.*

[362] Kelvin Quan & Jessica Lynch, *The High Costs of Language Barriers in Medical Malpractice* (2010), p.17, *http://www.healthlaw.org/images/stories/High_Costs_of_Language_Barriers_in_Malpractice.pdf.*

[363] ASPE, *Caring for Immigrants: Health Care Safety Nets in Los Angeles, New York, Miami and Houston,* (2001), *https://aspe.hhs.gov/execsum/caring-immigrants-health-care-safety-nets-los-angeles-new-york-miami-and-houston;* Elizabeth A. Jacobs, Donald S. Shepard, Jose A. Suaya and Esta-Lee Stone, *Overcoming Language Barriers in Health Care: Costs and Benefits of Interpreter Services, Am. J. Public Health (2004), http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1448350/;* Unequal Treatment, *supra* note 360 at 141.

[364] *Unequal Treatment, supra* note 360 at 141.

[365] *The High Costs of Language Barriers in Medical Malpractice, supra* note 362 at 15.

[366] Agency for Healthcare Research and Quality, Improving Patient Safety Systems for Patients With Limited English Proficiency: A Guide for Hospitals (2012), *http://www.ahrq.gov/sites/default/files/publications/files/lepguide.pdf.*

changes in behavior will also result in benefits.

The provisions prohibiting sex discrimination in the ACA increase the affordability and accessibility of health care for women and transgender individuals. However, despite the ACA improving access to health services and health insurance, many women and transgender individuals continue to experience discrimination in the health care context, which can lead to denials of adequate health care and increases in existing health disparities in underserved communities. This continued discrimination demonstrates the need for further clarification regarding the prohibition of discrimination on the basis of sex.

Prior to the enactment of the ACA, insurance companies were allowed to impose higher premiums on women or deny women coverage altogether. If issuers did cover women, they frequently did not cover a number of women's health services, including routine preventive services, such as pap smears or mammograms. Insurance premiums previously could differ by sex, and were often higher for females relative to males. The ACA prohibits differential treatment based on sex, includes maternity coverage in essential health benefits, and requires non-grandfathered plans to cover women's preventive services without copays, among other benefits.

For transgender individuals, a major barrier to receiving care is a concern over being refused medical treatment based on bias against them.[367] In a 2010 report, 26.7% of transgender respondents reported that they were refused needed health care.[368] A 2011 survey revealed that 25% of transgender individuals reported being subject to harassment in medical settings, and 50% reported having to teach their medical providers about transgender care.[369] We received many comments expressing anecdotal evidence of these statistics.

Another potential barrier for transgender individuals to care is covered entities' nondiscrimination policies, which often do not include gender identity. The 2014 Human Rights Campaign Healthcare Equality Index, which evaluates health care facilities' LGBT policies and practices, found that among the 640 hospitals it evaluated, 501 had patient nondiscrimination policies but of those only 257 had a patient nondiscrimination policy that included both the terms ''sexual orientation'' and ''gender identity.'' [370]

Yet another barrier to care for transgender individuals is the process of obtaining health insurance coverage. A study by the Center for American Progress found that transgender individuals have often experienced difficulties when seeking insurance coverage.[371] Similarly, in 2014, Out2Enroll, a national campaign that serves as a key link between LGBT communities and the ACA by connecting LGBT people with information about their new coverage options, issued findings in a report entitled *''Key Lessons for LGBT Outreach and Enrollment under the Affordable Care Act.''* [372] The report focuses on the lack of adequate training of Navigator staff when encountering LGBT individuals seeking access to the Health Insurance Marketplaces. A major complaint was that Navigator staff was unaware of the multitude of discriminatory practices and policy restrictions in which issuers engage to deny or restrict coverage of transgender individuals, and that Navigator staff lacked basic knowledge of health issues that are unique to transgender individuals.[373]

Ultimately, transgender individuals who have experienced discrimination in the health care context often postpone or do not seek needed health care, which may lead to negative health consequences.[374] A study by the National Center for Transgender Equality and the National Gay and Lesbian Task Force found that ''one-quarter of the more than 6,400 transgender and gender-nonconforming respondents reported . . . being denied needed treatment[,] . . . being harassed in health care settings[,] . . . [and] postponing medical care because of discrimination by providers.'' [375] We received several comments echoing these statements, both from individuals citing personal experiences and from entities citing data. This kind of discrimination exacerbates health disparities experienced by the LGBT population, including: higher rates of mental health issues, including depression and suicide attempts; higher risk of HIV/AIDS; higher use of tobacco and other drugs; and higher risk of certain cancers, such as breast cancer, with some portion of the differential potentially attributable to barriers to health care.[376]

By prohibiting discrimination on the basis of sex, Section 1557 would result in more women and transgender individuals obtaining coverage and accessing health services. Since 2013, the uninsured rate for women has declined, with nearly 9.5 million women gaining health coverage as of 2016.[377] Similarly, uninsured rates for LGBT individuals dropped from 34% in 2013 to 26% in 2014.[378] While these declines in the rates of the uninsured are attributable to many factors, among these factors may be provisions in the ACA prohibiting discriminatory practices in insurance. We expect that the Section 1557 regulation may contribute to a continued reduction in the number of individuals who are uninsured, although the reduction would be much more modest.

For a representative example, we look to a State of California economic impact assessment of State practices prohibiting gender discrimination in health care, which cites the following benefits: [379]

1. Reduced violence against affected individuals;
2. Reduced depression and suicide attempts among the affected population; and
3. Overall declines in substance abuse, smoking and alcohol abuse rates, and improvements in mental health among treated individuals in LGBT populations who receive appropriate medical treatment.

Moreover, because discrimination contributes to health disparities, the prohibition of sex discrimination in health care under Section 1557 can help

[367] Lambda Legal, *supra* note 333 at 12–13.

[368] *Id.* at 10.

[369] National Center for Transgender Equality and National Gay and Lesbian Task Force, Injustice at Every Turn: A Report of the National Transgender Discrimination Survey, 5–6 (2011), *http://www.thetaskforce.org/.*

[370] Human Rights Campaign, Healthcare Equality Index 2014, *http://www.hrc.org/reports/hei.*

[371] Laura E. Durso, Kellan Baker, and Andrew Cray, Center for American Progress Issue Brief: LGBT Communities and the Affordable Care Act Findings from a National Survey, (Oct. 10, 2013), *http://www.preventionjustice.org/wp-content/uploads/2013/10/CAP–LGBT-Messaging-Research.pdf.*

[372] Out2Enroll, Key Lessons for LGBT Outreach and Enrollment under the Affordable Care Act (July 24, 2014), *http://out2enroll.org/lgbthealthcare/wp-content/uploads/2014/07/O2E_KeyLessons_FINAL.pdf.*

[373] *Id.* at 24.

[374] Kellan E, Baker, Center for American Progress, Open Doors for All, Sexual Orientation and Gender Identity Protections in Health Care (Apr. 30, 2015), *https://www.americanprogress.org/issues/lgbt/report/2015/04/30/112169/open-doors-for-all/.*

[375] *Id.*

[376] *Id.*

[377] U.S. Dep't of Health & Human Servs., Office of the Assistant Secretary for Planning and Eval., ASPE Issue Brief: Health Insurance Coverage and the Affordable Care Act 201–2016, 2 (Mar. 3, 2016) *https://aspe/hhs.gov.*

[378] Kellan Baker, Laura E. Durso, and Andrew Cray, Center for American Progress, Moving the Needle, The Impact of the Affordable Care Act on LGBT Communities, 3 (Nov. 2014), *https://www.americanprogress.org/issues/lgbt/report/2014/11/17/101575/moving-the-needle/.*

[379] California Department of Insurance, *supra* note 346, at 10–12.

reduce health disparities. While it is not possible to quantify the benefits of the reduction in health disparities, the benefits would include more people receiving adequate health care, regardless of their sex, including gender identity.

The health and longevity benefits discussed above as potential effects of this rule assume additional or higher-quality medical services are provided to affected individuals. These services would be associated with costs (which we lack data to estimate). As mentioned in the earlier discussion of actuarial risk, to the extent that changes in insurance premiums do not alter how society uses its resources, the final rule would result in transfers between members of society, rather than social costs or benefits. In addition to women and transgender individuals, health service providers and the Federal government could also be recipients of these transfers. For example, in 2013, $53.3 billion was paid to offset uncompensated care, of which the Federal government paid for approximately $32.8 billion.[380] Based on estimated coverage gains in 2014, uncompensated care costs are expected to continue to fall substantially following continued major insurance coverage expansions, including coverage expansions through the Health Insurance Marketplace℠.[381] While issuance of the Section 1557 regulation is not a factor in this projection, we believe that the Section 1557 regulation will likewise contribute to a decrease in payments by the Federal government for uncompensated care by promoting an increase in the number of individuals who have coverage when they receive care.

Aside from the specific benefits and transfers that women and transgender individuals, and the health care community can be expected to gain from the enactment of the regulation, there are additional benefits that are intangible and unquantifiable that derive from providing equal access to health care for all.

[380] Teresa A. Coughlin, John Holahan, Kyle Caswell, and Megan McGrath, The Henry J. Kaiser Family Foundation, Uncompensated Care for the Uninsured in 2013: A Detailed Examination (May 30, 2014), p. 4. *https://kaiserfamilyfoundation.files.wordpress.com/2014/05/8596-uncompensated-care-for-the-uninsured-in-2013.pdf.*

[381] U.S. Dep't of Health & Human Servs., Office of the Assistant Sec'y for Planning and Eval., Thomas DeLeire, Karen Joynt, and Ruth McDonald, ASPE Issue Brief, Impact of Insurance Expansion on Hospital Uncompensated Care Costs in 2014 (Sept. 24, 2015) *https://aspe.hhs.gov/sites/default/files/pdf/77061/ib_UncompensatedCare.pdf.*

IV. Alternatives Considered

In the course of developing this regulation, OCR considered various alternatives. Some of those alternatives are discussed in the preamble. A discussion of alternatives cannot cover all alternatives considered by OCR. The following alternatives are meant to be a representative sample to show how burden reduction was a major consideration in constructing the standards in this regulation.

The first option is no new regulatory action. We did not select this option because we believe the regulation provides substantial benefits to society, net of the costs. We received a comment suggesting that we consider either writing a more informative than prescriptive regulation or delaying the regulation, based on a possible trend of increased voluntary compliance by health care agencies with nondiscrimination statutes. OCR's current experience, however, points to the importance of and need for a prescriptive regulation. OCR provides education and information on the civil rights statutes and regulations, conducts technical assistance and outreach to promote compliance, and is developing training materials to provide information and technical assistance on this rule. However, OCR has found that providing information and outreach is not sufficient to ensure nondiscrimination in health care programs and activities. OCR continues to receive and resolve many complaints of discrimination and to hear of ongoing discrimination through outreach and communications with stakeholders. The regulation will inform stakeholders of their rights so that affected individuals know that they can seek OCR's assistance, and will provide clarity for covered entities, limiting uncertainty and promoting compliance. In addition, the majority of the comments from the public in response to the proposed rule favored issuance of a regulation.

OCR considered requiring covered entities to provide separate notices, covering separate content, *e.g.,* separate notices on the requirements concerning the provision of meaningful access for individuals with limited English proficiency, requirements concerning effective communication for individuals with disabilities, and policies on nondiscrimination. To reduce the burden on covered entities, OCR rejected this option in favor of a comprehensive single-notice requirement. We are also permitting entities to combine the Section 1557 notice with other notices that the entities may be required to post.

OCR decided to further reduce the burden imposed on covered entities by the notice requirement by making available a sample notice, located in Appendix A. OCR allows covered entities flexibility in complying with the notice requirement by giving covered entities the option of using the sample notice or developing their own notice. Although OCR considered requiring covered entities to post the notice in 15 languages (Spanish (or Spanish Creole), Chinese, Vietnamese, Korean, Tagalog, Russian, Arabic, French Creole, French (including Patois, Cajun), Portuguese (or Portuguese Creole), Polish, Japanese, Italian, German, and Persian (Farsi)), we rejected that option. Instead, we are providing the notice translated into 64 languages, and are allowing covered entities the discretion to post one or more of the translated notices. We believe that making translated notices readily available to covered entities maximizes efficiency and economies of scale, provides flexibility while minimizing burden, and helps provide greater access for beneficiaries and consumers. Additionally, although OCR considered requiring covered entities to create their own taglines in the top 15 national languages spoken by individuals with limited English proficiency, we rejected that option. Instead, OCR is making available to covered entities the taglines in 64 languages. As the tagline requirement for the covered entities only requires the cost of printing and posting, this burden is expected to be minimal.

OCR considered not providing training materials to covered entities on the requirements of the regulation. However, in order to reduce costs and burden, OCR is providing these materials, which will reduce covered entities' costs of developing training materials from $500 per entity to $125 per entity, resulting in a savings of approximately $104 million. Entities are assumed to bear one quarter of the total costs. These costs result from paying the presenters who will run the training sessions, providing classroom space, and supplementing the training materials that OCR is making available (should they choose to do so).

OCR considered remaining silent on covered entities' obligations to comply with Section 1557's prohibition of national origin discrimination as it affects individuals with limited English proficiency. We rejected this approach because we were concerned that OCR's silence would create ambiguity about covered entities' obligations to individuals with limited English proficiency and could jeopardize the access of individuals with limited

English proficiency to covered entities' health programs and activities. Clearly explaining the standards also promotes compliance and reduces enforcement costs. Options for addressing the prohibition of national origin discrimination as it affects individuals with limited English proficiency are discussed in the preamble to the proposed rule.

OCR considered a regulatory scheme requiring covered entities to provide meaningful access to each individual with limited English proficiency by providing effective language assistance services, at no cost, unless such action would result in an undue burden or fundamental alteration. OCR also considered requiring covered entities of a certain type or size to have enhanced obligations to provide language assistance services. Such enhanced obligations would include providing a predetermined range of language assistance services in certain non-English languages that met defined thresholds. A covered entity that was not of a certain type or size still would be required to provide meaningful access to each individual with limited English proficiency in its health programs and activities, but the covered entity would not have to provide a predetermined range of language assistance services in certain non-English languages. OCR also explored applying the threshold requirement to standardized vital documents on a national, State, or county level, as well as specific to a covered entity's geographic service area.

The strengths of these alternate regulatory schemes included limited obligations for small businesses providing health programs or activities and defined standards for larger entities. The costs of these approaches included the complexity of the regulatory scheme and the potential burden on the covered entities of a certain type or size that would have enhanced applications. OCR determined these costs outweigh the benefits.

OCR considered drafting new provisions addressing effective communication (apart from communication through electronic and information technology) with individuals with disabilities, but instead is incorporating provisions of the regulation implementing Title II of the ADA to ensure consistency for covered entities and potentially reduce burden by limiting resources spent on training and modification of policies and procedures.

Options regarding communication through electronic and information technology are discussed in the preamble to the regulation. Regarding the accessibility requirements under the proposed regulation, OCR at first considered a narrower interpretation that the rule applied only to access to health programs and activities provided through covered entities' Web sites. However, we chose a broader interpretation, to include both Web sites and other means of electronic and information technology. While this could potentially increase the burden on recipients of Federal financial assistance and State-based Marketplaces, this would offer clarity to covered entities, increase the benefit of the rule, and help enhance access for individuals with disabilities.

In the area of compliance, OCR considered having one set of procedures for all compliance activities involving recipients of Federal financial assistance and State-based Marketplace℠ entities. Instead, OCR decided to adopt the unique Age Act procedures [382] for age-related compliance activities under Section 1557 because Age Act compliance activities and Section 1557 compliance activities regarding age discrimination are likely to substantially overlap.

With regard to other areas of compliance, OCR considered developing a separate set of procedures for Section 1557 compliance activities involving HHS health programs and activities, but decided to largely adopt the existing procedures for disability compliance activities involving HHS health programs and activities (with some enhancement) to improve efficiencies for OCR and the HHS health programs and activities covered by Section 1557.

V. Unfunded Mandates Reform Act of 1995

Section 202 of the Unfunded Mandates Reform Act of 1995 requires that agencies assess anticipated costs and benefits before issuing any rule that includes a Federal mandate that could result in expenditure in any one year by State, local, or tribal governments, in the aggregate, or by the private sector, of $100 million in 1995 dollars, updated annually for inflation. In 2016, that threshold level is approximately $146 million.

The Unfunded Mandates Reform Act does not address the total cost of a final rule. Rather, it focuses on certain categories of cost, mainly those ''Federal mandate'' costs resulting from: (1) Imposing enforceable duties on State, local, or tribal governments, or on the private sector; or (2) increasing the stringency of conditions in, or decreasing the funding of, State, local, or tribal governments under entitlement programs.

Our impact analysis shows that burden associated with training staff working for covered entities will be spread widely across health care entities, State and local governmental entities, and a substantial number of health insurance issuers. The analysis estimates the unfunded burden will be about $422 million in training and familiarization costs. We project that for the first few years following promulgation of the final rule, private sector costs for investigating discrimination complaints may amount to $87 million per year. Within the first five years following the final rule's promulgation, we anticipate complaints will increase, and then eventually drop off as covered entities modify their policies and practices in response to the final rule.

As we explain in the RIA, we believe there will be benefits gained from the promulgation of this regulation in the form of reduction in discrimination based on race, color, national origin, sex, age, and disability, and the corresponding improvement in the quality of care to underserved communities. In response to comments concerning the costs to covered entities, we note that we have not included some changes that would have been beneficial to individuals because we recognize that they would be costly for covered entities.

VI. Executive Order 13132: Federalism

As required by Executive Order 13132 [383] on Federalism, OCR examined the effects of provisions in the regulation on the relationship between the Federal government and the States. OCR has concluded that the regulation does have Federalism implications but preempts State law only where the exercise of State authority directly conflicts with the exercise of Federal authority under the Federal statute.

The regulation attempts to balance State autonomy with the necessity of creating a Federal floor that will provide a uniform level of nondiscrimination protection across the country. The regulation restricts regulatory preemption of State law to the minimum level necessary to achieve the objectives of the underlying Federal statute, Section 1557 of the ACA.

[382] The Age Act procedures, for example, require mediation of all age discrimination complaints, and exhaustion of administrative remedies prior to the filing of a civil lawsuit. 45 CFR 91.43, 91.50.

[383] Exec. Order No. 13132, 64 FR 43255 (1999).

It is recognized that the States generally have laws that relate to nondiscrimination against individuals on a variety of bases. State laws continue to be enforceable, unless they prevent application of the final rule. The final rule explicitly provides that it is not to be construed to supersede State or local laws that provide additional protections against discrimination on any basis articulated under the regulation. Provisions of State law relating to nondiscrimination that is ''more stringent'' than the proposed Federal regulatory requirements or implementation specifications will continue to be enforceable.

Section 3(b) of Executive Order 13132 recognizes that national action limiting the policymaking discretion of States will be imposed only where there is constitutional and statutory authority for the action and the national activity is appropriate in light of the presence of a problem of national significance. Discrimination issues in relation to health care are of national concern by virtue of the scope of interstate health commerce. The ACA's provisions reflect this position.

Section 3(d)(2) of Executive Order 13132 requires that where possible, the Federal government defer to the States to establish standards. Title I of the ACA authorized the Secretary to promulgate regulations to implement Section 1557, and we have done so accordingly.

Section 4(a) of Executive Order 13132 expressly contemplates preemption when there is a conflict between exercising State and Federal authority under a Federal statute. Section 4(b) of the Executive Order authorizes preemption of State law in the Federal rulemaking context when ''the exercise of State authority directly conflicts with the exercise of Federal authority under the Federal statute.'' The approach in this regulation is consistent with these standards in the Executive Order in superseding State authority only when such authority is inconsistent with standards established pursuant to the grant of Federal authority under the statute.

Section 6(b) of Executive Order 13132 includes some qualitative discussion of substantial direct compliance costs that State and local governments could incur as a result of a proposed regulation. We have determined that the costs of the final rule will not impose substantial direct compliance costs on State or local governments. We have considered the cost burden that this rule will impose on State and local health care and benefit programs, and estimate State and local government costs will be in the order of $17.8 million in the first two years of implementation. The $17.8 million represents the sum of the costs of training State workers and enforcement costs attributable to State agencies analyzed above.

VII. Regulatory Flexibility Act (RFA)

The RFA requires agencies that issue 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'').

HHS uses as its measure of significant economic impact on a substantial number of small entities a change in revenues of more than 3% for 5% 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.

A. Entities That Will Be Affected

HHS has traditionally classified most health care 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.

1. 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 $11 million.[384] 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 17,835 entities or 9.6% of all physician offices defined as ''large.'' This left 167,814 offices or 90.4% as ''small.''[385]

2. Pharmacies

Pharmacies also are businesses, and the size standard for them is annual receipts of less than $27.5 million. According to Census Statistics of U.S. Businesses, there are 18,852 pharmacy and drug store firms (North American Industry Classification System code 44611). 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.[386] The number of firms with fewer than 20 employees is 16,520 and represents 88% 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 16,520. 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.

3. 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 $38.5 million. Although the Blue Cross/Blue Shield companies that operate in some markets are organized as nonprofit entities, they often are large enough so as to not meet the definition of ''small entity.''

[384] U.S. Small Business Administration, Table of Small Business Size Standards Matched to North American Industry Classification System Codes. Small Business Administration, (June, 2016), *https://www.sba.gov/sites/default/files/Size5FStandards5FTable.pdf.*

[385] Physician practices may earn more than $11 million per year and that would reduce the number of ''large'' practices to be excluded from the analysis. But as we will later show, large practices will have proportionally larger workforce staff that must be excluded from the analysis.

[386] U.S. Census Bureau, Statistics of U.S. Businesses, *supra* note 314.

Unfortunately, we cannot use the Census revenue data for estimating the number of small health insurance issuers because the Census data combines life and health insurance. Substituting costs for revenues allows us to obtain a rough estimate of the number of large insurance issuers, realizing that cost will probably be less than revenues, thus giving us a lower count of large issuers. Using the National Health Expenditure for 2013, net cost of health insurance equaled $173.6 billion. However, the 2012 Census data report a total of 815 health insurance issuers. Dividing the $174 billion in costs by the number of insurance issuers reported in the census tables yields average costs of over $213 million, which means that average annual revenues per issuer exceeds $213 million. We concluded, therefore, that there are almost no small insurance issuers. The above analysis comports with the conclusion CMS published in the Health Insurance Web Portal Requirements.[387]

4. Local Government Entities

We also excluded local governmental entities from our count of small entities 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 proposed rule.

TABLE 6—SMALL COVERED ENTITIES

NAIC	Entity type	Number of firms
62142	Outpatient mental health and substance abuse centers	4,987
62141	HMO medical centers	104
62142	Kidney dialysis centers	492
62143	Freestanding ambulatory surgical and emergency centers	4,121
621498	All other outpatient care centers	5,399
6215	Medical and diagnostic laboratories	7,958
6216	Home health care services	21,668
6219	All other ambulatory health care services	6,956
62321	Residential mental retardation facilities	6,225
62199	General medical and surgical hospitals	3,067
621991	Psychiatric and substance abuse hospitals	411
6221	Specialty (except psychiatric and substance abuse) hospitals	373
6231	Nursing care facilities (skilled nursing facilities)	8,623
44611	Pharmacies and drug stores	16,520
6211	Offices of physicians	167,814
	Navigator grantees	100
	Total small entities	254,998

B. Whether the Rule Will Have a Significant Economic Impact on Covered Small Entities

Total undiscounted costs associated with the final rule are an average of $189 million per year over a five year period. If all of those costs are borne by small entities, this amounts to an average of $739 each year over that five year period. As a result, we believe that fewer than 5% of all small entities will experience a burden of greater than 3% of their revenues. Ambulatory health care services facilities (North American Industry Classification System 621), for example, are small entities with an average of 13 employees and revenue of $1.7 million based on 2012 reported data for employees of 6.4 million and total revenues of $825.7 million for 485,235 firms.[388] In addition, the majority of the costs associated with this final rule are proportional to the size of entities, meaning that even the smallest of the affected entities are unlikely to face a substantial impact. Thus, we would not consider this regulation a significant burden on a substantial number of small entities, and, therefore, the Secretary certifies that the final rule will not have a significant impact on a substantial number of small entities.

VIII. Conclusion

For the most part, because this regulation is consistent with existing standards applicable to the covered entities, the new burdens created by its issuance are minimal. The major impacts are in the areas of voluntary training, posting of notices, enforcement (where increased caseloads pose incremental costs on covered entities), voluntary development of language access plans, and revisions or development of new policies and procedures. The final rule does not include broad expansions of existing civil rights requirements on covered entities, and therefore minimizes the imposition of new burdens. Nevertheless, it is still a major rule with economically significant costs. The annualized cost of this rule over the first five years following its publication is $192.5 million using a discount rate of 3%, and $197.8 million using a discount rate of 7%. This RIA was organized and designed to explain the origin of these cost impacts and to incorporate relevant public comments.

[387] 75 CFR 24481, May 5, 2010.

[388] U.S. Dep't of Labor, Bureau of Labor Statistics, Industries at a Glance, *http://www.bls.gov/iag/tgs/iag621.htm* (last visited Mar. 26, 2016).

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TABLE 7—ACCOUNTING STATEMENT

Accounting statement				
Category	Primary estimate	Low estimate	High estimate	Source
BENEFITS				
Qualitative Benefits (02)	• Potential health improvements and longevity extensions as a result of reduced barriers to medical care for transgender individuals.		....	RIA
COSTS (millions)				
Annualized monetized	Covered entities train 40% of their employees on the new regulations	Covered entities train 60% of their employees on the new regulations	....	
3%	192.5	177.0	208.1	RIA
7%	197.8	181.4	214.2	RIA
Non-quantified costs (02)	Costs of increased provision of health care services as a result of reduced barriers to access for transgender individuals.		....	RIA
Transfers (02)	Health insurance premium reductions for affected women, with offsetting increases for other premium payers in affected plans.		....	RIA
Effects on State and Local Governments (02)	$17.8 million costs in the first 2 years (training + enforcement)		....	RIA
Effects on Small Entities (02)	Average of less than $1,000 per small entity per year		....	RFA

List of Subjects in 45 CFR Part 92

Administrative practice and procedure, Civil rights, Discrimination, Elderly, Health care, Health facilities, Health insurance, Health programs and activities, Individuals with disabilities, Nondiscrimination, Reporting and recordkeeping requirements, Sex discrimination.

For the reasons set forth in the preamble, the Department of Health and Human Services adds 45 CFR part 92 as follows:

PART 92—NONDISCRIMINATION ON THE BASIS OF RACE, COLOR, NATIONAL ORIGIN, SEX, AGE, OR DISABILITY IN HEALTH PROGRAMS OR ACTIVITIES RECEIVING FEDERAL FINANCIAL ASSISTANCE AND HEALTH PROGRAMS OR ACTIVITIES ADMINISTERED BY THE DEPARTMENT OF HEALTH AND HUMAN SERVICES OR ENTITIES ESTABLISHED UNDER TITLE I OF THE PATIENT PROTECTION AND AFFORDABLE CARE ACT

Subpart A—General Provisions

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 of responsible employee and adoption of grievance procedures.
92.8 Notice requirement.

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 standards for buildings and facilities.
92.204 Accessibility of electronic and information technology.
92.205 Requirement to make reasonable modifications.
92.206 Equal program access on the basis of sex.
92.207 Nondiscrimination in health-related insurance and other health-related coverage.
92.208 Employer liability for discrimination in employee health benefit programs.
92.209 Nondiscrimination on the basis of association.

Subpart D—Procedures

92.301 Enforcement mechanisms.
92.302 Procedures for health programs and activities conducted by recipients and State-based Marketplaces.
92.303 Procedures for health programs and activities administered by the Department.
Appendix A to Part 92—Sample Notice Informing Individuals About Nondiscrimination and Accessibility

Requirements and Sample Nondiscrimination Statement
Appendix B to Part 92—Sample Tagline Informing Individuals With Limited English Proficiency of Language Assistance Services
Appendix C to Part 92—Sample Section 1557 of the Affordable Care Act Grievance Procedure

Authority: 42 U.S.C. 18116, 5 U.S.C. 301.

Subpart A—General Provisions

§ 92.1 Purpose and effective date.

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, or disability in certain health programs and activities. Section 1557 provides that, except as 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 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, Title I entities that administer health programs or activities, and Department-administered health programs or activities. The effective date of this part shall be July 18, 2016, except to the extent that provisions of this part require changes to health insurance or group health plan benefit design (including covered benefits, benefits limitations or restrictions, and cost-sharing mechanisms, such as coinsurance, copayments, and deductibles), such provisions, as they apply to health insurance or group health plan benefit design, have an applicability date of the first day of the first plan year (in the individual market, policy year) beginning on or after January 1, 2017.

§ 92.2 Application.

(a) Except as provided otherwise in this part, this part applies to every health program or activity, any part of which receives Federal financial assistance provided or made available by the Department; every health program or activity administered by the Department; and every health program or activity administered by a Title I entity.

(b)(1) Exclusions to the application of the Age Discrimination Act of 1975, as set forth at 45 CFR 91.3(b)(1), apply to claims of discrimination based on age under Section 1557 or this part.

(2) Insofar as the application of any requirement under this part would violate applicable Federal statutory protections for religious freedom and conscience, such application shall not be required.

(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 construed so as to continue to give maximum effect to the provision permitted by law, unless such holding shall be one of utter invalidity or unenforceability, in which event the provision 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) *Rule of interpretation.* 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) *Other laws.* Nothing in this part shall be construed to invalidate or limit the rights, remedies, procedures, or legal standards available to individuals under Title VI of the Civil Rights Act of 1964, Title VII of the Civil Rights Act of 1964, the Architectural Barriers Act of 1968, Title IX of the Education Amendments of 1972, Sections 504 or 508 of the Rehabilitation Act of 1973, the Age Discrimination Act of 1975, the Americans with Disabilities Act of 1990, as amended by the Americans with Disabilities Act Amendments Act of 2008, or other Federal laws or 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 the 2010 ADA Standards for Accessible Design, as defined at 28 CFR 35.104.

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 an individual is, or the number of elapsed years from the date of an individual's birth.

Age Act means the Age Discrimination Act of 1975 (42 U.S.C. 6101 *et seq.*), as amended.

Applicant means an individual who applies to participate in a health program or activity.

Auxiliary aids and services include:

(1) Qualified interpreters on-site or through video remote interpreting (VRI) services, as defined in 28 CFR 35.104 and 36.303(b); 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 telecommunication products and systems, text telephones (TTYs), videophones, and captioned telephones, or equally effective telecommunications devices; videotext displays; accessible electronic and information technology; or other effective methods of making aurally delivered information available to individuals 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; large print materials; accessible electronic and information technology; or other effective methods of making visually delivered materials available to individuals who are blind or have low vision;

(3) Acquisition or modification of equipment and devices; and

(4) Other similar services and actions.

Covered entity means:

(1) An entity that operates a health program or activity, any part of which receives Federal financial assistance;

(2) An entity established under Title I of the ACA that administers a health program or activity; and

(3) The Department.

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.

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. Where this part cross-references regulatory provisions that use the term ''handicap,'' ''handicap'' means ''disability'' as defined in this section.

Electronic and information technology means the same as ''electronic and information technology,'' or any term that replaces ''electronic and information technology,'' as it is defined in 36 CFR 1194.4.

Employee health benefit program means:

(1) Health benefits coverage or health insurance coverage provided to employees and/or their dependents established, operated, sponsored or administered by, for, or on behalf of one or more employers, whether provided or administered by entities including but not limited to an employer, group health plan (as defined in the Employee Retirement Income Security Act of 1974 (ERISA), 29 U.S.C. 1191b(a)(1)), third party administrator, or health insurance issuer.

(2) An employer-provided or employer-sponsored wellness program;

(3) An employer-provided health clinic; or

(4) Long term care coverage or insurance provided or administered by an employer, group health plan, third party administrator, or health insurance issuer for the benefit of an employer's employees.

Federal financial assistance. (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 provides or otherwise makes available assistance in the form of:

(i) Funds;

(ii) Services of Federal personnel; or

(iii) Real and 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 all tax credits under Title I of the ACA, as well as payments, subsidies, or other funds extended by the Department to any entity providing health-related insurance coverage for payment to or on behalf of an individual obtaining health-related insurance coverage from that entity or extended by the Department directly to such individual for payment to any entity providing health-related insurance coverage.

Federally-facilitated Marketplace[SM] means the same as ''Federally-facilitated Exchange'' defined in 45 CFR 155.20.

Gender identity means 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. The way an individual expresses gender identity is frequently called ''gender expression,'' and may or may not conform to social stereotypes associated with a particular gender. A transgender individual is an individual whose gender identity is different from the sex assigned to that person at birth.

Health Insurance Marketplace[SM] means the same as ''Exchange'' defined in 45 CFR 155.20.

Health program or activity means the provision or administration of health-related services, health-related insurance coverage, or other health-related coverage, and the provision of assistance to individuals in obtaining health-related services or health-related insurance coverage. For an entity principally engaged in providing or administering health services or health insurance coverage or other health coverage, all of its operations are considered part of the health program or activity, except as specifically set forth otherwise in this part. Such entities include a hospital, health clinic, group health plan, health insurance issuer, physician's practice, community health center, nursing facility, residential or community-based treatment facility, or other similar entity. A health program or activity also includes all of the operations of a State Medicaid program, a Children's Health Insurance Program, and the Basic Health Program.

HHS means the U.S. Department of Health and Human Services.

Individual with a disability means any individual who has a disability as defined for the purpose of Section 504 of the Rehabilitation Act of 1973, 29 U.S.C. 705(20)(B)–(F), as amended. Where this part cross-references regulatory provisions applicable to a ''handicapped individual,'' ''handicapped individual'' means ''individual with a disability'' as defined in this section.

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.

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 languages other than English; and

(3) Taglines.

National origin includes, but is not limited to, an individual's, or his or her ancestor's, place of origin (such as country or world region) or an individual's manifestation of the physical, cultural, or linguistic characteristics of a national origin group.

On the basis of sex includes, but is not limited to, discrimination on the basis of pregnancy, false pregnancy, termination of pregnancy, or recovery therefrom, childbirth or related medical conditions, sex stereotyping, and gender identity.

Qualified bilingual/multilingual staff means a member of a covered entity's workforce who is designated by the covered entity to provide oral language assistance as part of the individual's current, assigned job responsibilities and who has demonstrated to the covered entity that he or she:

(1) Is 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) is able to effectively, accurately, and impartially communicate directly with individuals with limited English proficiency in their primary languages.

Qualified individual with a disability means, with respect to a health program or activity, an individual with a disability who, with or without reasonable modifications to policies, practices, or procedures, 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 aids, benefits, or services offered or provided by the health program or activity.

Qualified interpreter for an individual with a disability. (1) A qualified interpreter for an individual with a disability means an interpreter who via a remote interpreting service or an on-site appearance:

(i) Adheres to generally accepted interpreter ethics principles, including client confidentiality; and

(ii) is able to interpret effectively, accurately, and impartially, both receptively and expressively, using any necessary specialized vocabulary, terminology and phraseology.

(2) For an individual with a disability, qualified interpreters can include, for example, sign language interpreters, oral transliterators (individuals who represent or spell in the characters of another alphabet), and cued language transliterators (individuals who represent or spell by using a small number of handshapes).

Qualified interpreter for an individual with limited English proficiency means an interpreter who via a remote interpreting service or an on-site appearance:

(1) Adheres to generally accepted interpreter ethics principles, including client confidentiality;

(2) has demonstrated proficiency in speaking and understanding both spoken English and at least one other spoken language; and

(3) is able to interpret effectively, accurately, and impartially, both receptively and expressly, to and from such language(s) and English, using any necessary specialized vocabulary, terminology and phraseology.

Qualified translator means a translator who:

(1) Adheres to generally accepted translator ethics principles, including client confidentiality;

(2) has demonstrated proficiency in writing and understanding both written English and at least one other written non-English language; and

(3) is able to translate effectively, accurately, and impartially to and from such language(s) and English, using any necessary specialized vocabulary, terminology and phraseology.

Recipient means any State or its political subdivision, or any instrumentality of a State or its political subdivision, any public or private agency, institution, or organization, or other entity, or any individual, to whom Federal financial assistance is extended directly or through another recipient and which operates a health program or activity, including any subunit, successor, assignee, or transferee of a recipient.

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).

Sex stereotypes means stereotypical notions of masculinity or femininity, including expectations of how individuals represent or communicate their gender to others, such as behavior, clothing, hairstyles, activities, voice, mannerisms, or body characteristics. These stereotypes can include the expectation that individuals will consistently identify with only one gender and that they will act in conformity with the gender-related expressions stereotypically associated with that gender. Sex stereotypes also include gendered expectations related to the appropriate roles of a certain sex.

State-based Marketplace SM means a Health Insurance Marketplace SM established by a State pursuant to 45 CFR 155.100 and approved by the Department pursuant to 45 CFR 155.105.

Taglines mean short statements written in non-English languages that indicate the availability of language assistance services free of charge.

Title I entity means any entity established under Title I of the ACA, including State-based Marketplaces and Federally-facilitated Marketplaces.

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 IX means Title IX of the Education Amendments of 1972 (Pub. L. 92–318; 20 U.S.C. 1681 *et seq.*), as amended.

§ 92.5 Assurances required.

(a) *Assurances.* An entity applying for Federal financial assistance to which this part applies shall, 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 a Health Insurance Marketplace SM or a State seeking approval to operate a State-based Marketplace SM to which Section 1557 or this part applies shall, as a condition of certification or approval, submit an assurance, on a form specified by the Director, that the 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 a Health Insurance Marketplace SM or approval to operate a State-based Marketplace SM.

(b) *Duration of obligation.* The duration of the assurances required by this subpart 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-based Marketplace SM 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-based Marketplace SM shall 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 or State-based Marketplace SM to take remedial action with respect to:

(i) Individuals who are no longer participants in the recipient's or State-based Marketplace SM's health program or activity but who were participants in the health program or activity when such discrimination occurred; or

(ii) Individuals who would have been participants in the health program or

activity had the discrimination not occurred.

(b) *Voluntary action.* A covered entity may take 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 individuals on the basis of race, color, national origin, sex, age, or disability.

§ 92.7 Designation of responsible employee and adoption of grievance procedures.

(a) *Designation of responsible employee.* Each covered entity that employs 15 or more persons shall designate at least one employee to coordinate its efforts to comply with and carry out its responsibilities under Section 1557 and this part, 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. For the Department, including the Federally-facilitated Marketplaces, the Director will be deemed the responsible employee under this section.

(b) *Adoption of grievance procedures.* Each covered entity that employs 15 or more persons shall adopt grievance procedures that incorporate appropriate due process standards and that provide for the prompt and equitable resolution of grievances alleging any action that would be prohibited by Section 1557 or this part. For the Department, including the Federally-facilitated Marketplaces, the procedures for addressing complaints of discrimination on the grounds covered under Section 1557 or this part will be deemed grievance procedures under this section.

§ 92.8 Notice requirement.

(a) Each covered entity shall take appropriate initial and continuing steps to notify beneficiaries, enrollees, applicants, and members of the public of the following:

(1) The covered entity does not discriminate on the basis of race, color, national origin, sex, age, or disability in its health programs and activities;

(2) The covered entity provides appropriate auxiliary aids and services, including qualified interpreters for individuals with disabilities and information in alternate formats, free of charge and in a timely manner, when such aids and services are necessary to ensure an equal opportunity to participate to individuals with disabilities;

(3) The covered entity provides language assistance services, including translated documents and oral interpretation, free of charge and in a timely manner, when such services are necessary to provide meaningful access to individuals with limited English proficiency;

(4) How to obtain the aids and services in paragraphs (a)(2) and (3) of this section;

(5) An identification of, and contact information for, the responsible employee designated pursuant to § 92.7(a), if applicable;

(6) The availability of the grievance procedure and how to file a grievance, pursuant to § 92.7(b), if applicable; and

(7) How to file a discrimination complaint with OCR in the Department.

(b) Within 90 days of the effective date of this part, each covered entity shall:

(1) As described in paragraph (f)(1) of this section, post a notice that conveys the information in paragraphs (a)(1) through (7) of this section; and

(2) As described in paragraph (g)(1) of this section, if applicable, post a nondiscrimination statement that conveys the information in paragraph (a)(1) of this section.

(c) For use by covered entities, the Director shall make available, electronically and in any other manner that the Director determines appropriate, the content of a sample notice that conveys the information in paragraphs (a)(1) through (7) of this section, and the content of a sample nondiscrimination statement that conveys the information in paragraph (a)(1) of this section, in English and in the languages triggered by the obligation in paragraph (d)(1) of this section.

(d) Within 90 days of the effective date of this part, each covered entity shall:

(1) As described in paragraph (f)(1) of this section, post taglines in at least the top 15 languages spoken by individuals with limited English proficiency of the relevant State or States; and

(2) As described in paragraph (g)(2) of this section, if applicable, post taglines in at least the top two languages spoken by individuals with limited English proficiency of the relevant State or States.

(e) For use by covered entities, the Director shall make available, electronically and in any other manner that the Director determines appropriate, taglines in the languages triggered by the obligation in paragraph (d)(1) of this section.

(f)(1) Each covered entity shall post the notice required by paragraph (a) of this section and the taglines required by paragraph (d)(1) of this section in a conspicuously-visible font size:

(i) In significant publications and significant communications targeted to beneficiaries, enrollees, applicants, and members of the public, except for significant publications and significant communications that are small-sized, such as postcards and tri-fold brochures;

(ii) In conspicuous physical locations where the entity interacts with the public; and

(iii) In a conspicuous location on the covered entity's Web site accessible from the home page of the covered entity's Web site.

(2) A covered entity may also post the notice and taglines in additional publications and communications.

(g) Each covered entity shall post, in a conspicuously-visible font size, in significant publications and significant communications that are small-sized, such as postcards and tri-fold brochures:

(1) The nondiscrimination statement required by paragraph (b)(2) of this section; and

(2) The taglines required by paragraph (d)(2) of this section.

(h) A covered entity may combine the content of the notice required in paragraph (a) of this section with the content of other notices if the combined notice clearly informs individuals of their civil rights under Section 1557 and this part.

Subpart B—Nondiscrimination Provisions

§ 92.101 Discrimination prohibited.

(a) *General.* (1) Except as provided in Title I of the ACA, an individual shall not, on the basis of race, color, national origin, sex, age, or disability, be excluded from participation in, be denied the benefits of, or otherwise be subjected to discrimination under any health program or activity to which this part applies.

(2) This part does not apply to employment, except as provided in § 92.208.

(b) *Specific discriminatory actions prohibited.* Under any health program or activity to which this part applies:

(1)(i) Each covered entity must comply with the regulation implementing Title VI, at § 80.3(b)(1) through (6) of this subchapter.

(ii) No covered entity shall, on the basis of race, color, or national origin, aid or perpetuate discrimination against any person by providing significant assistance to any entity or person that discriminates on the basis of race, color, or national origin in providing any aid, benefit, or service to beneficiaries of the covered entity's health program or activity.

(2)(i) Each recipient and State-based Marketplace[SM] must comply with the regulation implementing Section 504, at §§ 84.4(b), 84.21 through 84.23(b), 84.31, 84.34, 84.37, 84.38, and 84.41 through 84.52(c) and 84.53 through 84.55 of this subchapter. Where this paragraph cross-references regulatory provisions that use the term ''recipient,'' the term ''recipient or State-based Marketplace[SM]'' shall apply in its place.

(ii) The Department, including the Federally-facilitated Marketplaces, must comply with the regulation implementing Section 504, at §§ 85.21(b), 85.41 through 85.42, and 85.44 through 85.51 of this subchapter.

(3)(i) Each covered entity must comply with the regulation implementing Title IX, at § 86.31(b)(1) through (8) of this subchapter. Where this paragraph cross-references regulatory provisions that use the term ''student,'' ''employee,'' or ''applicant,'' these terms shall be replaced with ''individual.''

(ii) A covered entity may not, directly or through contractual or other arrangements, utilize criteria or methods of administration that have the effect of subjecting individuals to discrimination on the basis of sex, or have the effect of defeating or substantially impairing accomplishment of the objectives of the program with respect to individuals on the basis of sex.

(iii) In determining the site or location of a facility, a covered entity may not make selections that have the effect of excluding individuals from, denying them the benefits of, or subjecting them to discrimination under any programs to which this regulation applies, on the basis of sex; or with the purpose or effect of defeating or substantially impairing the accomplishment of the objectives of the program or activity on the basis of sex.

(iv) A covered entity may operate a sex-specific health program or activity (a health program or activity that is restricted to members of one sex) only if the covered entity can demonstrate an exceedingly persuasive justification, that is, that the sex-specific health program or activity is substantially related to the achievement of an important health-related or scientific objective.

(4)(i) Each covered entity must comply with the regulation implementing the Age Act, at § 91.11(b) of this subchapter.

(ii) No covered entity shall, on the basis of age, aid or perpetuate discrimination against any person by providing significant assistance to any agency, organization, or person that discriminates on the basis of age in providing any aid, benefit, or service to beneficiaries of the covered entity's health program or activity.

(5) The enumeration of specific forms of discrimination in this paragraph does not limit the generality of the prohibition in paragraph (a) of this section.

(c) The exceptions applicable to Title VI apply to discrimination on the basis of race, color, or national origin under this part. The exceptions applicable to Section 504 apply to discrimination on the basis of disability under this part. The exceptions applicable to the Age Act apply to discrimination on the basis of age under this part. These provisions are found at §§ 80.3(d), 84.4(c), 85.21(c), 91.12, 91.15, and 91.17–.18 of this subchapter.

(d) Where the regulatory provisions referenced in paragraphs (b)(1), (b)(3), and (b)(4), and paragraph (c) of this section use the term ''recipient,'' the term ''covered entity'' shall apply in its place. Where the regulatory provisions referenced in paragraphs (b)(1), (b)(3), and (b)(4) and paragraph (c) of this section use the terms ''program or activity'' or ''program'' or ''education program,'' the term ''health program or activity'' shall apply in their place.

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 shall take reasonable steps to provide meaningful access to each individual with limited English proficiency eligible to be served or likely to be encountered in its health programs and activities.

(b) *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 whether a covered entity has developed and implemented an effective written language access plan, that is appropriate to its particular circumstances, to be prepared to meet its obligations in § 92.201(a).

(c) *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 independence of the individual with limited English proficiency.

(d) *Specific requirements for interpreter and translation services.* Subject to paragraph (a) of this section:

(1) A covered entity shall offer a qualified interpreter to an individual with limited English proficiency when oral interpretation is a reasonable step to provide meaningful access for that individual with limited English proficiency; and

(2) A covered entity shall use a qualified translator when translating written content in paper or electronic form.

(e) *Restricted use of certain persons to interpret or facilitate communication.* A covered entity shall not:

(1) Require an individual with limited English proficiency to provide his or her own interpreter;

(2) Rely on an adult accompanying an individual with limited English proficiency to interpret or facilitate communication, except:

(i) 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; or

(ii) Where the individual with limited English proficiency specifically requests that the 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;

(3) Rely on a minor child to interpret or facilitate communication, except 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; or

(4) Rely on staff other than qualified bilingual/multilingual staff to communicate directly 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 shall 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 individual's face regardless of the individual's body position;

(3) A clear, audible transmission of voices; and

(4) Adequate training to users of the technology and other involved individuals so that they may quickly and efficiently set up and operate the video remote interpreting.

(g) *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 shall take appropriate steps to ensure that communications with individuals with disabilities are as effective as communications with others in health programs and activities, in accordance with the standards found at 28 CFR 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 recipient or State-based Marketplace[SM] shall provide appropriate auxiliary aids and services to persons with impaired sensory, manual, or speaking skills, where necessary to afford such persons an equal opportunity to benefit from the service in question.

§ 92.203 Accessibility standards for buildings and facilities.

(a) 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-based Marketplace[SM] shall comply with the 2010 Standards as defined in § 92.4, 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-based Marketplace[SM], was not covered by the 2010 Standards prior to July 18, 2016, such facility or part of a facility shall comply with the 2010 Standards, as defined in § 92.4, if the construction was commenced after January 18, 2018. 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 shall comply with the requirements for a ''public building or facility'' as defined in Section 106.5 of the 2010 Standards.

(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-based Marketplace[SM] in conformance with the 1991 Standards or the 2010 Standards as defined in § 92.4 shall be deemed to comply with the requirements of this section and with 45 CFR 84.23(a) and (b), cross-referenced in § 92.101(b)(2)(i) with respect to those facilities, if the construction or alteration was commenced on or 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-based Marketplace[SM] in conformance with the Uniform Federal Accessibility Standards as defined in § 92.4, shall be deemed to comply with the requirements of this section and with 45 CFR 84.23(a) and (b), cross-referenced in § 92.101(b)(2)(i) with respect to those facilities, if the construction was commenced before July 18, 2016 and such facility was not covered by the 1991 Standards or 2010 Standards.

§ 92.204 Accessibility of electronic and information technology.

(a) Covered entities shall ensure that their health programs or activities provided through electronic and information 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. When undue financial and administrative burdens or a fundamental alteration exist, the covered entity shall provide information in a format other than an electronic format that would not result in such undue financial and administrative burdens or a fundamental alteration but would ensure, to the maximum extent possible, that individuals with disabilities receive the benefits or services of the health program or activity that are provided through electronic and information technology.

(b) Recipients and State-based Marketplaces shall ensure that their health programs and activities provided through Web sites comply with the requirements of Title II of the ADA.

§ 92.205 Requirement to make reasonable modifications.

A covered entity shall 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. 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 covered entity shall provide individuals equal access to its health programs or activities without discrimination on the basis of sex; and a covered entity shall treat individuals consistent with their gender identity, except that a covered entity may not deny or limit health services that are ordinarily or exclusively available to individuals of one sex, to a transgender individual based on the fact that the individual's sex assigned at birth, gender identity, or gender otherwise recorded is different from the one to which such health services are ordinarily or exclusively available.

§ 92.207 Nondiscrimination in health-related insurance and other health-related coverage.

(a) *General.* A covered entity shall not, in providing or administering health-related insurance or other health-related coverage, discriminate on the basis of race, color, national origin, sex, age, or disability.

(b) *Discriminatory actions prohibited.* A covered entity shall not, in providing or administering health-related insurance or other health-related coverage:

(1) Deny, cancel, limit, or refuse to issue or renew a health-related insurance plan or policy 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, or disability;

(2) Have or implement marketing practices or benefit designs that discriminate on the basis of race, color, national origin, sex, age, or disability in a health-related insurance plan or policy, 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, for any health services that are ordinarily or exclusively available to individuals of one sex, to a transgender individual based on the fact that an individual's sex assigned at birth, gender identity, or gender otherwise recorded is different from the one to which such health services are ordinarily or exclusively available;

(4) Have or implement a categorical coverage exclusion or limitation for all health services related to gender transition; or

(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 if such denial, limitation, or restriction results in discrimination against a transgender individual.

(c) The enumeration of specific forms of discrimination in paragraph (b) does not limit the general applicability of the prohibition in paragraph (a) of this section.

(d) Nothing in this section is intended to determine, or restrict a covered entity from determining, whether a particular health service is medically necessary or otherwise meets applicable coverage requirements in any individual case.

§ 92.208 Employer liability for discrimination in employee health benefit programs.

A covered entity that provides an employee health benefit program to its employees and/or their dependents shall be liable for violations of this part in that employee health benefit program only when:

(a) The entity is principally engaged in providing or administering health services, health insurance coverage, or other health coverage;

(b) The entity receives Federal financial assistance a primary objective of which is to fund the entity's employee health benefit program; or

(c) The entity is not principally engaged in providing or administering health services, health insurance coverage, or other health coverage, but operates a health program or activity, which is not an employee health benefit program, that receives Federal financial assistance; except that the entity is liable under this part with regard to the provision or administration of employee health benefits only with respect to the employees in that health program or activity.

§ 92.209 Nondiscrimination on the basis of association.

A covered entity shall not exclude from participation in, deny the benefits of, or otherwise discriminate against an individual or entity in its health programs or activities on the basis of the race, color, national origin, sex, age, or disability of an individual with whom the individual or entity is known or believed to have a relationship or association.

Subpart D—Procedures

§ 92.301 Enforcement mechanisms.

(a) 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, or the Age Discrimination Act of 1975 shall apply for purposes of Section 1557 as implemented by this part.

(b) Compensatory damages for violations of Section 1557 are available in appropriate administrative and judicial actions brought under this rule.

§ 92.302 Procedures for health programs and activities conducted by recipients and State-based Marketplaces.

(a) The procedural provisions applicable to Title VI apply with respect to administrative enforcement actions concerning discrimination on the basis of race, color, national, origin, sex, and disability discrimination under Section 1557 or this part. These procedures are found at §§ 80.6 through 80.11 of this subchapter and part 81 of this subchapter.

(b) The procedural provisions applicable to the Age Act apply with respect to enforcement actions concerning age discrimination under Section 1557 or this part. These procedures are found at §§ 91.41 through 91.50 of this subchapter.

(c) When a recipient fails to provide OCR with requested information in a timely, complete, and accurate manner, OCR may find noncompliance with Section 1557 and initiate appropriate enforcement procedures, including beginning the process for fund suspension or termination and taking other action authorized by law.

(d) An individual or entity may bring a civil action to challenge a violation of Section 1557 or this part in a United States District Court in which the recipient or State-based Marketplace SM is found or transacts business.

§ 92.303 Procedures for health programs and activities administered by the Department.

(a) This section applies to discrimination on the basis of race, color, national origin, sex, age, or disability in health programs or activities administered by the Department, including the Federally-facilitated Marketplaces.

(b) The procedural provisions applicable to Section 504 at §§ 85.61 through 85.62 of this subchapter shall apply with respect to enforcement actions against the Department concerning discrimination on the basis of race, color, national origin, sex, age, or disability under Section 1557 or this part. Where this 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.

(c) The Department shall 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 individual, and the other agency, institution or individual shall fail or refuse 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.

(d) The Department shall not intimidate, threaten, coerce, or discriminate against any individual for the purpose of interfering with any right or privilege secured by Section 1557 or this part, or because such individual 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 shall be kept confidential by OCR, except to the extent necessary to carry out the purposes of Section 1557 or this part.

Appendix A to Part 92—Sample Notice Informing Individuals About Nondiscrimination and Accessibility Requirements and Sample Nondiscrimination Statement: Discrimination is Against the Law

[Name of covered entity] complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability, or sex. [Name of covered entity] does not exclude people or treat them differently because of race, color, national origin, age, disability, or sex.

[Name of covered entity]:

- Provides free aids and services to people with disabilities to communicate effectively with us, such as:

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○ Qualified sign language interpreters
○ Written information in other formats (large print, audio, accessible electronic formats, other formats)
• Provides free language services to people whose primary language is not English, such as:
○ Qualified interpreters
○ Information written in other languages

If you need these services, contact [Name of Civil Rights Coordinator]

If you believe that [Name of covered entity] has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability, or sex, you can file a grievance with: [Name and Title of Civil Rights Coordinator], [Mailing Address], [Telephone number], [TTY number—if covered entity has one], [Fax], [Email]. You can file a grievance in person or by mail, fax, or email. If you need help filing a grievance, [Name and Title of Civil Rights Coordinator] is available to help you. You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights electronically through the Office for Civil Rights Complaint Portal, available at *https://ocrportal.hhs.gov/ocr/portal/lobby.jsf,* or by mail or phone at: U.S. Department of Health and Human Services, 200 Independence Avenue SW., Room 509F, HHH Building, Washington, DC 20201, 1–800–868–1019, 800–537–7697 (TDD).

Complaint forms are available at *http://www.hhs.gov/ocr/office/file/index.html.*

Nondiscrimination statement for significant publications and signification communications that are small-size:

[Name of covered entity] complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability, or sex.

Appendix B to Part 92—Sample Tagline Informing Individuals With Limited English Proficiency of Language Assistance Services

ATTENTION: If you speak [insert language], language assistance services, free of charge, are available to you. Call 1–xxx–xxx–xxxx (TTY: 1–xxx–xxx–xxxx).

Appendix C to Part 92—Sample Section 1557 of the Affordable Care Act Grievance Procedure

It is the policy of [Name of Covered Entity] not to discriminate on the basis of race, color, national origin, sex, age or disability. [Name of Covered Entity] has adopted an internal grievance procedure providing for prompt and equitable resolution of complaints alleging any action prohibited by Section 1557 of the Affordable Care Act (42 U.S.C. 18116) and its implementing regulations at 45 CFR part 92, issued by the U.S. Department of Health and Human Services. Section 1557 prohibits discrimination on the basis of race, color, national origin, sex, age or disability in certain health programs and activities. Section 1557 and its implementing regulations may be examined in the office of [Name and Title of Section 1557 Coordinator], [Mailing Address], [Telephone number], [TTY number—if covered entity has one], [Fax], [Email], who has been designated to coordinate the efforts of [Name of Covered Entity] to comply with Section 1557.

Any person who believes someone has been subjected to discrimination on the basis of race, color, national origin, sex, age or disability may file a grievance under this procedure. It is against the law for [Name of Covered Entity] to retaliate against anyone who opposes discrimination, files a grievance, or participates in the investigation of a grievance.

Procedure:

• Grievances must be submitted to the Section 1557 Coordinator within (60 days) of the date the person filing the grievance becomes aware of the alleged discriminatory action.
• A complaint must be in writing, containing the name and address of the person filing it. The complaint must state the problem or action alleged to be discriminatory and the remedy or relief sought.
• The Section 1557 Coordinator (or her/his designee) shall conduct an investigation of the complaint. This investigation may be informal, but it will be thorough, affording all interested persons an opportunity to submit evidence relevant to the complaint. The Section 1557 Coordinator will maintain the files and records of [Name of Covered Entity] relating to such grievances. To the extent possible, and in accordance with applicable law, the Section 1557 Coordinator will take appropriate steps to preserve the confidentiality of files and records relating to grievances and will share them only with those who have a need to know.
• The Section 1557 Coordinator will issue a written decision on the grievance, based on a preponderance of the evidence, no later than 30 days after its filing, including a notice to the complainant of their right to pursue further administrative or legal remedies.
• The person filing the grievance may appeal the decision of the Section 1557 Coordinator by writing to the (Administrator/Chief Executive Officer/Board of Directors/etc.) within 15 days of receiving the Section 1557 Coordinator's decision. The (Administrator/Chief Executive Officer/Board of Directors/etc.) shall issue a written decision in response to the appeal no later than 30 days after its filing.

The availability and use of this grievance procedure does not prevent a person from pursuing other legal or administrative remedies, including filing a complaint of discrimination on the basis of race, color, national origin, sex, age or disability in court or with the U.S. Department of Health and Human Services, Office for Civil Rights. A person can file a complaint of discrimination electronically through the Office for Civil Rights Complaint Portal, which is available at: *https://ocrportal.hhs.gov/ocr/portal/lobby.jsf,* or by mail or phone at: U.S. Department of Health and Human Services, 200 Independence Avenue SW., Room 509F, HHH Building, Washington, DC 20201.

Complaint forms are available at: *http://www.hhs.gov/ocr/office/file/index.html.* Such complaints must be filed within 180 days of the date of the alleged discrimination.

[Name of covered entity] will make appropriate arrangements to ensure that individuals with disabilities and individuals with limited English proficiency are provided auxiliary aids and services or language assistance services, respectively, if needed to participate in this grievance process. Such arrangements may include, but are not limited to, providing qualified interpreters, providing taped cassettes of material for individuals with low vision, or assuring a barrier-free location for the proceedings. The Section 1557 Coordinator will be responsible for such arrangements.

Dated: May 11, 2016.

Sylvia M. Burwell,

Secretary.

[FR Doc. 2016–11458 Filed 5–13–16; 11:15 am]

BILLING CODE 4153–01–P

EXHIBIT 2

AUTHENTICATED U.S. GOVERNMENT INFORMATION GPO

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare and Medicaid Services

42 CFR Parts 438, 440, and 460

Office of the Secretary

45 CFR Parts 86, 92, 147, 155, and 156

RIN 0945–AA11

Nondiscrimination in Health and Health Education Programs or Activities, Delegation of Authority

AGENCY: Centers for Medicare & Medicaid Services (CMS); Office for Civil Rights (OCR), Office of the Secretary, Department of Health and Human Services (HHS).

ACTION: Final rule.

SUMMARY: The Department of Health and Human Services (''the Department'' or ''HHS'') is committed to ensuring the civil rights of all individuals who access or seek to access health programs or activities of covered entities under Section 1557 of the Patient Protection and Affordable Care Act (''ACA''). After considering public comments, in this final rule, the Department revises its Section 1557 regulations, Title IX regulations, and specific regulations of the Centers for Medicare & Medicaid Services (''CMS'') as proposed, with minor and primarily technical corrections. This will better comply with the mandates of Congress, address legal concerns, relieve billions of dollars in undue regulatory burdens, further substantive compliance, reduce confusion, and clarify the scope of Section 1557 in keeping with pre-existing civil rights statutes and regulations prohibiting discrimination on the basis of race, color, national origin, sex, age, and disability.

DATES: This rule is effective August 18, 2020.

FOR FURTHER INFORMATION CONTACT: Luben Montoya, Supervisory Civil Rights Analyst, HHS Office for Civil Rights, at (800) 368–1019 or (800) 537–7697 (TDD).

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I. Executive Summary

A. Purpose

This regulation finalizes the Department's proposed rule concerning Nondiscrimination in Health and Health Education Programs or Activities issued in the **Federal Register** on June 14, 2019 (84 FR 27846), with minor and primarily technical corrections. It makes changes to the Department's existing regulation [1] (''2016 Rule'') implementing Section 1557 of the ACA, 42 U.S.C. 18116. It makes a related amendment to the Department's regulations implementing Title IX of the Education Amendments of 1972 (''Title IX''), and it makes conforming amendments to nondiscrimination provisions within various CMS regulations.

Through Section 1557 of the ACA, Congress applied certain long-standing civil rights nondiscrimination requirements to any health programs or activities that receive Federal financial assistance, and any programs or activities administered by an Executive agency under Title I of the ACA or by an entity established under such Title. It did so by cross-referencing statutes that specify prohibited grounds of discrimination, namely, race, color, national origin, sex, age, or disability, in an array of Federally funded and administered programs or activities. To ensure compliance, Congress dictated that ''[t]he enforcement mechanisms provided for and available under'' such laws ''shall apply for purposes of violations of'' Section 1557.[2]

This final rule returns to the enforcement mechanisms provided for, and available under, those longstanding statutes and the Department's implementing regulations. It eliminates many of the provisions of the 2016 Rule in order to better comply with the mandates of Congress, relieves approximately $2.9 billion in undue regulatory burdens (over five years), furthers substantive compliance, reduces confusion, and clarifies the scope of Section 1557. It empowers the Department to continue its robust enforcement of civil rights laws by making clear that the substantive protections of Title VI of the Civil Rights Act of 1964 (''Title VI''), Title IX, the Age Discrimination Act of 1975 (''Age Act''), and Section 504 of the Rehabilitation Act of 1973 (''Section 504'') remain in full force and effect.[3]

This final rule is needed because the Department has determined that portions of the 2016 Rule are duplicative or confusing, impose substantial unanticipated burdens, or impose burdens that outweigh their anticipated benefits. Additionally, two Federal district courts have determined that the Department exceeded its authority in promulgating parts of the regulation, and one has vacated and remanded those parts of the 2016 Rule. By substantially repealing much of the 2016 Rule, including removing the vacated provisions from the Code of Federal Regulations, the Department reverts to longstanding statutory interpretations that conform to the plain meaning of the underlying civil rights statutes and the United States Government's official position concerning those statutes.

The Department initially estimated the costs from the 2016 Rule at over $942 million across the first five years. 81 FR 31458–59. This figure, however, significantly underestimated actual costs, according to the Department's current estimates. As estimated now, the costs derived merely from the 2016 Rule's requirement to provide notices and taglines with all significant communications, after accounting for electronic delivery, amount to an average annual burden of $585 million per year, for a five-year burden of $2.9 billion. Based on the Department's re-examination of the burden on regulated entities, and after reviewing public comments, the Department has determined that the potential public benefits of imposing such requirements are outweighed by the large costs those requirements impose on regulated entities and other parties.

B. Summary of Major Provisions

(1) Changes to the Section 1557 Regulation

a. Elimination of Overbroad Provisions Related to Sex and Gender Identity

This final rule eliminates certain provisions of the 2016 Rule that exceeded the scope of the authority delegated by Congress in Section 1557. The 2016 Rule's definition of discrimination ''on the basis of sex'' encompassed 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''). In line with that definition, the 2016 Rule imposed several requirements regarding medical treatment and coverage on the basis of gender identity. The same definition also encompassed discrimination on the basis of ''termination of pregnancy'' without incorporating the explicit abortion-neutrality language of 20 U.S.C. 1688 (which some commenters referred to as the Danforth Amendment) in Title IX, and it imposed a high burden of proof on providers to justify offering gynecological or other single-sex medical services.

All of these are essentially legislative changes that the Department lacked the

[1] 81 FR 31375–473 (May 18, 2016) codified at 45 CFR part 92.

[2] 42 U.S.C. 18116.

[3] While Section 1557 does not incorporate nondiscrimination provisions by reference to Title VII, it provides that nothing in Title I of the ACA is to be construed as invalidating or limiting the rights, remedies, procedures, or legal standards available under certain civil rights laws, and mentions Title VII specifically. 42 U.S.C. 18116(b).

authority to make. They purported to impose additional legal requirements on covered entities that cannot be justified by the text of Title IX, and in fact are in conflict with express exemptions in Title IX, even though Title IX provides the only statutory basis for Section 1557's provision against discrimination ''on the basis of sex.'' For this reason, these provisions have already been vacated and remanded by court order. This final rule omits the vacated language concerning gender identity and termination of pregnancy, thereby bringing the provisions of the Code of Federal Regulations into compliance with the underlying statutes and up-to-date as to the effect of the court's order.

The Department also believes that various policy considerations support this action. The 2016 Rule's provisions on sex discrimination 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. As a result, those provisions would have imposed confusing or contradictory demands on providers, interfered inappropriately with their medical judgment, and potentially burdened their consciences. By contrast, under this final rule, each State may balance for itself the various sensitive considerations relating to medical judgment and gender identity, within the limits of applicable Federal statutes (which are to be read according to their plain meaning).

b. Clarification of Scope of Covered Entities

In an additional effort to avoid exceeding the Department's statutory authority, this final rule modifies the 2016 Rule's definition of entities covered by Section 1557 in order to align it more closely with the statutory text.

c. Elimination of Unnecessary or Duplicative Language on Civil Rights Enforcement

This final rule also eliminates provisions of the 2016 Rule that, by unnecessarily duplicating or overlapping with existing civil rights law and regulations, were either inconsistent or redundant with existing law and regulations, and so were likely to cause confusion about the rights of individuals and the corresponding responsibilities of providers. This final rule prohibits any covered entity from discriminating on the basis of race, color, national origin, sex, age, and disability, according to the meaning of these terms in the underlying Federal civil rights statutes that Section 1557 incorporates, and it commits the Department to enforcing these prohibitions through the enforcement mechanisms already available under those statutes' respective implementing regulations. It eliminates the 2016 Rule's definitions of terms and its list of examples of discriminatory practices, as well as its provisions related to discrimination on the basis of association, disparate impact on the basis of sex, health insurance coverage, certain employee health benefits programs, notification of beneficiaries' rights under civil rights laws, designation of responsible employees and adoption of grievance procedures, access granted to OCR for review of covered entities' records of compliance, prohibitions on intimidation and retaliation, enforcement procedures, private rights of action, remedial action, and voluntary action. In all of these matters, this final rule will defer to the relevant existing regulations and the relevant case law with respect to each of the underlying civil rights statutes, as applied to the health context under Section 1557. It will not create, as the 2016 Rule did, a new patchwork regulatory framework unique to Section 1557 covered entities.

d. Elimination of Unnecessary Regulatory Burdens

This final rule modifies provisions of the 2016 Rule that imposed regulatory burdens on covered entities greater than what was needed in order to ensure compliance with civil rights law. Specifically, it eliminates the burdensome requirement for covered entities to send notices and taglines with all significant communications, clarifies that the provision of health insurance, as such, is not a ''health program or activity,'' brings requirements of meaningful access for persons with limited English proficiency (LEP) into conformity with longstanding DOJ and HHS guidance, and permits remote English-language interpreting services to be audio-based rather than requiring them to be video-based.

The final rule retains numerous other provisions of the 2016 Rule that furthered the goal of civil rights compliance without imposing burdens unnecessary to that goal. These include the obligation for covered entities to submit assurances of compliance, as well as most of the 2016 Rule's provisions ensuring access for individuals with LEP and individuals with disabilities.

e. Other Clarifications and Minor Modifications

This final rule modifies the 2016 Rule's discussion of its own relation to other laws, offering a clearer commitment to implement Section 1557 in conformity with the text of the statutes it incorporates, as well as with the text of numerous other applicable civil rights and conscience statutes. It also makes other minor modifications to the regulatory text.

(2) Related and Conforming Amendments to Other Regulations

a. Title IX

Because the Department's failure to incorporate the abortion neutrality language at 20 U.S.C. 1688 (hereinafter ''abortion neutrality'') and the Title IX religious exemption formed part of the *Franciscan* court's reasoning when it vacated parts of the 2016 Rule, this final rule amends the Department's Title IX regulations to explicitly incorporate relevant statutory exemptions from Title IX, including abortion neutrality and the religious exemption.

b. CMS

Ten provisions in CMS regulations, all of which cover entities that are also subject to Section 1557, have in recent years had language inserted that prohibits discrimination on the basis of sexual orientation and gender identity. In light of this final rule's return to the plain meaning of ''on the basis of sex'' in the civil rights statutes incorporated under Section 1557, and the overarching applicability of Section 1557 to these programs, the Department here finalizes amendments to those regulations to ensure greater consistency in civil-rights enforcement across the Department's different programs by deleting the provisions on sexual orientation and gender identity.

C. Summary of the Costs and Benefits of the Major Provisions

This final rule is an economically significant deregulatory action. The Department projects that this final rule will result in approximately $2.9 billion in cost savings (undiscounted) over the first five years after finalization. The Department anticipates that the largest proportion of these estimated savings would result from repealing the 2016 Rule's provisions related to mandatory notices. The Department projects additional savings from eliminating the requirement for OCR to weigh the presence or absence of language access plans, and from repealing provisions that duplicate existing regulatory requirements regarding the

establishment of grievance procedures. The Department estimates that there will be some additional costs to covered entities regarding training and revision of policies and procedures.

The Department believes that the anticipated benefits—which include consistency with Federal statutes, appropriate respect for the roles of Federal courts and Congress, and reduction or elimination of ineffective, unnecessary, or confusing provisions—far outweigh any costs or burdens that may arise from the changes.

Provision(s)	Savings and benefits	Costs
Sec. 1557: Elimination of Overbroad Provisions Related to Sex and Gender Identity.	For provisions already vacated, eliminating them brings the Code of Federal Regulations in line with current law. For other provisions, eliminating them restores the rule of law by confining regulation within the scope of the Department's legal authority; restores Federalism by leaving to the States decisions properly reserved to them; and removes unjustified burdens on providers' medical judgment.	No costs are anticipated for provisions already vacated, and any possible costs for related provisions are not calculable based on available data.
Sec. 1557: Clarification of Scope of Covered Entities.	Correcting this provision improves the rule of law by interpreting the statute according to its plain meaning as closely as possible.	Costs are not calculable based on available data.
Sec. 1557: Elimination of Unnecessary or Duplicative Language on Civil Rights Enforcement.	Eliminating these provisions reduces duplication, inconsistency, and possible confusion in the Department's civil rights regulations, making it easier for covered entities and individuals to know their respective responsibilities and rights.	The Department estimates $275.8 million of costs in the first year for revision of policies and procedures, along with corresponding retraining of employees. (These costs encompass the next listed set of provisions as well.)
Sec. 1557: Elimination of Unnecessary Regulatory Burdens.	Eliminating these provisions reduces unnecessary, unjustified, or excessive burdens on health providers, as well as excessive and confusing paper notices for patients. This will make healthcare more affordable and accessible for Americans and is estimated to save $585 million per year over the first five years.	See above.
Sec. 1557: Other Clarifications and Minor Modifications.	Amending these provisions improves the rule of law by ensuring that regulations remain subject to statutory protections for conscience and other civil rights, and otherwise contributes to the goals of the other regulatory changes listed above.	No costs are anticipated, and any possible costs are not calculable based on available data.
Title IX regulations, related amendment.	This amendment ensures the rule of law by clarifying that Title IX regulations are subject to the statute's own abortion-neutrality language and religious exemption.	No costs are anticipated, and any possible costs are not calculable based on available data.
CMS regulations, conforming amendments.	These amendments restore the rule of law by confining regulations within the scope of their legal authority, and ensure consistency in civil-rights enforcement across the Department's different programs.	Costs are not calculable based on available data.

II. Background

On May 18, 2016, the Department finalized a regulation implementing Section 1557 of the ACA. The Department had received 402 comments [4] in response to a related request for information in 2015, and 24,875 comments [5] in response to the relevant Notice of Proposed Rulemaking, 80 FR 54172–221 (''2015 NPRM'').

Multiple States and private plaintiffs challenged the 2016 Rule in Federal district courts in Texas and North Dakota on the grounds that it violated Federal laws, including the Administrative Procedure Act (''APA'') and the Religious Freedom Restoration Act (''RFRA'').[6] 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.[7]

On May 2, 2017, the Department of Justice, on behalf of HHS, filed a motion for voluntary remand to reassess the reasonableness, necessity, and efficacy of the enjoined provisions. On May 24, 2019, HHS issued a notice of proposed rulemaking (''the proposed rule'' or ''the 2019 NPRM'') to amend the 2016 Rule, as well as its regulations effectuating Title IX,[8] and to make conforming amendments to certain nondiscrimination provisions of CMS regulations [9] covered by Section 1557. On June 14, 2019, HHS published the proposed rule in the **Federal Register** [10] and accepted public comment for 60 days thereafter.

On October 15, 2019, upon motion of the plaintiffs, and adopting the reasoning from its preliminary injunction order, the U.S. District Court for the Northern District of Texas vacated and remanded the ''the unlawful portions'' of the 2016 Rule that had been subject to that order.[11] On

[4] *https://www.regulations.gov/docket?D=HHS-OCR-2013-0007.* The comment docket identifies 162 submissions, but some submissions to the docket aggregated multiple comments.

[5] *https://www.regulations.gov/docket?D=HHS-OCR-2015-0006.* The comment docket identifies 2,188 submissions, but some submissions to the docket aggregated multiple comments, and ''the great majority'' of comments were not electronic but were submitted by mail as part of ''mass mail campaigns organized by civil rights/advocacy groups.'' 81 FR 31376.

[6] Complaint, *Franciscan All., Inc.* v. *Burwell,* No. 7:16–cv–00108–O (N.D. Tex. Aug. 23, 2016); *Religious Sisters of Mercy* v. *Burwell,* No. 3:16–cv–386 (D.N.D. filed Nov. 7, 2016); *Catholic Benefits Association* v. *Burwell,* No.3:16–cv–432 (D.N.D. filed Dec. 28, 2016).

[7] *See Franciscan All., Inc.* v. *Burwell,* 227 F. Supp. 3d 660, 696 (N.D. Tex. 2016).

[8] 20 U.S.C. 1681 *et seq.*; 45 CFR part 86 (Nondiscrimination on the Basis of Sex in Education Programs or Activities Receiving Federal Financial Assistance).

[9] 42 CFR 438.3, 438.206, 440.262, 460.98, 460.112; 45 CFR 147.104, 155.120, 155.220, 156.200, 156.1230.

[10] 84 FR 27846 (June 14, 2019) (''Nondiscrimination in Health and Health Education Programs'').

[11] *Franciscan All., Inc.* v. *Azar,* 414 F. Supp. 3d 928, 945 (N.D. Tex. Oct. 15, 2019) (''Since the Court concludes that ''the Rule's conflict with its incorporated statute—Title IX—renders it contrary to law under the APA,'' the appropriate remedy is *vacatur.* Order 38, ECF No. 62. Accordingly, the Court VACATES and REMANDS the unlawful portions of the Rule for Defendants' further consideration in light of this opinion and the Court's December 31, 2016 Order.''; *id.* at 947 (''The Court ADOPTS its prior reasoning from the

Continued

November 21, 2019, the court clarified that ''the Court vacates only the portions of the Rule that Plaintiffs challenged in this litigation,'' namely, ''insofar as the Rule defines *'On the basis of sex'* to include gender identity and termination of pregnancy . . . The remainder of 45 CFR part 92 remains in effect.'' [12]

The Department herein finalizes the proposed rule without change, except as set forth below, after careful consideration of and responses to public comments.

III. Response to Public Comments on the Proposed Rule

The Department received 198,845 comments in response to the proposed rule during the public comment period.[13] Commenters included Members of Congress, State and local governments, State-based Exchanges, tribes and tribal governments, healthcare providers, health insurers, pharmacies, religious organizations, civil rights groups, non-profit organizations, and individuals, among others.

A. General Comments

Comment: Several commenters, including healthcare providers, explained that although they support nondiscrimination in healthcare and equal access to healthcare for all patients, they have difficulty complying with the parameters of the 2016 Rule. They believe that civil rights protections should be balanced against the burdens they create. Accordingly, these commenters support the proposed regulation as it limits the burdens imposed on providers.

Response: The Department agrees with these commenters' support of nondiscrimination in healthcare and intends to robustly enforce the civil rights authorities. The Department is also cognizant of unduly burdensome regulations. For example, the 2016 Rule did not anticipate some costs to covered entities that range from hundreds of millions to billions of dollars as a result of notice and taglines requirements. Therefore, this final rule seeks to alleviate certain burdens on covered entities while still enforcing the nondiscrimination requirements of Title VI, Title IX, the Age Act, and Section 504.

Comment: Some commenters said the proposed rule would stabilize services for individuals with disabilities and create a more equitable distribution of health services.

Response: The Department agrees. This final rule maintains appropriate protections for individuals with disabilities and will provide clarity for providers and individuals.

Comment: Several commenters expressed concern that eliminating discrimination protections in Section 1557 will cause confusion about patients' rights and remove access to administrative remedies that were previously available.

Response: The Department recommits itself in this rule to enforcing nondiscrimination on the basis of all categories protected by statute. The Department is confident that the clarity associated with maintaining longstanding prohibitions on discrimination under Title VI, Title IX, the Age Act, and Section 504, and their respective implementing regulations, will outweigh any initial confusion stemming from the change.

Comment: Some commenters noted the extensive process involved in developing the 2016 Rule, which included a request for information, the 2015 NPRM, and the 2016 Rule, with the Department considering more than 24,875 public comments. Such commenters suggested this proposed rule unnecessarily reopens the 2016 Rule and ignores the reasoned process that the Department had previously completed. Also, a commenter asked why the Department did not publish a request for information before the proposed rule. Others stated that the proposed rule relies disproportionately on a single district court case, *Franciscan Alliance,*[14] to justify a new interpretation of sex. The commenters go on to suggest that the Department relied exclusively on *Franciscan Alliance* to open up the entire 2016 Rule for edits while ignoring numerous other court cases that come to opposing conclusions regarding sex discrimination.[15]

Response: On December 31, 2016, the *Franciscan Alliance* court preliminarily enjoined the 2016 Rule's gender identity and termination of pregnancy provisions on a nationwide basis, finding them unlawful under the APA and RFRA. A few weeks later, a second Federal district court preliminarily stayed enforcement of the 2016 Rule against two other plaintiffs, citing the *Franciscan* decision.[16] Because of the nationwide preliminary injunction, the Department could not enforce certain provisions from the 2016 Rule. In the process of reconsidering the 2016 Rule, and consistent with applicable Executive Orders and deregulatory priorities, the Department examined the rule more broadly and concluded that, for the reasons explained in the 2019 NPRM, the 2016 Rule had significantly underestimated the costs and burdens it imposed. Because Section 1557 authorizes, but does not require, the creation of new implementing regulations, the Department considered it appropriate to repeal certain portions of the 2016 Rule and enforce Section 1557 using the underlying regulations the Department has used to enforce the relevant civil rights statutes identified in Section 1557. The Department also considered the Executive Branch's most recent statements concerning the interpretation of statutory provisions that prohibit discrimination on the basis of sex.

The Department published its proposed rule in the **Federal Register** on June 14, 2019, opening a two-month public comment period. The Department received nearly 200,000 comments for its review. Through this public comment period, the public was given a full opportunity to provide the Department with information regarding the proposal. It is not necessary to engage in an additional solicitation of public comments through a request for information before the notice of proposed rulemaking. The Department also reviewed the 2016 Rule record and its public comments in considering this final rule.

Through this rulemaking, the Department has provided a comprehensive rationale for this final rule. The 2019 NPRM summarized the Department's legal authority to change the 2016 Rule along with policy rationales for doing so. The quantum of evidence necessary to justify rescinding provisions of a rule is not greater than the evidence needed for issuing it in the

preliminary injunction (ECF No. 62) and now HOLDS that the Rule violates the APA and RFRA. Accordingly, the Court VACATES and REMANDS the Rule for further consideration.'').

[12] Order, *Franciscan Alliance,* No. 7:16–cv–00108–O *2 (N.D. Tex. filed Nov. 21, 2019).

[13] *See https://www.regulations.gov/docket?D=HHS-OCR-2019-0007.* The comment docket identifies 155,966 submissions, but some submissions to the docket aggregated multiple comments. HHS estimates the disaggregated number of comments to be 198,845.

[14] *Franciscan Alliance, Inc.* v. *Burwell,* 227 F. Supp. 3d 660 (N.D. Tex. 2016).

[15] Commenters cited *Boyden* v. *Conlin,* 341 F. Supp. 3d 979 (W.D. Wisc. 2018) (holding Wisconsin's use of transgender exclusions in its state employee health insurance plan constituted sex discrimination in violation of Section 1557 and Title VII); *Flack* v. *Wis. Dept. of Health Servs.,* 328 F. Supp. 3d 931, 951 (W.D. Wis. 2018); *Prescott* v. *Rady Children's Hospital-San Diego,* 265 F. Supp. 3d 1090, 1098–100 (S.D. Cal. 2017) (finding Section 1557's plain language bars gender identity discrimination); *Tovar* v. *Essential Health,* 342 F. Supp. 3d 947, 957 (D. Minn. 2018) (same).

[16] *Religious Sisters of Mercy* v. *Burwell,* Nos. 3:16–cv–386 & 3:16–cv–432 (D.N.D. Order of January 23, 2017). *See* 84 FR 27848.

first place.[17] Moreover, after publication of the proposed rule, the Court in *Franciscan Alliance* issued its final judgment vacating and remanding the unlawful portions of the 2016 Rule for the Department's further consideration. The Department has considered that *vacatur,* along with the legal authorities and policy rationales discussed in the NPRM and this preamble, and more thoroughly calculated the costs and effects of the notice and taglines requirements, to arrive at this final rule. Specific responses to comments on its various provisions, including on sex discrimination, are found below.

Comment: Some commenters expressed concern that the updated Section 1557 regulations will have unintended consequences and costs for healthcare providers and individuals seeking healthcare and insurance, particularly pertaining to access standards for people with LEP and communication-based disabilities, in part because the regulatory drafting period was shorter than the period for the 2016 Rule.

Response: The Department has spent several months carefully reviewing comments, providing responses to them in this rule, and finalizing the proposed rule. The Department is leaving several substantive provisions of the 2016 Rule unchanged or substantially unchanged. The changes largely consist of excisions of regulatory text as opposed to the addition of new text, so it is unsurprising that the regulatory drafting period was shorter than the period for the 2016 Rule. In many instances where new or modified regulatory text was proposed, such text was based on existing guidance or regulatory text. The Department considers this to be an adequate process and a sufficient period of time to engage in such rulemaking.

This final rule maintains vigorous protections for people with LEP and communication-based disabilities, as discussed in detail below, and the Department intends to continue robust enforcement of those protections.

Comment: Several commenters indicated that the cost savings cited in the proposed rule are unsupported or based on insufficient data. Several commenters also contend that the proposed rule ignores the costs to individuals, especially LEP individuals, who will allegedly encounter additional barriers to accessing healthcare as a result of the proposed changes. Some commenters were concerned that the proposed rule would help eliminate access to a wide range of affordable preventive health services, including cancer screenings, contraception, and reproductive health services. The commenters believe this loss of access will largely be caused by the proposed changes to the definition of sex discrimination. Many commenters expressed concern that the proposed rule would remove civil rights protections for a number of vulnerable groups, including LEP individuals, LGBT individuals, individuals with disabilities, and women seeking reproductive healthcare. Such commenters state that the removal of these protections would, in turn, result in even greater health disparities for these vulnerable populations. Some commenters stated that the proposed rule would lead to increased discrimination in healthcare, which would lead people to delay or forego healthcare and would result in adverse health outcomes and greater overall healthcare costs to individuals. Some of these commenters note that based on these anticipated increased disparities, the proposed rule is effectively encouraging discrimination.

Response: This final rule leaves in place all statutory civil rights protections for vulnerable groups. Cost savings are treated in the Regulatory Impact Analysis below, which discusses the data, estimates, and assumptions used to support its calculations. Potential health disparities or other alleged costs to individuals or vulnerable groups, including those due to discrimination or barriers to access, are discussed in the relevant sections below (*e.g.,* potential costs to LEP individuals are discussed in comments on those sections of the regulation that deal with national-origin discrimination and/or LEP, while potential costs relating to the gender identity provision are discussed in comments on the section regarding ''discrimination on the basis of sex'').

Comment: Many commenters expressed their belief that this proposed rule diverges from the current body of civil rights laws. These commenters believe that limiting protections based on gender identity, termination of pregnancy, and LEP, runs contrary to civil rights protections.

Response: Current civil rights laws and their protections are discussed, respectively, in the relevant sections below (*e.g.,* civil rights law on gender identity is discussed in the section on ''discrimination on the basis of sex,'' because the 2016 Rule had classified gender identity discrimination as a form of sex-based discrimination).

Comment: Some commenters stated that civil rights protections should not be eliminated because of compliance costs faced by covered entities, and that such balancing runs contrary to the Affordable Care Act and the Administrative Procedure Act. Such commenters argue that if the Department determines that particular protections are too costly or onerous, it should advance more limited protections rather than eliminating them entirely.

Response: This final rule does not, and could not, repeal or eliminate specific protections under any of the four civil rights statutes referenced in Section 1557, and it does not remove the protections provided by the implementing regulations for those statutes.

The Department has, however, chosen to reduce some excessive burdens that were applied to covered entities by the 2016 Rule, but were not required by Section 1557, where the relevant civil rights protections could be enforced using the underlying regulations without the unnecessary burdens imposed by the 2016 Rule.

Comment: Commenters stated that the Department exceeded its authority by proposing this rule. Some commenters indicated that the Department's positions as advanced in the proposed rule are not worthy of deference under the framework established in *Chevron, U.S.A., Inc.* v. *Nat. Res. Def. Council, Inc.,* 467 U.S. 837 (1984), because the proposed rule is contrary to clear congressional intent and is inconsistent with the agency's past policies concerning sex protections. Many of these commenters assert that the changes set forth in the proposed rule run contrary to the requirements of the ACA, pointing to 42 U.S.C. 18114 (Section 1554), which states that the Department shall not ''promulgate any regulation that—(1) creates any unreasonable barriers to the ability of individuals to obtain appropriate medical care; (2) impedes timely access to health care services. . .'' These commenters also state that the Department is attempting to make a legislative change through an administrative action. Some commenters contend that the proposed rule runs contrary to the general intent of the ACA, namely that all individuals should be provided access to healthcare.

Response: The 2016 Rule tried to make essentially legislative changes through administrative action, and those changes were rightly held to be in violation of the APA. The Department does not exceed its authority by rescinding the portions of the 2016 Rule that exceeded the Department's authority. The Department also does not

[17] *See* 84 FR 27850; *F.C.C.* v. *Fox Television Stations, Inc.,* 556 U.S. 502, 514–15 (2009).

violate Section 1554 of the ACA by not including the gender identity and termination of pregnancy provisions in this final rule, which were not supported by the text of the underlying civil rights laws incorporated in Section 1557, and in addition were vacated by court order.

With respect to both Sections 1554 and 1557, the Department interprets the ACA by the plain meaning of its text, and as will be shown below, this final rule brings the Department's Section 1557 regulations in line with a proper understanding of the ACA's text. Parts of the 2016 Rule exceeded the Department's authority under the ACA, and this final rule formally eliminates those portions from the Code of Federal Regulations. The Department believes this approach adheres more closely to the text of the statutes referenced in Section 1557, along with the regulations that the Department has used to implement those statutes for decades. Other parts of the 2016 Rule are being modified or repealed in order to save providers from unnecessary burdens not required by the ACA, so that they are better able to achieve the statute's goal of providing healthcare access to all Americans. Such a reconsideration and elimination of certain regulatory provisions, particularly regulations that the ACA itself did not require to be issued, neither ''creates'' unreasonable regulatory barriers nor impedes timely access to healthcare. If it were otherwise, Section 1554 would essentially serve as a one-way ratchet, preventing the Department from ever reconsidering a regulation that could be characterized as improving access to healthcare in some sense, regardless of the other burdens such regulation may impose on access to health care. The Department's approach in this final rule is also consistent with the Ninth Circuit's recent interpretation of Section 1554: ''[t]he most natural reading of § 1554 is that Congress intended to ensure that HHS, in implementing the broad authority provided by the ACA, does not improperly impose regulatory burdens on doctors and patients.'' [18] As explained throughout the preamble, the Department's rule avoids precisely such burdens by bringing the section 1557 regulations into alignment with the longstanding requirements of the applicable civil rights laws and their implementing regulations (thereby also avoiding additional conscience burdens that the 2016 Rule potentially imposed) and by removing notice and taglines requirements that imposed unjustified burdens on the healthcare system as a whole (some of which would likely have been passed on to individuals).

Comment: Commenters said that Section 1557 should be construed broadly because throughout the ACA, Congress prohibited a variety of forms of discrimination, such as against pre-existing conditions and combating health disparities. Commenters also indicated that the ACA is intended to reduce the cost of healthcare discrimination against the poor, so the Section 1557 rule should implement cost sharing and other insurance requirements.

Response: In the ACA, Congress labeled several provisions other than 1557 as prohibiting discrimination [19] in healthcare, but did not incorporate those other provisions of the ACA into Section 1557. Those other provisions are different from the civil rights provisions set forth in Section 1557 in substance, implementation, and enforcement. This final rule commits the Department to robust enforcement of the nondiscrimination grounds applicable under Section 1557.

Comment: A commenter contended that the Department provided little or no legal, policy, or cost-benefit analysis along with the proposed rule and combined too many changes into a single rule. Some commenters claimed the proposed rule is arbitrary, capricious, and contrary to law, is inconsistent with the agency's mission, and lacks reasoned explanations justifying the policy reversals. Other commenters stated that HHS failed to account for the extensive history of healthcare discrimination, and provided no contrary data to counter the original factual findings in the 2016 Rule. Furthermore, they said that individuals have reasonably placed their reliance upon the Federal government to protect their civil rights as explained in the 2016 Rule.

Response: The Department provided ample legal, policy, and cost-benefit analysis for the proposed rule and provides additional support here for the final rule.[20] The Department proposed changes to the provisions of the 2016 Rule because that rule exceeded the Department's authority under Section 1557, adopted erroneous and inconsistent interpretations of civil rights law, caused confusion, imposed unjustified and unnecessary costs, and conflicted with applicable court decisions. It is unfortunate that, by administrative action, the 2016 Rule may have unreasonably raised expectations about nondiscrimination protections that are not found in the underlying statutes, but this final rule cannot be held responsible for that. The Department gave extensive reasons for its changes in the 2019 NPRM, and gives further reasons in response to comments below. The public comment process provided adequate opportunity to present legal, policy, and cost-benefit analyses, all of which were considered in finalizing this rule, as discussed herein.

The Department also updates and discusses the regulatory impact analysis based on comments and data received. While there are still some questions addressed by this final rule where robust data are unavailable, were not found by the Department, or have not been brought to the Department's attention, the Department is allowed to engage in rulemaking even where the impact of a rule change is difficult or impossible to quantify. The Department has diligently considered the relevant and significant data of which it is aware.

There is no artificial limit on the number of changes a proposed rule may contain—or on the number of parts in the Code of Federal Regulations that can be addressed in a rulemaking. This final rule contains many fewer changes than the 2016 Rule did, and it substantially streamlines the existing 1557 regulation as opposed to enlarging it. Its inclusion of conforming changes to various CMS regulations still gives the final rule a size and scope that is well within the range of other significant proposed rules.

Comment: Several commentators stated that the proposed rule's language that Title IX and Section 1557 must be ''exercised with respect for State sovereignty'' runs contrary to the Supreme Court's decision that Congress has the authority to prohibit discrimination in commercial activity.

Response: This final rule does not, nor does the Department intend to, remove any protection against State action that Congress has provided by statute. It also does not deny States the ability to provide protections that exceed those required by Federal civil rights law. The reference to State sovereignty simply refers to the Department's intention to protect the States by respecting their sovereignty to the extent that doing so does not infringe on Federal law.

Comment: One commenter noted that, after the 2016 Rule was passed, the

[18] *California* v. *Azar,* No. 19–15974, 2020 WL 878528, at *18 (9th Cir. Feb. 24, 2020) (en banc).

[19] *See, e.g.,* ACA Section 2701 (''discriminatory premium rates''); Section 2716 (''discrimination based on salary''); Section 2705 (''discrimination against individual participants and beneficiaries based on health status''); Section 2716 (''discrimination in favor of highly compensated individuals'').

[20] *See* 45 FR at 27875–88.

Department released resources and educational materials, including fact sheets, to explain the 2016 Rule. The commenter requested that the Department release similar resources and educational materials following the finalization of this rule.

Response: The Department is providing the responses to comments contained in this preamble to clarify issues and answer questions concerning this final rule. Furthermore, the Department continues to be committed to providing resources and educational materials to explain civil rights requirements and to assist covered entities with compliance with civil rights statutes and the regulations thereunder, including this regulation.

B. Section 1557 Regulation, Subpart A: General Requirements and Prohibitions

The Department proposed changes to the Section 1557 rule at 45 CFR part 92 to be composed of Subpart A on general requirements and prohibitions, and Subpart B on specific applications related to disability nondiscrimination and language access.

(1) Proposed Repeal of Definitions in § 92.4 of the 2016 Rule

Comments: A commenter contended that eliminating the definitions section in the Section 1557 Regulation would cause confusion, misinterpretation, and inconsistency of terms among the regulations that currently reference or otherwise rely on the underlying definitions in the 2016 Rule.

Response: In significant part, the definitions section of the 2016 Rule duplicates definitions already incorporated into the Section 1557 regulation by reference, and hence creates either inconsistency or redundancy. In other cases, the 2016 Rule contained definitions inconsistent with the text of applicable statutes; indeed, on those grounds, a Federal district court vacated the 2016 Rule's definition of ''on the basis of sex'' insofar as it encompassed gender identity and termination of pregnancy. The Department will continue to enforce Section 1557 using HHS regulations for the underlying civil rights statutes. Many of these regulations have definition sections and operate based on longstanding understandings of how the laws are enforced.

Comments: Some commenters argued that eliminating the phrases ''covered entities'' and ''health program or activities'' would allow many plans and programs to be exempt from the Section 1557 regulation. Other commenters stated that the existing definitions provide clarity and consistency for covered entities. Another commenter stated that the proposed rule would limit Section 1557's application to the specific program or activity that receives Federal assistance, rather than a healthcare entity's entire operations.

Response: See below, under ''Scope of Application in Proposed § 92.3,'' for a discussion of the entities subject to this final rule.

Comment: Some commenters asked the Department to retain the definition of ''auxiliary aids and services'' concerning effective communication for individuals with disabilities. They also asserted that the Department has altered important definitions related to effective communication, without explanation or acknowledgement. While some commenters appreciated the Department's efforts to incorporate many of the current definitions of Title II of the Americans with Disabilities Act [21] (''ADA''), some claim the Department has erred in tracking the language of those definitions.

Response: The Department is not required to track ADA definitions in its Section 1557 regulation. This final rule applies many definitions based on those found in the ADA or its regulations (including ''disability'' and ''auxiliary aids and services''), technical definitions and standards under the ADA, and Uniform Federal Accessibility Standards as promulgated; as discussed below, it also departs from ADA definitions in certain cases. Additionally, this final rule retains effective communication standards for individuals with disabilities under § 92.102; these provisions are drawn from regulations promulgated by the Department of Justice implementing Title II of the ADA.[22] Specific definitions and provisions related to individuals with disabilities are discussed below.

The proposed rule apprised the public of the language the Department sought to finalize in the rule, gave the Department's reasons for changes relative to the 2016 Rule, and provided an opportunity to comment on the proposed language.

Comment: Some commenters opposed the proposed removal of the definition for ''national origin,'' saying it would lead to confusion among providers and recipients as to what constitutes discrimination on the basis of national origin.

Response: The term ''national origin'' is not specifically defined in Title VI or in HHS's implementing regulation, but the Department has appropriately enforced the prohibition on national origin discrimination under Title VI for decades in accord with relevant case law. In implementing this final rule, the Department intends to enforce vigorously the prohibition on national origin discrimination in a manner consistent with the current interpretation under Title VI, including under *Lau* v. *Nichols,* as discussed below.[23]

Comment: Some commenters asserted that the removal of definitions weakens protections for LEP individuals and signals a lack of priority for enforcement by the Department.

Response: As discussed below, meaningful access for individuals with LEP is a key component of the national origin protections under Title VI and Section 1557, and will be well protected by this final rule. The streamlining of this regulation through the elimination of largely redundant definitions will in no way impede the Department's strong commitment to meaningful access for LEP individuals.

Summary of Regulatory Changes: The Department finalizes its repeal of § 92.4 of the 2016 Rule without change. Additional comments concerning the definitions of sex, gender identity, and other specific definitions are discussed in more detail below.

(2) General Changes to 2016 Rule

a. Purpose of Regulation, Revising § 92.1 of the 2016 Rule

The Department proposed to revise the statement of the purpose of the regulation in § 92.1 from ''implement[ation]'' of Section 1557 to ''provid[ing] for the enforcement'' of Section 1557. 84 FR at 27861.

Comment: A commenter said this change in language allows the Department to minimize its involvement in ensuring that nondiscrimination protections are effective.

Response: This is the opposite of the Department's intention. This final rule's title and citation to statutory authority already make clear that it is implementing Section 1557. By changing the rule's language from ''implement'' to ''provide for the enforcement of,'' the Department simply means to emphasize, in terms accessible to a lay audience, that it will fully enforce Section 1557 and the underlying nondiscrimination laws as they fall within the jurisdiction of the Department, according to the text of those laws and their implementing regulations.

[21] 42 U.S.C. 12101 *et seq.*

[22] 42 U.S.C. 12311; *see also* 28 CFR 35.160–164.

[23] *Lau* v. *Nichols,* 414 U.S. 563 (1974).

b. Effective Date

The Department proposed that the effective date of the revised regulation be 60 days after publication of the final rule, in order to relieve significant regulatory burdens, particularly the taglines requirements.[24] The 2016 Rule's effective date was July 18, 2016 (60 days after publication of the final rule), with the exception of the provisions on health insurance and benefit design, which went into effect on January 1, 2017 (the first day of the first plan year following the effective date).[25] The new rule does not include a different effective date for health insurance and benefit design.

Comment: Commenters asked that the Department make the effective date several months prior to the plan open enrollment period that occurs between November 1 and December 15, in order for the covered entities to have sufficient time to incorporate the regulatory changes into the next plan year.

Response: The Department has endeavored to issue this final rule sufficiently in advance of the plan year cycle, so that plans can incorporate the regulatory changes into the next plan year. Moreover, because this final rule generally relieves regulatory requirements rather than adding them, it should be easier for issuers to incorporate such changes into the plans they will offer for the next plan year.

Comment: Commenters stated that it is inappropriate to finalize the change to the definition of sex as it relates to Section 1557 in light of current litigation before the Supreme Court, which may be resolved by the end of the court's term or before. These commenters note that the Supreme Court's ruling in *R.G. & G.R. Harris Funeral Homes* v. *EEOC & Aimee Stephens*[26] will determine whether Title VII of the Civil Rights Act of 1964 extends sex discrimination protections to transgender status, and that the ruling may apply to the definition of sex under Title IX as well. Accordingly, these commenters urge the Department to wait until the Supreme Court decides *Harris Funeral Homes* before publishing a rule that deals with the same subject matter, or allow for commenters to comment again once the case has been decided.

Response: The Department acknowledges the commenters' point of view but respectfully disagrees. The U.S. government has taken the position in *Harris* and other relevant litigation that discrimination ''on the basis of sex'' in Title VII and Title IX does not encompass discrimination on the basis of sexual orientation or gender identity.[27] The Department shares that position and is permitted to issue regulations on the basis of the statutory text and its best understanding of the law and need not delay a rule based on speculation as to what the Supreme Court might say about a case dealing with related issues. The Department also agrees with the *Franciscan Alliance* ruling, according to which the 2016 Rule's extension of sex-discrimination protections to encompass gender identity was contrary to the text of Title IX and hence not entitled to *Chevron* deference.[28] Moreover, to the extent that a Supreme Court decision is applicable in interpreting the meaning of a statutory term, the elimination of a regulatory definition of such term would not preclude application of the Court's construction.

The Department continues to expect that a holding by the U.S. Supreme Court on the meaning of ''on the basis of sex'' under Title VII will likely have ramifications for the definition of ''on the basis of sex'' under Title IX.[29] Title VII case law has often informed Title IX case law with respect to the meaning of discrimination ''on the basis of sex,''[30] and the reasons why ''on the basis of sex'' (or ''because of sex,'' as used in Title VII) does not encompass sexual orientation or gender identity under Title VII have similar force for the interpretation of Title IX. At the same time, as explained below, the binary biological character of sex (which is ultimately grounded in genetics) takes on special importance in the health context. Those implications might not be fully addressed by future Title VII rulings even if courts were to deem the categories of sexual orientation or gender identity to be encompassed by the prohibition on sex discrimination in Title VII. As a result, the Department considers it appropriate to finalize this rule, which does not define sex, but relies on the plain meaning of the term under Title IX, and does so in the health context within which the Department applies Title IX under Section 1557.

Comment: Commenters disagreed with the Department's reliance on the litigation and court order in *Franciscan Alliance* to justify revisiting the rule, because the injunctive order was not permanent, was allegedly limited to enforcement actions of HHS, and does not require new rulemaking, and because other litigants have intervened in the case to defend the 2016 Rule. Some commenters stated that although the U.S. District Court in *Franciscan Alliance* ruled against the 2016 Rule's definition of sex, other courts have come to conclusions that suggest the opposite, and HHS is not required to alter Department-wide policy based on the injunction in *Franciscan Alliance.* Others argued that the Department improperly relied on one legal decision that they said conflicts with the clear weight of case law. Another commenter stated it would be inappropriate to publish any new rule before a final ruling in *Franciscan Alliance,* as the case is being appealed.

Response: Nearly three years after the preliminary injunction, and after the comment period on the proposed rule had concluded, the court in *Franciscan Alliance* issued a final ruling vacating the 2016 Rule ''insofar as the Rule defines *'On the basis of sex'* to include gender identity and termination of pregnancy,'' and remanding the Rule for further consideration.[31] This final ruling is binding on the Department despite the appellate proceedings still pending in that case: The Department's Section 1557 regulation, as currently operative, does not contain the 2016 Rule's definition of ''on the basis of sex'' to encompass gender identity and termination of pregnancy. The *Franciscan Alliance* court's 2016 injunction gave the Department good cause to reconsider the 2016 Rule, but neither the injunction nor the *vacatur* was the Department's only reason for revising it, as the proposed rule made clear and as the Department's responses to comments in this preamble reiterate. Nothing in the appellate litigation prohibits the Department from finalizing this rule, which it does for the reasons given in this preamble. As for the weight of case law, it is discussed below with respect to the respective provisions of this final rule.

Comment: One commenter noted that the Department's announcement of the proposed rule on May 24, 2019 had stated that a fact sheet explaining the changes in the proposed rule would be

[24] 84 FR at 27888.

[25] 81 FR at 31378.

[26] *R.G. & G.R. Harris Funeral Homes, Inc.* v. *E.E.O.C.,* 139 S. Ct. 1599 (2019).

[27] As noted elsewhere in this preamble, it has been the consistent position of the federal government that ''on the basis of sex'' under Section 1557 does not encompass sexual orientation, including the decision in the 2016 Rule not to include sexual orientation in the definition of that term. *See* 81 FR at 31390.

[28] *Franciscan All., Inc.* v. *Azar,* 414 F. Supp. 3d 928, 945 (N.D. Tex. Oct. 15, 2019) (incorporating its previous ruling at 227 F. Supp. 3d at 685–87).

[29] *See* 84 FR 27855.

[30] *See, e.g., Yusuf* v. *Vassar Coll.,* 35 F.3d 709, 714 (2d Cir. 1994).

[31] Order, *Franciscan Alliance,* No. 7:16–cv–00108–O *2 (N.D. Tex. filed Nov. 21, 2019).

provided in Spanish. However, no such fact sheet has been provided. Accordingly, the commenter requested that the comment period be extended until 60 days after the fact sheet is published in Spanish.

Response: The proposed rule itself did not purport to offer information in Spanish, and the Department was not under a legal obligation to offer a separate fact sheet or to translate it. The Department's press release indicated that a fact sheet, separately created in connection with the press release, would be translated. That is not a basis for reopening the comment period on the proposed rule, because the proposed rule provided the public with adequate notice and a 60-day public comment period, which were legally sufficient.

c. Severability

The Department proposed to repeal the provision in § 92.2(c) of the 2016 Rule stating that if a regulatory provision in this part were held invalid or unenforceable on its face or as applied to a specific person or circumstances, the provision should be construed to the maximum effect permissible by law and be severable such that it would not affect other persons or circumstances that are dissimilar.

Comment: Commenters asked the Department to add a severability provision to the final rule. Specific points recommended included severing repeal of the provisions related to the notices and taglines, and/or the changed scope of applicability, from the sex discrimination provisions. Commenters said that the Supreme Court case *K-Mart Corp.* v. *Cartier, Inc.,* 108 S. Ct. 1811 (1988), would allow the Department to sever the changes in the taglines provision from the proposed rule and implement those changes even in the event that a court delays or suspends the proposed rule.

Response: In part due to these comments, the Department has decided not to finalize the proposal to eliminate the severability provision from the 2016 Rule. Instead the Department will retain that severability provision, but has moved it to § 92.3(d), because § 92.3 is now the provision addressing the application of the rule. This change will be discussed again below in the discussion of § 92.3.

d. Summary of Regulatory Changes

For the reasons described in the proposed rule, and having considered the comments received, the Department finalizes the proposed § 92.1 without change, and confirms that the effective date of this final rule will be 60 days after its publication in the **Federal Register**.

(3) Scope of Application in Proposed § 92.3; Repeal of § 92.208

The Department proposed to repeal § 92.2 of the 2016 Rule, and instead address the scope of application of Section 1557 in a new § 92.3. 84 FR at 27862–63. The Department also proposed to repeal § 92.208 of the 2016 Rule, which had expanded the scope of the Section 1557 statutory provision to apply to certain employee health benefits programs.[32]

a. Generally

Comment: Commenters argued the Department did not provide a reasoned legal, policy, or cost-benefit analysis to support the repeal of § 92.208, which hindered their ability to provide meaningful comments as required by the APA. The commenters maintained that the Department's comparison of § 92.208 to Title IX[33] was flawed, in part because HHS's Title IX regulation does not apply to all bases of discrimination or many of the same covered entities as addressed under Section 1557. Some commenters noted that employees deserve protection from discrimination in employer-sponsored plans.

Response: As seen below in the response to a similar comment on § 92.207, § 92.208 appears in the NPRM in a list of sections of the 2016 Rule that ''are duplicative of, inconsistent with, or may be confusing in relation to the Department's preexisting Title VI, Section 504, Title IX, and the Age Act regulations.''[34] The Department repeals § 92.208 for reasons similar to those given at greater length below in discussing § 92.207: It seeks to relieve regulatory burden and possible confusion by enforcing the relevant nondiscrimination statutes through their existing regulations.

The Department is not aware of data and methods available to make reliable estimates of all economic impacts predicted by various commenters. The Department's estimates of regulatory impact are discussed below.

Comment: Commenters stated that individuals protected by Section 1557, particularly individuals with disabilities, frequently experience discrimination in healthcare. Commenters expressed concerns that the narrowed application would reduce the number of covered entities and would lead to more discrimination, lack of care, and adverse health outcomes, which they argued is contrary to the stated Congressional intent and purpose of the ACA to expand access to and end discrimination in health insurance. Several State and local government commenters expressed concern that the proposed rule would negatively affect public health in their States and increase costs to States due to more people seeking care through government-funded programs, such as Medicaid.

Conversely, other commenters were supportive of the proposed rule's revised scope and agreed that the 2016 Rule was far too broad in its application. They concurred that narrowing the scope of application would help rein in the regulatory excess and burden of the 2016 rule.

Response: The Department must follow the text of the ACA. To the extent that Congressional intent and purpose are relevant, they are best determined by looking to the plain meaning of the statutory text. This final rule will enforce Section 1557's discrimination requirements against the entities that Congress intended them to be enforced against. The Department's specific reasoning in interpreting Section 1557's scope of coverage follows.

b. § 92.3(a): Covered Programs and Activities

The Department proposed in § 92.3(a) that, except as otherwise provided in part 92, the Section 1557 rule will apply to (1) any health program or activity, any part of which is receiving Federal financial assistance (including credits, subsidies, or contracts of insurance) provided by the Department; (2) any program or activity administered by the Department under Title I of the ACA; or (3) any program or activity administered by any entity established under Title I of the ACA.

Comment: Some commenters opposed removing the full definition of ''Federal financial assistance'' from the 2016 Rule and replacing it with the limited text under proposed § 92.3(a)(1). They stated that the lack of specificity could lead to ambiguity and confusion. Commenters further asserted that the proposed rule was inconsistent with the Department's recently promulgated *Protecting Statutory Conscience Rights in Health*

[32] *Compare* 45 CFR 92.208 (employer liability for discrimination in employee health benefit programs in Section 1557) *with* 45 CFR 86.56 (discrimination on the basis of sex in fringe benefits under Title IX. The enforcement Memorandum of Understanding (MOU) between OPM and the Department, signed by OCR on 11 January 2017, is moot upon publication of this final rule.

[33] 84 FR at 27869, n.148 (comparing § 92.208 with 45 CFR 86.56 (discrimination on the basis of sex in fringe benefits under Title IX)).

[34] 84 FR 27869.

Care (''2019 Conscience Rule''),[35] which included an expansive definition of ''Federal financial assistance.''[36]

Response: The Department concludes it is appropriate to have a definition of Federal financial assistance that mirrors Section 1557's statutory text to include ''credits, subsidies, or contracts of insurance.'' In addition, the definitions applicable under the preexisting civil rights statutes still apply, and the Department believes it is more appropriate to apply those existing definitions than to maintain the ones in the 2016 Rule. Section 1557 says the enforcement mechanisms provided for and available under the underlying civil rights statutes shall apply, and the Department believes operating under those mechanisms and the definitions that have long been applicable to them, along with the language the Department retains in this final rule, is appropriate moving forward. The 2019 Conscience Rule was based on different statutes.

Comment: Some commenters opposed the proposed rule's exclusion of Federal financial assistance that the Department ''plays a role'' in providing or administering, which had been included in the 2016 Rule's definition of Federal financial assistance. Commenters argued that the statute applies to programs or activities administered by ''an Executive Agency'' and thus should not be limited to HHS. In particular, they objected to the result that qualified health plans (QHPs) would no longer be covered under the rule on the basis that HHS plays a role in administering tax credits. The commenters argued that this interpretation is contrary to a plain reading of the statute, which not only uses the broad term ''Federal financial assistance'' (without a modifier to limit it to assistance directly administered by HHS), but also expressly includes ''credits'' as part of Federal financial assistance. Further, some commenters noted that the Department took an inconsistent and broader approach in its Conscience Rule, wherein HHS exerts jurisdiction over statutes and funding also administered by the U.S. Departments of Labor and Education.

Response: The statutory text of Section 1557 refers simply to ''any health program or activity, any part of which is receiving Federal financial assistance, including credits, subsidies, or contracts of insurance.'' Because the Section 1557 regulation applies only to the Department, the 2015 NPRM had reasonably sought to limit its scope to Federal financial assistance from the Department, leaving other Departments to enforce Section 1557 within their own sphere.[37] In the 2016 Rule, however, wishing to encompass tax credits administered under Title I, the Department expanded the rule's scope to encompass ''Federal financial assistance that the Department plays a role in providing or administering.''[38] The Department now regards this expansion as overbroad. While Section 1557 still applies to any health program or activity receiving any Federal financial assistance, this final rule prescribes enforcement only by the Department and within the Department's jurisdiction. The Department does not consider it appropriate in this final rule to apply its provisions to any programs that the Department ''plays a role in'' administering.

Commenters' concerns about covering QHPs are misplaced: These plans remain subject to this rule because they are sold on the Exchanges established under Title I of the ACA (see § 92.3(a)(3) of this final rule). This final rule only prescribes enforcement of Section 1557 by the Department and within the Department's jurisdiction, so the Department believes it is appropriate for this regulation to not include activities funded or administered solely by other Federal agencies even if Section 1557 may apply in those instances.

The 2019 Conscience Rule (as stated above) relied on different statutes than the Section 1557 rule, and the Department drafts its regulations as appropriate for the underlying statutes.

Comment: Commenters disapproved of proposed § 92.3(a)(2), which would limit the rule's application in the context of HHS-administered programs or activities to only those administered under Title I of the ACA. Commenters argued that this interpretation is inconsistent with the statutory text of Section 1557, which applies to ''any program or activity administered by an Executive Agency *or* any entity established under this title [*sc.,* Title I].'' (emphasis added). Commenters argued the proposed § 92.3(a)(2) would incorrectly apply ''under this title'' to modify both phrases. Furthermore, they argued that the Department did not provide an adequate rationale for its interpretation in the proposed rule.

Response: As explained in the 2019 NPRM, the statutory text of Section 1557 applies to ''any program or activity'' administered by an Executive Agency or Title I entities, but does not include the modifier ''health'' with respect to those programs or activities.[39] In the 2016 Rule, the Department limited its application by adding ''health'' to ''programs or activities'' because the Department recognized that Section 1557 was not intended to apply to every program or activity administered by every Executive Agency, whether or not it related to health.[40] The 2016 Rule acknowledged implicitly what the Department now states more clearly: The grammar of the relevant sentence in the Section 1557 statutory text concerning limits to its scope is less clear than it could have been. In resolving the sentence's ambiguity, however, the Department no longer agrees with the 2016 Rule's decision to add a limiting modifier (*i.e.,* ''health'') that Congress did not include in the statutory text. Instead, the Department concludes that Congress had already placed a limitation in the text of Section 1557 by applying the statute to any program or activity administered by an Executive Agency ''under this title'' (meaning Title I of the ACA), as well as to any program or activity administered by an entity established under such title. The Department believes that either this interpretation of the statutory text, or the 2016 Rule's addition of the modifier ''health,'' is necessary in order to make sense of the statutory text; this final rule offers a technical reading of the text that is at least as reasonable as the 2016 Rule's addition of a word not present in the text of the statute.

Comment: Commenters argued that the proposed interpretation to limit coverage to HHS Title I programs or activities would exclude a number of important programs and activities operated by HHS and is inconsistent with Section 504's application to ''any program or activity conducted by an

[35] *Protecting Statutory Conscience Rights in Health Care; Delegations of Authority,* 84 FR 23170–01 (2019).

[36] 45 CFR 88.2.

[37] 80 FR 54173 (''Section 1557 applies to all health programs and activities, any part of which receives Federal financial assistance from any Federal Department. However, this proposed rule would apply only to health programs and activities any part of which receives Federal financial assistance from HHS. This narrowed application is consistent with HHS' enforcement authority over such health programs and activities, but other Federal agencies are encouraged to adopt the standards set forth in this proposed rule in their own enforcement of Section 1557.'').

[38] 81 FR 31467, 31384; *cf.* 80 FR 54216.

[39] 42 U.S.C. 18116(a) (applying Section 1557, in relevant part, to ''any program or activity that is administered by an Executive Agency or any entity established under this title (or amendments).''). *See also* 84 FR at 27861–62 (discussing the Department's statutory interpretation).

[40] 45 CFR 92.2 (applying the final rule, in relevant part, to ''every *health* program or activity administered by the Department; and every *health* program or activity administered by a Title I entity'') (emphasis added).

Executive Agency.'' [41] They point out that HHS's Section 504 regulation applies to ''all programs or activities'' conducted by HHS and all its components, including CMS, HRSA, CDC, and SAMHSA.[42] Further, commenters stated that excluding non-Title I HHS-administered programs and activities, contrary to Section 504, will result in confusion and cause illogical results, whereby recipients would be covered by Section 1557 but the agencies administering the program would not be covered. For example, State Medicaid programs would be subject to Section 1557, but CMS, which oversees those Medicaid programs, would not be covered.

Response: Section 1557 is a nondiscrimination statute under the ACA, which uniquely applies to healthcare, whereas Section 504 is a statute of general applicability. Section 1557 incorporates Section 504's prohibited grounds of discrimination but not its scope: Section 1557's scope differs from that of the underlying statutes. For instance, Section 504 does not include ''contracts of insurance'' in its definition of Federal financial assistance,[43] but this final rule follows the text of Section 1557 by including ''contracts of insurance'' within Federal financial assistance.[44] With respect to CMS, it is covered under this final rule to the extent that it either administers health programs and activities receiving Federal financial assistance or administers programs and activities under Title I. In addition, it is important to note that, as a federal agency, CMS has long been subject to various constitutional and statutory prohibitions on discrimination.

c. § 92.3(b): Scope of the Term ''Health Program or Activity''

The Department proposed in § 92.3(b) to clarify that ''health program or activity'' encompasses all of the operations of entities ''principally engaged in the business of providing healthcare'' that receive Federal financial assistance. The Department proposed to further clarify that for any entity not principally engaged in the business of providing healthcare, such entity's operations are subject to the Section 1557 Rule only to the extent any such operation receives Federal financial assistance provided by the Department.

Comment: Commenters opposed limiting application of the rule when the entity is not principally engaged in the business of providing healthcare. Commenters argued that this would dramatically limit the scope of the rule and is contrary to Congressional intent and the plain meaning of the statute, which covers ''any health program or activity, any part of which is receiving Federal financial assistance. . . .'' Commenters stated that the entire entity receiving Federal financial assistance should be covered, not just the portion receiving funding. Commenters also argued the new framework would cause uncertainty and confusion for covered entities, which would have to clarify the extent of their own compliance, and also would make it harder for consumers to enforce their rights because they would have difficulty determining which entities and which portion of their programs or activities are subject to the rule. Commenters contended this uncertainty could result in lack of access to care, increased health disparities, and increased uncompensated care, all of which would increase overall healthcare costs.

Some commenters stated that the rule incorrectly incorporates the Civil Rights Restoration Act (CRRA) [45] into Section 1557. Commenters argued that the CRRA predates the ACA; nothing in the CRRA's text applies it to future statutes or Section 1557; Congress did not incorporate the CRRA into the Section 1557 statute; and Section 1557 itself is more expansive than the laws amended by the CRRA. Therefore, they say, a broader definition of covered programs and activities should apply to include all health insurers as covered entities. Others argued that the proposed rule's application of the CRRA contravenes the approach taken by Congress in the CRRA. They stated that Congress made clear in the CRRA that if any part of a program or activity receives Federal financial assistance, the entire program or activity must comply with the applicable civil rights laws. Thus, the commenters argued that the proposed rule's limited application when entities are not principally engaged in the business of healthcare, to cover only the specific operation that receives Federal financial assistance, is contrary to the CRRA. Another commenter stated that incorporating the CRRA into Section 1557 would be subject to judicial review, to the extent the Department relies on Section 1557's references to ''grounds'' and ''enforcement mechanisms'' of the underlying statutes to do so, because the Supreme Court held in *Consolidated Rail Corp.* v. *Darrone* that a statute's incorporation of another statute's enforcement mechanisms does not necessarily incorporate its substantive law.[46]

Conversely, other commenters were supportive of reducing regulatory burden by limiting application of the rule in this way. They stated that the 2016 Rule defined ''covered entities'' far too broadly, and that narrowing the scope will help rein in the regulatory excess of that rule. Commenters explained that healthcare entities often provide a variety of services and products, such as insurance coverage for life, disability, or short-term limited duration insurance coverage, and third-party administrative services, which do not receive Federal financial assistance. These commenters agreed that Section 1557 is intended to apply only to those programs receiving Federal funding and not to other parts of the entity's businesses or products when an entity is not principally engaged in the business of providing healthcare.

Response: Section 1557 explicitly incorporates statutes amended by the CRRA, and in this final rule the Department is aligning Section 1557's definition of ''health program or activity'' with the standard articulated in the CRRA in order to provide clarity and consistency. The CRRA clarified the scope of nondiscrimination prohibitions under the civil rights statutes that Section 1557 incorporates. For example, with respect to the health sector, it applied those prohibitions to all health programs or activities receiving Federal financial assistance, but not to all providers of health insurance: It applied ''program or activity'' to cover all of the operations of an entity only when that entity is ''principally engaged in the business of providing . . . health care . . . .'' [47] This final rule clarifies that the term ''health program or activity'' used in Section 1557 should be understood in light of the CRRA's limitations on the term ''program or activity'' as applied to statutes on which Section 1557 relies. As for *Consolidated Rail Corp.* v. *Darrone,* Congress specifically and intentionally

[41] 29 U.S.C. 794 (applying to ''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'').

[42] 45 CFR, part 85.

[43] 45 CFR 84.3(h).

[44] 42 U.S.C. 18116(a).

[45] Public Law 100–259, 102 Stat. 28 (Mar. 22, 1988).

[46] *See Consolidated Rail Corp.* v. *Darrone,* 465 U.S. 624, 635 (1984) (holding that Section 504's incorporation of the ''remedies, procedures, and rights'' set forth in Title VI did not mean that Section 504 incorporated Title VI's substantive limitations on actionable discrimination).

[47] *See, e.g.,* CRRA § 3(a) (adding § 908(3)(A)(ii) to Title IX of the Education Amendments of 1972 (codified at 20 U.S.C. 1687(3)(A)(ii)).

overturned that case through the passage of the CRRA.[48]

The 2016 Rule also articulated a standard for ''health program or activity'' that relied upon the ''principally engaged'' prong of the CRRA, which was contested neither before nor after that rule's publication. In the regulatory text, the 2016 Rule defined ''health program or activity'' to apply to all operations of an entity only when it is principally engaged in providing or administering health services, health insurance coverage, or other health coverage.[49] The 2016 Rule preamble clarified that if an entity is not principally engaged in providing health benefits, the Department would apply the rule to its Federally funded health programs and activities.[50]

The Department believes that by specifying the degree to which the Section 1557 regulation covers entities not principally engaged in the business of providing healthcare, this final rule more clearly and consistently applies the CRRA's limitations on ''health program or activity'' across the regulation. The Department agrees with commenters who suggest that in doing so this final rule also advances its goal of reducing regulatory burdens under the ACA in furtherance of Executive Order 13765.

Comment: Commenters argued that limiting the application of the rule to only the portion of the health program or activity that receives Federal financial assistance for entities not principally engaged in the business of providing healthcare is not consistent with the Department's application of Title VI as set forth in HHS's 2003 LEP guidance. This guidance provided that Title VI applies to all parts of a covered entity receiving Federal financial assistance, not just the portion receiving Federal funds.[51]

Response: As a policy guidance document, the Department's LEP guidance cannot be used to create binding standards by which the Department will determine compliance with existing regulatory or statutory requirements.[52] Accordingly, the scope of application as set forth under the CRRA and this final rule would prevail over any conflicting text in the Department's LEP guidance.

d. § 92.3(c) Health Insurance and Healthcare

The Department proposed in § 92.3(c) to state that an entity principally or otherwise engaged in the business of providing health insurance would not be considered to be principally engaged in the business of providing healthcare, and on that sole basis, subject to the Section 1557 regulation. The proposed rule sought comment on whether it should define ''healthcare'' in the rule according to the statutes cited in the proposed rule.

Comment: Several commenters supported the distinction between entities principally engaged in the business of providing healthcare and those principally engaged in the business of providing health insurance. As one commenter stated, ''[p]aying for healthcare is not providing healthcare.'' Other commenters were opposed to this distinction. They argued that it is not consistent with Section 1557's statutory text or the proposed regulatory text at § 92.3(a)(1), both of which specifically include ''contracts of insurance'' as an example of Federal financial assistance. They also stated that this limited application is not consistent with Congressional intent to expand access to healthcare and create new nondiscrimination protections in health insurance.

Some commenters argued that health insurance is inextricably linked with the provision of healthcare. They pointed out that the statutory definition of ''healthcare'' relied upon in the proposed rule is unrelated to either the ACA, health insurance, or discrimination, and thus is not intended for or relevant to Section 1557 or health insurance.[53] Further, they argued that the definition of ''health insurance coverage'' referenced in the proposed rule, 42 U.S.C. 300gg–91, actually bolsters the argument that health insurance includes healthcare, as it defines ''health insurance coverage'' to include ''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). They also pointed out that definitions in 42 U.S.C. 300gg–91 are most relevant to Section 1557 because Title I of the ACA relied upon this section for definitions.

Response: The CRRA defined ''program or activity'' in the underlying statutes to apply to all of an entities' operations when it is principally engaged in the business of providing ''healthcare.'' On the other hand, the 2016 Rule expansively interpreted Section 1557's application to ''health programs or activities'' to include all operations of entities that ''provide health insurance coverage or other health coverage,'' whether or not they provided healthcare. Prior to the 2016 Rule, the Department had not interpreted the CRRA's term ''healthcare'' to cover the operations of health insurance issuers (as such).

Commenters are correct that Section 1557 includes ''contracts of insurance'' as a type of Federal financial assistance. The Department agrees that health programs or activities that receive contracts of insurance from the Federal government are covered entities under Section 1557. But this does not mean that health insurers, as such, are health programs or activities.

The Department pointed to 5 U.S.C. 5371, as well as to 45 CFR 160.103, in order to support its conclusion that the plain meaning of ''healthcare'' differs from insurance. And although 42 U.S.C. 300gg–91 explicitly encompasses payment, ''group health plans,'' and ''definitions relating to health insurance'' specifically, it should not be taken out of context: It defines ''medical care'' as ''amounts paid for'' certain medical services, which is an appropriate definition in the health insurance field but not in the healthcare field generally. (When a doctor provides ''medical care,'' she is not providing ''amounts paid for'' medical services—she is providing the services themselves.) Other portions of 42 U.S.C. 300gg–91 also support the distinction between healthcare and health insurance: It says that ''health insurance coverage means benefits consisting of medical care,'' where ''medical care'' is defined as ''amounts paid for . . . the diagnosis, cure, mitigation, treatment, or prevention of disease, or amounts paid for the purpose of affecting any structure or function of the body,'' or

[48] *See McMullen* v. *Wakulla Cty. Bd. of Cty. Commissioners,* 650 F. App'x 703, 705 (11th Cir. 2016), citing S. Rep. No. 100–64, at 2 (1988), *as reprinted in* 1988 U.S.C.C.A.N. 3, 3–4.

[49] 81 FR at 31467. In the proposed rule, the Department disagreed with the 2016 Rule's usage of ''health services, health insurance coverage, or other health coverage'' as overbroad and inconsistent with the statutory text of the CRRA that uses the term ''healthcare.'' *See* 84 FR at 27862–63. However, the Department agrees with the 2016 Rule's limitation based on whether the entity is principally engaged.

[50] 81 FR at 31385–86, 31430–32.

[51] 68 FR 47311, 47313 (Aug. 8, 2003) (''Coverage extends to a recipient's entire program or activity, *i.e.,* to all parts of a recipient's operations. This is true even if only one part of the recipient receives the Federal assistance.'').

[52] *See* U.S. Dept. of Justice, Memorandum of the Office of the Attorney General, Prohibition on Improper Guidance Documents (Nov. 16, 2019), *https://www.justice.gov/opa/press-release/file/1012271/download;* U.S. Dept. of Justice, Memorandum of the Office of the Associate Attorney General, Limiting Use of Agency Guidance Documents In Affirmative Civil Enforcement Cases (Jan. 25, 2018), *https://www.justice.gov/file/1028756/download.*

[53] *See* 84 FR at 27862 (citing the definition of ''health care'' at 5 U.S.C. 5371). Commenters noted that this definition pertains to Federal personnel pay rates.

''amounts paid for transportation primarily for and essential to medical care'' in the primary sense just defined, or ''amounts paid for insurance covering medical care'' in either the primary sense just defined or the secondary sense of transportation for medical care.[54] It does not say that health insurance is healthcare, and it twice relies on the commonsense distinction between medical care proper and the health insurance that covers and pays for such care. It thus supports the Department's view that a health insurer is principally engaged in the business of providing coverage for benefits consisting in healthcare, which is not the same as the business of providing healthcare. This final rule brings the 1557 regulation's scope of coverage closer to the plain meaning of the 1557 statute, especially as read in light of the CRRA's definition of ''program or activity.''

Comment: Commenters were concerned that § 92.3(c) would result in exempting many of the plans, products, and operations of most health insurance issuers, such as self-funded group health plans, the Federal Employees Health Benefits (FEHB) Program, third-party administrator services, or short-term limited duration insurance plans. Commenters feared this would allow health insurance issuers to conduct their other activities in a discriminatory manner. Several commenters were particularly concerned about excluding short-term limited duration insurance plans because these plans have been known to engage in discriminatory practices based on disability, age, and sex.

Other commenters, in contrast, supported the proposed revisions. They stated the 2016 Rule was overly expansive, created an un-level playing field, and resulted in disincentives for issuers to participate in HHS-funded programs, such as offering QHPs or Medicare Advantage plans. This resulted in Section 1557's covering products that Congress explicitly excluded from the rest of the ACA, such as excepted benefits and short-term limited duration insurance plans. Commenters argued it was unlikely that Congress intended Section 1557 to regulate the same plans it had excluded from the ACA.

Response: The Department agrees with commenters who stated that the overly broad reach of the 2016 Rule subjected many insurance products that were not intended to be covered by the ACA to burdensome regulation, inconsistent with Congressional intent.

In the proposed rule, the Department stated that Section 1557 does not apply to short-term limited duration insurance as such, but only if it were offered by an entity for which all of the entity's activities are encompassed by Section 1557, or if such insurance received Federal financial assistance.[55] Under this final rule, where short-term limited duration insurance (1) is offered by an entity that is not principally engaged in the business of providing healthcare, and (2) does not receive Federal financial assistance, the protections of Section 1557 would not apply to it. The Department will robustly enforce the nondiscrimination requirements for QHPs under Title I of the ACA, for Exchange plans established by the ACA, and for any other insurance plans that Section 1557 covers. The reasons that this final rule does not cover FEHB plans are discussed in the response to the next comment.

Comment: The Department received comments related to the exclusion of employer plans and excepted benefits as a result of § 92.3(c). Several commenters objected to the exclusion of self-funded group health plans under the Employee Retirement Income Security Act of 1974 (ERISA) and the Federal Employees Health Benefits (FEHB) Program. Commenters argued that FEHB plans should be covered as a contract of insurance with the Federal government. Some suggested that employer group health plans, including self-funded plans, receive substantial Federal financial assistance in the form of favorable income tax treatment and thus should be covered.

Other commenters strongly supported excluding employer plans. Commenters noted that employers and group health plans are already subject to other Federal laws that prohibit discrimination, and that few employer-sponsored plans receive Federal financial assistance. They stated that the 2016 Rule's broad coverage exceeded statutory authority, encumbered the design and operation of employer group health plans, invited litigation regarding plan benefits, and increased the potential for costly new mandates, all of which were likely to increase healthcare costs for employers and employees alike without adding any additional protections against discrimination. Some commenters expressed support for the provision that third-party administrators of self-funded group health plans would no longer be subject to Section 1557 merely because other portions of their business receive Federal funding.

Some commenters requested further clarification by recommending that the regulatory text at proposed § 92.3(c) be revised to specify that other types of plans should not be considered entities principally engaged in the business of providing healthcare, including self-funded or fully insured group health plans under ERISA; self-funded or fully insured group health plans not covered under ERISA that are sponsored by either governmental employers (''government plans'') or certain religious employers (''church plans'' or ''denominational plans''); and benefit plans and programs excepted under the ACA.[56]

Response: The Department continues to take the position that FEHB plans are not covered under this rule. Even if FEHB plans were considered ''contracts of insurance,'' as suggested by some commenters, they still would not fall under the scope of this rule because the contract would be with the Office of Personnel Management (OPM), which operates the FEHB Program, not with the Department. As noted above, this final rule does not extend the Department's enforcement authority to a covered entity that is not principally engaged in the business of providing healthcare to the extent of its operations that do not receive financial assistance from the Department.

The Department agrees that this final rule will accomplish the Department's goal of reducing regulatory burden. The Department declines to offer further examples of non-covered entities in the regulatory text, as the rule's existing parameters are intended to broadly address different entities. To the extent that employer-sponsored group health plans do not receive Federal financial assistance and are not principally engaged in the business of providing healthcare (as set forth in the rule), they would not be covered entities. The same analysis would apply to employer-sponsored plans not covered by ERISA, such as self-insured church plans or

[54] 42 U.S.C. 300gg–91(b)(1), (a)(2).

[55] The Department notes by way of background that, subsequent to publication of the proposed rule, the U.S. District Court for the District of Columbia granted summary judgment for the Department, upholding its most recent rulemaking on short-term limited duration insurance. *See* Short-Term, Limited-Duration Insurance; Final Rule, 83 FR 38212 (August 3, 2018). The August 2018 final rule largely restored the long-standing definition for short-term limited duration insurance to the definition that was in effect from 1997 to 2016. The Court held that the restored definition was not arbitrary or capricious, finding that ''Congress clearly did *not* intend for the [ACA] to apply to all species of individual health insurance.'' *Association for Community Affiliated Plans* v. *U.S. Department of Treasury,* 392 F. Supp. 3d 22, 45 (D.D.C. 2019), *appeal filed* July 30, 2019.

[56] *See* 42 U.S.C. 300gg–91(c) (defining excepted benefits).

non-Federal governmental plans, as well as to excepted benefits.

Comment: Some commenters said that the proposed rule created confusion about whether QHPs are subject to the rule. Others requested clarification on the proposed rule's application to products offered through the Exchange. Others requested clarification on whether stand-alone dental plans and catastrophic plans, which are also sold through the Exchanges established under Title I, are covered under the rule. Another commenter requested confirmation that the proposed rule would not apply to individual or small-group market health insurance coverage that complies with the ACA but is sold outside of the Exchanges, regardless of whether the parent organization also offers on-Exchange QHPs. Others requested clarification as to how the rule would apply when one health insurance plan includes multiple types of enrollees, including subsidized Exchange enrollees, unsubsidized Exchange enrollees, and off-Exchange enrollees. The comments expressed concern that enrollees in the same plan deserved the same level of nondiscrimination protection and that the same standard should be applied.

Response: Health insurance products are often complex. While the Department provides general responses below in an attempt to clarify application of the rule, OCR will always engage in an individualized fact-based analysis when determining the extent of its jurisdiction over these or any other such products.

A QHP would be covered by the rule because it is a program or activity administered by an entity established under Title I (*i.e.,* an Exchange), pursuant to § 92.3(a)(3). A QHP could also be subject to Section 1557 if it were a recipient of Federal financial assistance, but as stated above, the premium tax credits that the Department plays a role in administering would no longer serve to bring an entity under the jurisdiction of this Section 1557 regulation.

Stand-alone dental plans and catastrophic plans offered through the Exchanges would similarly be subject to § 92.3(a)(3), as these plans are administered by an Exchange, which is an entity established under Title I.

Regarding ACA-compliant plans sold off-Exchange, because a health insurance issuer is not principally engaged in the business of providing healthcare, its operations would be subject to this rule only for the portion that receives Federal financial assistance. The issuer's components (*e.g.,* off-Exchange plans) that do not directly receive Federal financial assistance would not be subject to this rule.

Where a health insurance plan includes multiple types of enrollees, the Department would have to review the specific circumstance, but generally speaking, if a QHP is subject to Section 1557, this rule would apply consistently for all enrollees in the plan.

Comment: The Department received comments related to how the rule would apply to Medicare- and Medicaid-related products. One commenter asked whether the proposed limitation under § 92.3(c) would mean that Section 1557 would no longer apply to health insurance plans managed through Medicare and Medicaid.

A few commenters requested clarification on whether the proposed rule would apply to Employer Group Waiver Plans (EGWPs) and Medicare Part D Retiree Drug Subsidy (RDS) plans, or the employers that sponsor the plans. Commenters argued that applying the rule to these plans could disincentivize employers from sponsoring them and urged that the plans be exempt from the rule. Alternatively, one commenter requested that the Department exempt employer sponsors of ''800 series'' EGWPs, which are offered by Medicare Advantage Organizations (MAOs) or Part D Plan sponsors (PDP sponsors), because the employer is not the entity that receives funding from HHS. Finally, some commenters objected to excluding Medicare Part B from the rule.

Response: To be covered by the rule, a particular entity would have to satisfy one of the applicability requirements set forth in § 92.3. Entities that receive Federal funding through the Department's Medicare Part C (Medicare Advantage), Medicare Part D, or Medicaid programs would be subject to Section 1557 as recipients of Federal financial assistance. This would include Medicare Advantage plans, Medicaid managed care plans, EGWPs, or RDS plans, to the extent that they receive Federal financial assistance.

Pending further details, an employer that does not directly contract with CMS but offers an ''800 series'' EGWP through a MAO or PDP sponsor would not appear to be subject to this rule under this analysis because the employer does not receive the Federal financial assistance; meanwhile, the health insurance issuer offering the EGWP would be subject to the rule for its EGWP plan, due to receipt of either Medicare Part C or Part D funding.

As for Medicare Part B, it is not Federal financial assistance.[57] This remains unchanged from the 2016 Rule, which also determined that Medicare Part B was not Federal financial assistance under Section 1557.

Comment: Some commenters requested that this final rule be accompanied by explicit applicability guidance so that employers and plans could be able to ascertain if the final rule impacts their business.

Response: The Department seeks to provide sufficient clarity in this final rule. If OCR receives substantial questions about the rule's applicability after publication, OCR will consider issuing additional clarification, consistent with applicable law regarding issuance of sub-regulatory guidance.[58]

e. Summary of Regulatory Changes

For the reasons given in the proposed rule, and having considered comments received, the Department finalizes the proposed § 92.3, and repeal of § 92.2 of the 2016 Rule, without change, except that, as discussed in an earlier section of this preamble, and after considering comments on the issue, the Department is not finalizing the proposed repeal of § 92.2(c) concerning severability, but is retaining that provision and has moved it to § 92.3(d).

(4) Nondiscrimination Requirements in Proposed Revisions to § 92.2, and Repeal of § 92.8(d), 92.101, 92.206, 92.207, 92.209, and Appendix B of the 2016 Rule

The Department proposed to repeal § 92.8(d), 92.101, 92.206, 92.207, and Appendix B of the 2016 Rule (which includes repealing notice and taglines

[57] 45 CFR pt. 80 App A, No. 121; *https://www.hhs.gov/civil-rights/for-individuals/faqs/what-qualifies-as-Federal-financial-assistance/301/index.html. See also* 81 FR at 31383, 31385; 84 FR at 27863 (discussing the applicability of the rule to Medicare Part B and clarifying in footnote 100 that ''[t]he Department believes that the Federal financial assistance does not include Medicare Part B under the Social Security Act. *See* 2 CFR 200.40(c) (Uniform Administrative Requirement, Cost Principles, and Audit Requirements for Federal Awards); 45 CFR 75.502(h) (Uniform Administrative Requirement, Cost Principles, and Audit Requirements for HHS Awards).'').

[58] *See, e.g.,* Executive Order 13892 on Promoting the Rule of Law Through Transparency and Fairness in Civil Administrative Enforcement and Adjudication, 84 FR 55239 (Oct. 9, 2019); Executive Order 13891 on Promoting the Rule of Law Through Improved Agency Guidance Documents, 84 FR 55235 (Oct. 9, 2019); U.S. Dept. of Justice, Memorandum of the Office of the Associate Attorney General, Limiting Use of Agency Guidance Documents In Affirmative Civil Enforcement Cases (Jan. 25, 2018), *https://www.justice.gov/file/1028756/download;* U.S. Dept. of Justice, Memorandum of the Office of the Attorney General, Prohibition on Improper Guidance Documents (Nov. 16, 2019), *https://www.justice.gov/opa/press-release/file/1012271/download.*

provisions), and instead address nondiscrimination requirements in a new § 92.2. The Department proposed to repeal provisions that made applicable across all protected categories those particular requirements, prohibitions, or enforcement mechanisms that had previously applied only to particular circumstances.

The Department requested comments on all aspects of the proposed rule. The Department also specifically requested comment on any unaddressed discrimination on the basis of race, color, or national origin as applied to State and Federally-facilitated Exchanges, with any detailed supporting information. And the Department requested comment on whether, and if so how, the proposed rule addresses clarity and confusion over compliance requirements and the rights of persons protected against discrimination on the basis of race, color, national origin, sex, disability, or age.

The Department received many comments on these proposed changes. The Department will first discuss comments concerning each of the grounds in Section 1557: Race, color, national origin, disability, age, and sex. Then other grounds of discrimination will be discussed, followed by assessment of claims of discriminatory conduct when multiple grounds of discrimination are alleged. Comments concerning disability and LEP protections will be addressed below in the section on Subpart B of the Section 1557 rule.

a. Discrimination on the Basis of Race, Color, or National Origin

i. Generally

Comment: The Department received support for its commitment to continued enforcement of race, color, and national origin protections. Commenters stated that these characteristics are clear and simple to distinguish, contrasting them with gender identity, which is fluid and more difficult to define.

Response: The Department appreciates the support for its continued commitment to the enforcement of protections against discrimination on the basis of race, color, and national origin. The Department agrees that gender identity as a category is difficult to define. This is not, however, the Department's reason for not viewing gender identity as a protected category under Section 1557. The Department enforces statutory prohibitions on discrimination on the basis of race, color, national origin, age, disability, and sex discrimination because they are set forth in the text of statutes incorporated into Section 1557, and gender identity is not set forth as a protected category in those statutes.

Comment: Commenters contended that the proposed changes, including repeal of § 92.101 and the specific discrimination it prohibited, will lead to confusion among individuals and lead healthcare providers to discriminate based on race, color, and national origin. Commenters recommended that the Department retain clear, strong language prohibiting healthcare providers from discriminating based on race, color and national origin.

Response: This final rule's § 92.2 retains clear, strong language prohibiting discrimination on the basis of race, color, or national origin. Covered entities are still required to provide the Department with an assurance, and, pursuant to the underlying civil rights regulations, to post notices, that they do not so discriminate and are in compliance with Federal civil rights law. If the Department learns of confusion among covered entities or individuals as to their civil rights, it will consider issuing further guidance as needed.

Comment: Some commenters contended that the proposed changes will negatively impact women of color, who (according to these commenters) disproportionately rely on the short-term health plans that this final rule does not cover, and are more likely to experience pregnancy-related issues that will cause them to suffer from the rollback of termination of pregnancy protections.

Response: For reasons detailed below, this final rule (a) does not generally apply to short-term limited duration health insurance and (b) only covers termination of pregnancy to the extent permitted by Title IX's abortion-neutrality language, as required by the relevant statutes. The Department will vigorously enforce the prohibitions on discrimination based on race or sex, including under disparate impact analysis with respect to race discrimination as provided for in the relevant Title VI regulations, but the Department remains bound by the limits of the statutes enacted by Congress. The Department's Office of Minority Health also supports outreach to diverse populations and those facing particularized or disproportionate health challenges.

Comment: One commenter expressed concern that the changes in the proposed rule will have a negative impact on access to health screenings and vaccinations for patients. The commenter stated that removal of nondiscrimination requirements for many health insurance providers will leave these populations with little recourse if health insurance providers rescind coverage for preventative health services.

Response: Because this final rule continues to commit the Department to robust enforcement of its prohibitions on discrimination on the basis of race, color, national origin, sex, age, and disability, the Department does not anticipate that it will impede any population's access to preventive care and vaccinations, which (under separate provisions of the ACA) must be covered without cost sharing for group health plans and health insurance issuers offering group or individual health insurance coverage.[59]

ii. Repeal of Notice and Taglines Provisions at § 92.8(d) and Appendix B of the 2016 Rule

The Department proposed to repeal § 92.8(d) of the 2016 Rule, which required a nondiscrimination notice and taglines in all significant communications from covered entities, and also proposed to repeal the sample taglines notice in Appendix B to Part 92. 84 FR at 27857–60. The Department stated its assumption that this will correspondingly ease the burden of the LEP provision in CMS regulations at 45 CFR 155.205(c)(2)(iii)(A), which deemed compliance with the LEP provisions of the Section 1557 regulation to constitute compliance with CMS's requirements.[60]

The Department specifically sought comment to identify ''significant communications'' under the 2016 Rule sent by covered entities that include a notice and taglines but had not been considered by the analysis in the proposed rule, as well as the estimated annual volume of such communications. The Department also requested comment on which communications are significant in healthcare.

Comments: Some commenters stated that the removal of the 2016 Rule's notice and taglines provisions will result in LEP beneficiaries having less knowledge of available language assistance services and that they will likely rely more on family members to provide oral interpretation.

Response: The regulations of the underlying statutes referred to in Section 1557 (Title VI, Section 504, Title IX, and the Age Act) have long mandated that covered entities provide

[59] *See* 42 U.S.C. 300gg–13.

[60] 84 CFR 27887, n. 240, and 27881.

a notice of nondiscrimination.[61] This final rule maintains that requirement. Moreover, it continues to require covered entities to provide taglines whenever such taglines are necessary to ensure meaningful access by LEP individuals to a covered program or activity. It removes only the unduly broad, sometimes confusing, and inefficient requirement that all significant communications contain taglines. This requirement caused significant unanticipated expenses, as discussed in the regulatory impact analysis (RIA) below. Moreover, as discussed below, § 92.101 of this final rule reiterates longstanding criteria to help covered entities conduct an individualized assessment of their program and ensure meaningful access by persons with LEP, and retains the 2016 Rule's prohibition on covered entities' requiring an LEP individual to provide his or her own interpreter or relying on an accompanying adult to interpret or facilitate communication (except in limited circumstances).

Comment: Some commenters disagreed with the Department's proposal to make conforming amendments to the CMS requirements placed on Health Insurance Exchanges and Qualified Health Plan (QHP) issuers at 45 CFR 155.205. These commenters argued that the CMS requirements do not rely on the 2016 Rule's taglines provisions, nor does the 2016 Rule prevent the implementation of additional requirements in more specific programs, such as Medicaid and Medicare. Others agreed with the Department's proposal, raising concerns about CMS's requirements at 45 CFR 155.205, which state that Exchanges and QHP issues are only ''deemed'' in compliance with the CMS requirements ''if they are in compliance with'' the 2016 Rule's taglines provisions. These commenters argued that if the notice and taglines provisions are removed, the CMS compliance provision will cross-reference a repealed rule, which would require QHP issuers and Exchanges to comply with CMS's taglines rule instead. The CMS mandate for 15 taglines for the CMS list of critical documents is arguably as burdensome as the 2016 Rule's taglines provisions; therefore, these commenters argue that any benefit in efficiency yielded by the repeal of the 2016 Rule's taglines provisions would be lost for Exchanges and QHP issuers. These commenters suggest amending the 2016 Rule's provisions to state that there is no specific taglines requirement under Section 1557 and that a covered entity's compliance under applicable Federal and State laws will be considered under Section 1557's LEP meaningful access standards.

Response: The provision at 45 CFR 155.205(c)(2)(iii)(A) and the similar requirement placed on QHP issuers (see HHS Notice of Benefit and Payment Parameters for 2016; Final Rule, 80 FR 10750, 10788 (Feb. 27, 2015)), have not been directly amended in this regard. Nevertheless, as the Department stated in the proposed rule,[62] both of those requirements depend on or refer to the taglines requirements repealed in this final rule. As a result, covered entities are deemed compliant with those particular taglines requirements due to this final rule. Specifically, 45 CFR 155.205(c)(2)(iii)(A) sets forth taglines requirements and then states, ''Exchanges, and QHP issuers that are also subject to § 92.8 of this subtitle, will be deemed in compliance with paragraph (c)(2)(iii)(A) of this section if they are in compliance with § 92.8 of this subtitle.'' The Department informed the public of this interpretation in the proposed rule, and after reviewing public comments, the Department maintains the same position for essentially the same reason. Because this final rule repeals the taglines requirements of the 2016 Rule at § 92.8, entities will not be out of compliance with those requirements, and therefore they will satisfy the condition of the sentence quoted above from 45 CFR 155.205(c)(2)(iii)(A) that they not be out of compliance with taglines requirements in 45 CFR part 92. Although the Department did not propose conforming amendments to those two regulations, and therefore cannot finalize such amendments in this final rule, the Department will consider making appropriate changes to other regulations in the future.

Comment: Commenters, including a health insurance issuer, noted that the 2016 Rule's preamble vaguely defined ''significant communications'' to include ''not only documents intended for the public . . . but also written notices to an individual, such as those pertaining to rights or benefits.'' 81 FR 31402. These commenters argued that because almost all written communications would be considered ''significant'' under this definition, most covered entities included a one- to two-page addition containing the nondiscrimination notice and taglines with most written communications. One health insurance issuer estimated sending the notice and taglines approximately 15 million times in 2018, or about five times for every individual served. One commenter stated that because the Department determined that the notice and taglines requirement in the 2016 Rule imposes a significant financial burden on covered entities, the Department is within its authority to rescind it, especially because of an executive order that limits the effectiveness of subregulatory guidance. Others requested that the Department issue further guidance on what constitutes ''significant'' documents and communications, instead of removing the 2016 Rule's notice and taglines provisions.

Response: The Department agrees with comments that stated the 2016 Rule's notice and taglines requirements were imprecise and overly burdensome. The Department declines to retain those requirements while merely issuing more guidance on what constitute significant communications. First, the requirements are not mandated by statute, and although the 2016 Rule is a regulation and not subregulatory guidance, the Department has determined that its financial burden on covered entities was not justified by the protections or benefits it provided to LEP individuals. Second, the Department believes that other protections as finalized in this rule (and discussed below) better serve the language access needs of LEP individuals and, therefore, are more appropriate. Repeal of the notice and taglines requirements in this rule does not repeal all other notice and taglines requirements that exist under other statutes and rules.

b. Discrimination on the Basis of Disability

The Department is committed under this final rule to enforce protections against discrimination on the basis of disability, both in specific provisions set forth in § 92.102–92.105, and as applicable through the underlying Section 504 regulations, which are more broadly applicable under Section 1557 of the ACA. Comments on these issues are discussed in the section below on Subpart B of the Section 1557 regulation.

c. Discrimination on the Basis of Age

Comment: Commenters expressed concerns that the changes in the proposed rule will lead to discriminatory practices in health plans. In the absence of explicit language prohibiting health plans from discriminating based on age as set forth in § 92.207 of the 2016 Rule, they alleged, health plans may unlawfully

[61] *See* Title VI (45 CFR 80.6 and Appendix to Part 80), Section 504 (45 CFR 84.8), Title IX (45 CFR 86.9), and the Age Act (45 CFR 91.32).

[62] 84 FR at 27881.

deny, cancel, or limit policies, deny or limit coverage for claims, impose additional cost-sharing on coverage, or use discriminatory marketing practices or benefit designs because of age. In particular, some commenters believe that health insurance plans will offer formularies and plan options that deny treatment for older individuals who generally have more health complications. For example, they say, this practice may already be in place with some health plans that offer coverage for hearing aids to children and youths but deny it to older adults. Some commenters said the proposed rule will lead to discrimination against older LGBT adults, who already have high levels of poverty and health disparities, and will contribute to worse health outcomes. Some commenters also alleged the proposed rule encourages unlawful discrimination against LGBT youth, who are already at increased risk of discrimination.

Response: This final rule retains clear language prohibiting discrimination on the basis of age, as defined in the Age Act and enforced through its implementing regulations, in any covered programs and activities, including health plan marketing and benefit design. Moreover, the ACA has specific provisions which limit the extent to which health plans offered under the ACA can charge higher premiums based on age, as well as specific provisions which require guaranteed issuance, address permissible cost sharing requirements, and establish standards for essential benefits and formularies.

The Department remains committed to vigorous enforcement of this prohibition on behalf of all Americans, including LGBT adults and youth. The Department declines to comment on specific cases outside of the normal enforcement process but encourages anyone who has experienced unlawful discrimination, including with respect to health plans, to file a complaint with OCR.

Comment: Commenters expressed concern that the proposed rule will lead to health plans using their benefit design to discriminate against individuals with chronic conditions who are more expensive to insure, including children and youth with serious health conditions. One commenter represented a 13 year old with Down syndrome who, the commenter said, was denied coverage by a private health insurer because that health insurer categorically denied coverage for individuals with Down syndrome.

Response: Many serious health conditions, including Down syndrome, qualify as disabilities under Section 504, which Section 1557 incorporates. The Department 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. As finalized, the amended § 147.104 would prohibit health insurance issuers from employing ''benefit designs that . . . discriminate based on an individual's 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.'' The ACA also establishes requirements, applicable to health insurance issuers offering individual and group health insurance, concerning guaranteed issuance and renewal.[63] Concerns about whether private health insurers are covered entities are addressed below in the section on this rule's scope of application.

Comment: Some commenters contended the proposed rule will allow health plans to place age restrictions on certain medications, such as age restrictions on contraceptives for youth.

Response: To the extent that covered entities (including health plans) place restrictions based on age, OCR would assess on a case-by-case basis whether such restrictions violate Section 1557's incorporation of grounds prohibited under the Age Act. The Age Act does not forbid certain age distinctions in Federal, State, or local statutes and ordinances, or an action that reasonably takes age into account as a factor that is necessary to the normal operation or achievement of a statutory objective of a program.[64]

d. Discrimination on the Basis of Sex

i. Generally

Comment: Commenters offered different points of view on the definition of the term ''sex,'' as this relates to the definition of discrimination ''on the basis of sex.''

A number of commenters stated that the Department had proposed a new definition of ''sex'' for the Section 1557 rule. Some objected that any reinterpretation of ''sex'' should be addressed by Congress or left to the courts, rather than administrative agencies. Others stated that the proposed regulations realign the Department's interpretation with several decades of Federal court decisions and with the logical interpretation based on the statute's plain meaning of sex (namely sex in its biological meaning), which until 2017 had been the consistent consensus of the Federal courts.

Some commenters said that sex is a binary reality of male and female, and that Title IX and Section 1557 apply this historic understanding of sex. Some commenters stated that there is no evidence in the legislative history of either Title IX or the ACA that Congress intended to prohibit gender identity or sexual orientation discrimination in Section 1557, and that the purpose of Title IX is to ensure women (as biologically distinct from men) equal opportunities in Federally funded programs and activities.[65] Commenters said that the 2016 Rule exceeded the Department's authority by adopting a new, different, or expansive definition of prohibited sex discrimination in its Section 1557 regulation, although Congress declined to do so when presented with the opportunity and instead incorporated its meaning from Title IX which was passed in 1972. Some commenters noted that Congress has repeatedly considered adding gender identity and sexual orientation as protected categories in nondiscrimination laws related to education,[66] or to employment,[67] or in bills that would redefine discrimination ''on the basis of sex'' [68] as the 2016 Rule attempted, but that Congress has chosen not to do so.[69] Where Congress has chosen to prohibit ''gender identity'' discrimination in other statutes, it added the term ''gender identity'' as a

[63] *See* 42 U.S.C. 300gg–1, 300gg.2.

[64] 45 CFR 90.14, 90.15.

[65] Commenters cited 118 Cong. Rec. 5808 (1972); 44 FR at 71423.

[66] See, *e.g., Student Non-Discrimination Act of 2018,* H.R. 5374, 115th Congress, 2nd sess.; online at: *https://www.congress.gov/115/bills/hr5374/BILLS-115hr5374ih.pdf*: ''No student shall, on the basis of actual or perceived sexual orientation or gender identity . . . be excluded from participation in, or be denied the benefits of, or be subjected to discrimination under any program or activity receiving Federal financial assistance.''

[67] *See, e.g., Employment Non-Discrimination Act of 2013,* S. 815, 113th Congress, 1st sess.; online at: *https://www.govtrack.us/congress/bills/113/s815/text*: ''It shall be an unlawful employment practice for an employer—(1) to fail or refuse to hire or to discharge any individual, or otherwise discriminate against any individual . . . because of such individual's actual or perceived sexual orientation or gender identity . . .''

[68] *See, e.g., Equality Act,* H.R. 5, 116th Congress, 1st sess.; online at: *https://www.congress.gov/116/bills/hr5/BILLS-116hr5rfs.pdf*; amends *Civil Rights Act of 1964* ''by striking 'sex,' each place it appears and inserting 'sex (including sexual orientation and gender identity)' . . .''

[69] *See* H.R. 1652, 113th Cong. (2013); S. 439, 114th Cong. (2015). H.R. 3185, 114th Cong. (2015); S. 1858, 114th Cong. (2015); H.R. 2015, 110th Cong. (2007); H.R. 2981, 111th Cong. (2009); S. 811, 112th Cong. (2011); *See* H.R. 4636, 103rd Cong. (1994).

new and separate category of prohibited grounds in addition to ''sex'' without redefining ''sex'' itself.[70] Other commenters said that reliance on legislative history is an improper method of statutory interpretation, and that the Supreme Court has deemed reliance on Congressional inaction to be inappropriate.

One commenter cited U.S. Supreme Court cases as setting forth the binding legal standard of sex discrimination as a binary biological concept. The commenter cited *Tuan Anh Nguyen* v. *I.N.S.* as rejecting an approach of ''[m]echanistic classification of all our differences as stereotypes'' because it obscures the reality that ''physical differences between men and women . . . are enduring,'' 533 U.S. 53, 73 (2001), as well as Justice Ginsburg's majority opinion in *United States* v. *Virginia,* which held that '' '[T]he two sexes are not fungible; a community made up exclusively of one [sex] is different from a community composed of both.' '' 518 U.S. at 533 (1996).

Some commenters stated that changing cultural preferences should not be the standard for interpreting legal texts. Others analogized Title IX's lack of a definition of ''sex'' to the lack of a definition of ''race'' under the Civil Rights Act of 1964, where courts looked to the plain and ordinary meaning to interpret it as based on a person's ''family, tribe, people, or nation belonging to the same stock.'' Other commenters cited analyses of public meanings at the time of adoption, concluding that when ''gender'' was used, which was rare, it was used in contrast to sex: Gender referred to socially constructed roles, while sex, according to virtually every dictionary of the time, referred to biological differences between men and women.[71] Other commenters stated that use of the term ''gender'' (with regard to one's identity) as separate from ''sex'' (with regard to one's biology) is relatively new and is improperly interpreted today as evidence of support for gender-identity legal theories in prior legal precedents or decades-old statutes. Some commenters asserted that at the time of the passage of the underlying Federal civil rights statutes, ''sex'' and ''gender'' were commonly used identically under Title VII, Title IX, and the Equal Protection Clause to refer to biological sex.[72] However, other commenters disagreed, and stated that historical sources demonstrate the variability and complexity of the concept of sex to include ''[t]he sum of the morphological, physiological, and behavioral peculiarities of living beings.''

Some commenters stated that the terms male or female apply to everyone. Commenters stated that the ''sex'' of an organism is a clear, provable, objective, identifiable, biological, and binary reality according to relevant textbooks, studies, and articles from various specialties in the scientific community, including embryology, genomics, psychiatry, clinical anatomy, neuropsychology, developmental biology, genetics, endocrinology, neuropsychiatry, radiology, organismic and evolutionary biology, neuropharmacology, pediatrics, and pathology.[73] Healthcare providers stated that the reality of sex, as male or female, can be identified through advanced chromosomal testing such as karyotyping or simple genital identification at birth in roughly 99.98% of cases, leaving the remaining 0.02% as diagnoses with intersex or ambiguous conditions. Others stated that delineating a binary division on the basis of reproductive organs reflected an outdated paradigm and was not universally descriptive of transgender, transitioning, androgynous, intersex, two-spirit, or questioning individuals.

Some commenters stated that removal of a regulatory definition of ''sex'' leaves the regulation ambiguous, and the 2016 Rule was justified in clarifying by adding a definition that included gender identity and termination of pregnancy. Other commenters stated that the public widely understands the state of being either male or female, as determined by one's chromosomes or genetics, which leaves no ambiguity.

Response: Because Section 1557 incorporates Title IX's prohibition on discrimination ''on the basis of sex,'' it presupposes that the executive and judicial branches can recognize the meaning of the term ''sex.'' This final rule repeals the 2016 Rule's definition of ''on the basis of sex,'' but declines to replace it with a new regulatory definition. *See* 84 FR at 27857. Instead, the final rule reverts to, and relies upon, the plain meaning of the term in the statute.

''Sex'' according to its original and ordinary public meaning refers to the biological binary of male and female that human beings share with other mammals. As noted in briefs recently submitted by the Federal government to the Supreme Court, discrimination on the basis of sex means discrimination on the basis of the fact that an individual is biologically male or female.[74] Several commenters reference various sources of legislative history: That of Title IX, of Congress's decision to add protections on the basis of sexual orientation and gender identity to other statutes alongside protections on the basis of sex, and of Congress's repeated refusal to add those protections in other cases.[75] These sources support the plain

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[70] 18 U.S.C. 249(a)(2).

[71] Commenters cited Joanne Meyerowitz, A History of ''Gender,'' 113 a.m. Hist. Rev. 1346, 1353 (2008); David Haig, The Inexorable Rise of Gender and the Decline of Sex: Social Change in Academic Titles, Archives of Sexual Behavior 1945–2001 (Apr. 2004); Sari L. Reisner, *et al.,* ''Counting'' Transgender and Gender-Nonconforming Adults in Health Research, *Transgender Studies* Quarterly 37 (Feb. 2015); New Oxford Am. Dictionary 721–22, 1600 (3d ed. 2010).

[72] *See Glenn* v. *Brumby,* 663 F.3d 1312, 1315 (11th Cir. 2011) (citing *City of Cleburne* v. *Cleburne Living Ctr., Inc.,* 473 U.S. 432, 440–41 (1985). (''In describing generally the contours of the Equal Protection Clause, the Supreme Court noted its application to this issue, referencing both gender and sex, using the terms *interchangeably* . . .'').

[73] Commenters cited texts including, *e.g.,* T.W. Sadler, Ph.D., *Langman's Medical Embryology* (Philadelphia: Lippincott Williams & Wilkins, 2004), 40; William J. Larsen, Ph.D., *Human Embryology* (New York: Churchill Livingstone, 2001), 519; Keith L. Moore, Ph.D., DSc, and T.V.N. Persaud, M.D., Ph.D. DSc, FRCPath., *The Developing Human: Clinically Oriented Embryology* (Philadelphia: Saunders/Elsevier, 2003), 35; Maureen L. Condic, Ph.D. and Samuel B. Condic, Ph.D., ''Defining Organisms by Organization,'' National Catholic Bioethics Quarterly 5, no. 2 (Summer 2005): 336; Lawrence S. Mayer, Ph.D., and Paul R. McHugh, M.D., ''Sexuality and Gender Findings from the Biological, Psychological, and Social Sciences,'' *New Atlantis* 50 (Fall 2016): 89; Scott F. Gilbert, Ph.D. *Developmental Biology* (Sunderland, Mass.: Sinauer Associates, 2016), 519–20; and William J. Larsen, Ph.D., *Human Embryology* (New York: Churchill Livingstone, 2001), 307; Nichole Rigby, M.A. and Rob J. Kulathinal, Ph.D., ''Genetic architecture of sexual dimorphism in humans,'' *J. of Cellular Physiology* 230, no. 10 (2015): 2305; Jonathan C.K. Wells, Ph.D., ''Sexual dimorphism of body composition,'' *Best Practice & Research: Clinical Endocrinology & Metabolism* 21 (2007): 415; Larry Cahill, Ph.D., ''His Brain, Her Brain,'' *Scientific American,* October 1, 2012; Larry Cahill, Ph.D. ''A Half-Truth Is a Whole Lie: On the Necessity of Investigating Sex Influences on the Brain,'' *Endocrinology* 153 (2012): 2542; Madhura Ingalhalikar, Ph.D., et al., ''Sex differences in the structural connectome of the human brain,'' *Proceedings of the National Academy of Sciences* 111 (January 2014): 823–28.

[74] *Bostock* v. *Clayton Cty. Bd. of Commissioners,* 2019 WL 4014070 at *25 (U.S. 2019) (Brief for the United States as *Amicus Curiae* Supporting Affirmance in No. 17–1618 (*Bostock* v. *Clayton Cty. Bd. of Commissioners*) and Reversal in No. 17–1623 (*Altitude Express Inc.* v. *Zarda*)); Statement of Interest for DOJ, *Soule* v. *Conn. Ass'n of Schools,* 3:20–cv–00201–RNC (D. Conn., filed March 27, 2020) at 4–5 (''When Congress enacted Title IX in 1972, the 'ordinary, contemporary, common meaning' of 'sex' was biological sex. . . . Title IX consistently uses 'sex' as a binary concept capturing only two categories: Male and female.'').

[75] Examples of bills where Congress chose not to enact prohibitions on discrimination on the basis of sexual orientation or gender identity include: The Employment Non-Discrimination Act (ENDA), which has been introduced ten times in the U.S. House of Representatives but has never proceeded out of committee: H.R. 4636 (103rd Cong. 1994); H.R. 1863 (104th Cong. 1995); H.R. 1858 (105th Cong. 1997); H.R. 2355 (106th Cong. 1999); H.R. 2692 (107th Cong. 2001); H.R. 3285 (108th Cong.

meaning of Title IX, but are not the only source of support for the Department's understanding of the meaning of the word ''sex.'' Contemporaneous dictionaries and common usage make clear that ''sex'' in Title IX means biological sex.[76] Even today, the article on gender dysphoria in the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition defines ''sex'' to ''refer to the biological indicators of male and female (understood in the context of reproductive capacity), such as in sex chromosomes, gonads, sex hormones, and nonambiguous internal and external genitalia.'' [77] The term ''gender'' may sometimes be ambiguous. However, neither Title IX nor Section 1557 uses that term, and the ordinary public meaning of the term ''sex'' in Title IX is unambiguous. In order to avoid ambiguities associated with the term ''gender,'' the Department's regulations and guidance have, where relevant, distinguished sex (in its biological meaning) from gender, gender identity, or gender expression.[78]

Some commenters challenge the Department's approach by pointing to medical conditions that they refer to as ''intersex.'' The term refers to rare medical conditions that the medical literature, since 2006, has preferred to call ''disorders of sexual development'' (DSD).[79] DSD are estimated to be present in 0.0167%–0.022% of the population. More importantly, DSD are ''congenital conditions in which development of chromosomal, gonadal, or anatomic sex is atypical.'' [80] This medical definition refers to, and presupposes, the ordinary biological and binary meaning of ''sex,'' just as the definition of any medical disorder presupposes an understanding of healthy baseline functionality.

Title IX,[81] along with its implementing regulations,[82] consistently understands ''sex'' to refer to the biological binary categories of male and female only.[83] The Department of Justice has recently noted that ''[i]f the term 'sex' in Title IX included 'gender identity'—which, according to the American Psychiatric Association, may include 'an individual's identification as . . . some category *other than* male or female,' *Diagnostic and Statistical Manual of Mental Disorders Fifth Edition* 451 (2013) (emphasis added)—then multiple Title IX provisions would make little sense.'' [84] Many comments on the 2019 NPRM assume that Section 1557's protection against discrimination ''on the basis of sex'' covers women's health issues including pregnancy, uterine cancer, and prenatal and postpartum

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2003); H.R. 2015 (110th Cong. 2007); H.R. 2981 (111th Cong. 2009); H.R. 1397 (112th Cong. 2011); H.R. 1755 (113th Cong. 2013). Similarly, the Equality Act has been introduced in three successive sessions of Congress; it did not proceed out of committee in the 114th and 115th Congresses, and it passed the House of Representatives on May 17, 2019. *See* H.R. 3185 (114th Cong. 2015); S. 1828 (114th Cong. 2015); H.R. 2282 (115th Cong. 2017); S. 1006 (115th Cong. 2017); H.R. 5 (116th Cong.) (introduced Mar. 3, 2019).

[76] *See* New Oxford Am. Dictionary 721–22, 1600 (3d ed. 2010). Some Federal courts have gone farther, using the legislative history to show that ''Congress never considered nor intended'' for sex under Title VII (which is often used to interpret Title IX) to apply to ''anything other than the traditional concept of sex,'' and that coverage for a concept such as transgender status ''surely'' would have been mentioned in the legislative history had Congress intended such an ''all-encompassing interpretation.'' The Department finds the analysis in these Court decisions persuasive, but declines to rely on their reasoning. *See Ulane* v. *Eastern Airlines Inc.,* 742 F. 2d 1081, 1085 (7th Cir. 1984) (analyzing ''The total lack of legislative history supporting the sex amendment coupled with the circumstances of the amendment's adoption''); *see also Voyles* v. *Ralph K. Davies Medical Center,* 403 F. Supp. 456, 457 (N.D. Cal. 1975), *aff'd,* 570 F.2d 354 (9th Cir. 1978) (finding a ''void'' in the legislative history and concluding that Congress's ''paramount, if not sole, purpose in banning employment practices predicated upon an individual's sex was to prohibit conduct which, had the victim been a member of the opposite sex, would not have otherwise occurred. Situations involving transsexuals, homosexuals or bi-sexuals were simply not considered.'').

[77] American Psychiatric Ass'n, *Diagnostic and Statistical Manual of Mental Disorders,* 5th ed. (Arlington, VA: American Psychiatric Ass'n, 2013), 451–59.

[78] *See* 45 CFR 411.5; *also* 79 FR 77771, 84 FR 27854. *See* NIH, Office of Research on Women's Health, ''Sex & Gender,'' *https://orwh.od.nih.gov/sex-gender* (''NIH is committed to improving health by supporting the rigorous science that drives medical advances. Sex/gender influence health and disease, and considering these factors in research informs the development of prevention strategies and treatment interventions for both men and women. 'Sex' refers to biological differences between females and males, including chromosomes, sex organs, and endogenous hormonal profiles. 'Gender' refers to socially constructed and enacted roles and behaviors which occur in a historical and cultural context and vary across societies and over time. . . . With continuous interaction between sex and gender, health is determined by both biology and the expression of gender.'').

For these reasons, in general throughout this document the Department prefers to use simply the term ''sex'' because the plain, ordinary meaning of ''sex'' is already biological, so it is generally redundant to use the term ''biological sex.'' Where the Department uses the term ''biological sex,'' or similarly ''biological male'' or ''biological female,'' it does so merely to emphasize this point and for the purposes of clarity in particular contexts, and not to imply that there is a distinction between biological sex and sex under the plain meaning of the term.

[79] R.L.P. Romao, J.L. Pippi Salle, and D.K. Wherett, ''Update on the Management of Disorders of Sex Development,'' *Pediatric Clinics of North America* 59 (2012), 853–69; I.A. Hughes, ''Disorders of Sex Development: A New Definition and Classification,'' *Best Practice & Research Clinical Endocrinology & Metabolism* 22:1 (2008), 119–34.

[80] A. Rawal and P. Austin, ''Concepts and Updates in the Evaluation and Diagnosis of Common Disorders of Sexual Development,'' *Current Urology Reports* 16:83 (2015), 1–9; I. Hughes et al., ''Consequences of the ESPE/LWPES guidelines for diagnosis and treatment of disorders of sex development,'' *Best Practice & Research Clinical Endocrinology & Metabolism* 21:3 (2007), 351–65; P.A. Lee et al., ''Consensus Statement on Management of Intersex Disorders,'' *Pediatrics* 118:2 (2006), e488–500.

[81] *See* 42 U.S.C. 1681(a)(2)(''both sexes''), (a)(2) (''one sex'' and ''other sex''), (a)(6)(B) (''Men's'' and ''Women's''), (a)(6)(B) (''Boy'' and ''Girl''); (a)(7)(A) (''Boys'' and ''Girls''), (a)(7)(B)(i) (''Boys'' and ''Girls''), (a)(8) (''father-son'' ''mother-daughter''), and (a)(8) (''one sex'' and ''other sex''). *See also* 42 U.S.C. 1681(a)(2)(6)(''fraternity'' and ''sorority'').

[82] *See* language such as ''male and female,'' ''both sexes,'' ''each sex,'' ''one sex . . . the other sex,'' and ''boys'' and ''girls,'' at 45 CFR 86.2(s), 86.7, 86.17(b)(2), 86.21(c)(4), 86.31(c), 86.32(b)(2) and (c)(2), 86.33, 86.37(a)(3), 86.41(b) and (c), 86.55(a), 86.58(a) and (b), 86.60(b), and 86.61. *See* similarly Department of Education Title IX regulation at 34 CFR 106.2(s), 106.7, 106.17(b)(2), 106.21(c)(4), 106.31(c), 106.32(b)(2) and (c)(2), 106.33, 106.37(a)(3), 106.41(b) and (c), 106.55(a), 106.58(a) and (b), 106.60(b), and 106.61; Department of Justice Title IX regulation at 28 CFR 54.105, 54.130, 54.230(b)(2), 54.235(b)(3), 54.300(c)(4), 54.400(c), 54.405(b)(2) and (c)(2), 54.410, 54.430(a)(3), 54.450(b) and (c)(2), 54.520(a), 54.535(a) and (b), 54.545(b), and 54.550. *See also* DOJ Coordination and Compliance Division, Title IX Regulations by Agency, *https://www.justice.gov/crt/fcs/Agency_Regulations#2.*

[83] Federal courts have also made this observation. *See, e.g., Doe* v. *Boyertown Area Sch. Dist.,* 897 F.3d 518, 522 (3d Cir. 2018) ('''Sex' is defined as 'the anatomical and physiological processes that lead to or denote male or female.' Typically, sex is determined at birth based on the appearance of external genitalia.''); *Hively* v. *Ivy Tech Cmty. Coll.,* 853 F.3d 339, 362 (7th Cir. 2017) (''[i]n common, ordinary usage in 1964—and now, for that matter—the word 'sex' means biologically *male* or *female.*'') (Sykes, J., dissenting) (emphasis in original); *cf. id.* at 357 (''we, who are judges rather than members of Congress, are imposing on a half-century-old statute a meaning of 'sex discrimination' [to include sexual orientation] that the Congress that enacted it would not have accepted.'') (Posner, J., concurring); *G.G. ex rel Grimm* v. *Gloucester Cnty. Sch. Bd.,* 822 F.3d 709, 736 (4th Cir. 2016) (''Title IX was enacted in 1972 and the regulations were promulgated in 1975 and readopted in 1980, and during that time period, virtually every dictionary definition of 'sex' referred to the physiological distinctions between males and females, particularly with respect to their reproductive functions.'') (Niemeyer, J., dissenting); Statement of Interest for DOJ, *Soule* v. *Connecticut Association of Schools,* 3:20–cv–00201–RNC (D. Conn., filed March 27, 2020) at 5 (''Other provisions of Title IX employ ''sex'' as a binary term, and thus provide further confirmation that the prohibition on ''sex'' discrimination does not extend to discrimination on the basis of transgender status or gender identity.''); *Franciscan All., Inc.* v. *Burwell,* 227 F. Supp. 3d 660, 687 (N.D. Tex. 2016) (''the meaning of sex unambiguously refers to the biological and anatomical differences between male and female students as determined at their birth,'' quoting *Texas* v. *United States,* 201 F. Supp. 3d 810, 833 (N.D. Tex. 2016)); *Johnston* v. *Univ. of Pittsburgh of Commw. Sys. of Higher Educ,* 97 F. Supp. 3d 657, 676 (W.D. Pa. 2015) (''[o]n a plain reading of the statute, the term 'on the basis of sex' in Title IX means nothing more than male and female, under the traditional binary conception of sex consistent with one's birth or biological sex'').

[84] Statement of Interest for DOJ, *Soule* v. *Conn. Ass'n of Schools,* 3:20–cv–00201–RNC (D. Conn., filed March 27, 2020) at 5.

services. That assumption is correct: These issues are protected under Section 1557 because of the ordinary and biological meaning of ''sex.''

Prior to the ACA, OCR itself had always applied Title IX in its enforcement actions using the biological binary meaning of sex.[85] Recently, OCR has resolved a number of Section 1557/ Title IX cases of discrimination against women in healthcare programs and activities funded by the Department, again relying on a biological understanding of sex.[86] The 2016 Rule itself presupposed the biological meaning of sex when it permitted ''sex-specific'' health programs that are ''restricted to members of one sex,'' when it incorporated ''termination of pregnancy'' into discrimination on the basis of sex, and when it referred repeatedly to ''sex assigned at birth.''[87]

Supreme Court case law on Title IX has consistently presupposed the biological and binary meaning of ''sex.''[88] Even when some lower courts have recently extended Title VII or Title IX protections ''on the basis of sex'' to encompass gender identity, they have done so only by presupposing the ordinary public meaning of ''sex'' as a biological binary reality. In *Whitaker* v. *Kenosha Unified Sch. Dist.,* for example, the Seventh Circuit stated: ''Here, the School District's policy cannot be stated without referencing sex, as the School District decides which bathroom a student may use based upon the sex listed on the student's birth certificate. This policy is inherently based upon a sex-classification and heightened review applies.''[89] Likewise, in *Harris Funeral Homes,* the Sixth Circuit stated: ''Here, we ask whether Stephens would have been fired if Stephens had been a woman who sought to comply with the women's dress code. The answer quite obviously is no. This, in and of itself, confirms that Stephens's sex impermissibly affected Rost's decision to fire Stephens.''[90] In other words, Stephens ''quite obviously'' is not ''a woman'' because ''Stephens's sex'' is male.[91]

The Department does not deny that some courts have caused confusion as to the meaning of sex in civil rights law. Conflicting views in the lower courts, however, do not preclude the Department, consistent with the position of the U.S. government, as set forth in briefs filed in the Supreme Court, from returning to its decades-long practice of conforming to the original and ordinary public meaning of ''sex'' in Title IX, a meaning that continues to be presupposed even in the same rulings that have caused this confusion.

Some lower courts have recently held that discrimination ''on the basis of sex'' encompasses gender identity or sexual orientation even when ''sex'' is understood in its ordinary, biological, and binary sense. These views will be addressed below in the relevant subsections.

Comment: Some commenters argued that the proposed rule would be inconsistent with the purposes of the ACA; that the weight of law recognizes sexual orientation and gender identity as forms of sex discrimination; and that the proposed rule would undermine Congress's intent to expand access to healthcare and healthcare coverage. Commenters emphasized that it is unacceptable for a healthcare facility to deny medical care to a patient based on the patient's sexual orientation or transgender status.

Response: The Department does not condone the unjustified denial of needed medical care to anyone, and believes that everyone, regardless of gender identity or sexual orientation, should be treated with dignity and respect. The Department must interpret Congress's purpose in passing the ACA by reading that statute's plain text. The ACA sought to expand access to healthcare and healthcare coverage through some means but not others: in particular, Congress saw fit to incorporate into the ACA certain nondiscrimination protections, and not others. For example, in the unlikely event that a healthcare provider were to deny services to someone based solely on his or her political affiliation, the Department would not be able to address such denial of care under Section 1557. Under this final rule, OCR is committed to no less than full enforcement of the prohibitions on discrimination that Congress included in Section 1557, without exceeding the statutory text. Unlike other bases of discrimination, the categories of gender identity and sexual orientation (as well as political affiliation) are not set forth in those statutes.[92]

Comment: Some insurers stated that they already took steps to come into compliance with prohibitions related to gender identity and termination of pregnancy in their plans under the 2016 Rule, and that they will incur burdens to change their plans. Other commenters stated that the 2016 Rule created burdens that, if unrelieved, would encumber their day-to-day affairs and limit their ability to provide healthcare services for their patients or healthcare coverage for their employees.

Response: As discussed in the Regulatory Impact Analysis below, this rule removes certain requirements, without requiring providers to incur new burdens related to those requirements. Whether or not the Department revises the regulation, the past expenditures incurred by insurers and other commenters to come into

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[85] In the 2015 NPRM, the earliest record of the Department's new understanding of sex discrimination cited was an OCR letter dated 12 July 2012. 80 FR 54176.

[86] U.S. Department of Health and Human Services, ''HHS Office for Civil Rights Enters Into Agreement with Oklahoma Nursing Home to Protect Patients with HIV/AIDS from Discrimination'' (2018), *https://www.hhs.gov/about/news/2017/09/08/hhs-office-for-civil-rights-enters-into-agreement-with-oklahoma-nursing-home.html*; ''OCR works with DOJ to ensure Federally funded medical center provides communication services for deaf and hard of hearing patients'' (2018), *https://www.hhs.gov/about/news/2017/12/20/ocr-works-with-doj-to-ensure-Federally-funded-medical-center-provides-communication-services-for-deaf-and-hard-of-hearing-patients.html*; ''HHS OCR Secures Agreement with MSU to Resolve Investigation into Sexual Abuse by Larry Nassar'' (2019), *https://www.hhs.gov/about/news/2019/08/12/hhs-ocr-secures-agreement-msu-resolve-investigation-sexual-abuse-larry-nassar.html* (requiring chaperone policies where patients can request a chaperone of the same sex, meaning biological sex, during sensitive physical examinations).

[87] *See* 81 FR 31384, 31387, 31406, 31408–09, 31428, 31429, 31435, 31436, 31467, 31470, 31471, 31472.

[88] *See, e.g., Nat'l Collegiate Athletic Ass'n* v. *Smith,* 525 U.S. 459, 464 (1999) (Title IX claim based on allegation ''that the NCAA discriminates on the basis of sex by granting more waivers from eligibility restrictions to male than female postgraduate student-athletes''); *Cannon* v. *Univ. of Chicago,* 441 U.S. 677, 680 (1979) (Title IX claim based on allegation that plaintiff's ''applications for admission to medical school were denied . . . because she is a woman'').

[89] 858 F.3d 1034, 1051 (7th Cir. 2017).

[90] *Equal Emp't Opportunity Comm'n* v. *R.G. & G.R. Harris Funeral Homes,* 884 F.3d 560 (6th Cir. 2018), 575. *See also* certain passages during oral argument on appeal at the U.S. Supreme Court, *e.g.:* ''here, Ms. Stephens, was being treated differently because of her sex. . . .Yes, if she had not been a— if she had not been assigned at birth the sex that she was assigned at birth, she would have been treated differently'' (Kagan, J., Transcript of Oral Argument at 41, *R.G. & G.R. Harris Funeral Homes, Inc.* v. *E.E.O.C.,* 139 S. Ct. 1599 (2019) (No. 18–107), *https://www.supremecourt.gov/oral_arguments/argument_transcripts/2019/18-107_4gcj.pdf*); *See also* Mr. Cole, counsel for respondents at oral argument, *Id.* at 4–5: ''None of [our] arguments ask this Court to redefine or, in Judge Posner's words, update sex. They assume, arguendo, that sex means at a minimum sex assigned at birth based on visible anatomy or biological sex.'' *Id.* at 28: ''[O]ur argument rests on text meaning, at a minimum, sex assigned at birth or biological sex, and everybody agrees— . . . [we are] asking you to interpret the statute as it is written and as everybody agrees it applies to sex assigned at birth.''

[91] *Harris* 884 F.3d at 575. It is true that the *Harris* court referred to Stephens with female pronouns throughout the rest of its ruling, but it appeared to do so based on its concept of gender identity, not of sex. Had the *Harris* court employed female pronouns in the quoted passage, it would have visibly undermined the basis of its Title IX analysis.

[92] The Department responds below to comments with respect to sexual orientation and gender identity specifically.

compliance with the 2016 Rule are ''sunk costs'' that cannot be recovered. With the finalization of this rule, insurers have the option—as they have had since December 31, 2016—of providing such coverage or not. Presumably some insurers will maintain coverage consistent with the 2016 Rule's requirements and some will not. The final rule also does not alter the status quo, and thus does not impose burdens in this regard, because, independent of the finalization of this rule, the 2016 Rule's provisions on gender identity and termination of pregnancy have been vacated by a final order and decision of a federal court.

Comment: Commenters expressed concern that the proposed rule would result in lack of information about gender transition-related services or termination of pregnancy, leaving patients without information about different surgical procedures and prescription options, and in danger of harm. Some argued that women, members of the LGBT community, people with disabilities, people with LEP, and racial minorities need additional specific protections because they will face greater burdens accessing healthcare due to ''intersectionality'' theories. Others, however, said it was not appropriate or reflective of current civil rights law to analogize sexual orientation or gender identity to race or other protected categories.

Some commenters argued that the 2016 Rule had decreased LGBT patients' fears of discrimination, that the proposed rule will lead to discrimination against them (including by States, providers, marketplaces, agents, and brokers), and that this will increase their health disparities, mainly via poorer quality of care, lack of access to willing providers especially in rural areas, postponed care including preventive care, increased healthcare and insurance costs, and impediments to HIV patients' access to medication. Commenters said the rule would undermine the President's goal of eradicating HIV. Commenters relied on national and statewide reports and studies highlighting harm faced by LGBT people due to inadequate healthcare, including an increase in substance abuse; worsening psychiatric disorders; untreated depression leading to suicide; and higher rates of AIDS, HIV and other STIs, cancer, and behavioral health issues. These commenters also argued the proposed rule would permit LGBT people to suffer discrimination and hence stigmatic injury, which could also deter them from disclosing their LGBT status to their physicians and seeking proper care. Commenters alleged high rates of mental conditions (*e.g.,* depression),[93] behavioral conditions (*e.g.,* substance use disorder),[94] developmental conditions (*e.g.,* autism, learning disabilities), and physical conditions (*e.g.,* HIV, heart disease) among the LGBT population. Commenters also expressed concerns about lack of communication and consent between providers and patients, and alleged that the risk of discrimination is heightened in vulnerable populations, including persons with developmental disabilities, persons with LEP, elderly patients with diminished capacity, and those who rely on surrogates or guardians for making medical decisions on their behalf. Others stated that OCR does not have authority to protect all forms of discrimination that may negatively impact people, but that it must act within its statutory authority.

Response: The Department is concerned with the health of all Americans. It acts to the fullest extent of its statutory authority in its efforts to improve the health and wellbeing of all. Under its civil rights authority, it enforces Federal laws requiring nondiscrimination on specified grounds, which in the case of Section 1557 are race, color, national origin, sex, age, and disability. When OCR receives a claim alleging multiple grounds of prohibited discrimination, the Department analyzes the elements of each claim according to the statute applicable to that ground.

Consistent with the text of the ACA and, in this case, the underlying civil rights statutes incorporated into the ACA, the Department seeks, wherever possible, to remove barriers to healthcare. Those barriers include regulations that impede providers' ability to offer healthcare by interfering with their conscientious medical judgments or imposing unnecessary cost burdens on them. By removing such provisions from the 2016 Rule, the Department hopes to increase the availability of healthcare to all populations.

As a matter of policy, the Department recognizes and works to address barriers to treatment caused by stigma about depression, anxiety, substance use disorder, and other comorbid mental and behavioral health conditions.[95] With regard to HIV, this final rule does not alter or affect the longstanding Federal protections against discrimination for individuals with HIV: Section 504, and hence also this final rule, prohibits discrimination on the basis that an individual has HIV.[96] OCR continues to pursue major enforcement actions under its authorities [97] and to provide the public guidance [98] to protect the rights of persons with HIV or AIDS. HHS remains committed to ensuring that those living with HIV or AIDS receive full protection under the law, in accordance with full implementation of the President's National HIV/AIDS Strategy.[99]

Regarding commenters' worries about informed consent, this final rule does not repeal any informed consent requirements. Besides many relevant State laws,[100] CMS regulations also

[93] Commenters cited Remafedi G, French S, Story M, et al., The Relationship Between Suicide Risk and Sexual Orientation: Results of a Population-Based Study. Am J Public Health. 1998;88(1):57–60; McLaughlin KA, Hatzenbuehler ML, Keyes KM. Responses to Discrimination and Psychiatric Disorders Among Black, Hispanic, Female, and Lesbian, Gay, and Bisexual Individuals. Am J Public Health. 2010;100(8):1477–84.

[94] Commenters cited Banez GE, Purcell DW, Stall R, et al., Sexual Risk, Substance Use, and Psychological Distress in HIV Positive Gay and Bisexual Men Who Also Inject Drugs. AIDS. 2005;19 (suppl. 1):49–55.

[95] *See, e.g.,* Pain Management Task Force, ''Pain Management Best Practices, Fact Sheet on Stigma'' (Aug. 13, 2019), *https://www.hhs.gov/sites/default/files/pmtf-fact-sheet-stigma_508-2019-08-13.pdf* (''Compassionate, empathetic care centered on a patient-clinician relationship is necessary to counter the suffering of patients . . . . Patients with painful conditions and comorbidities, such as anxiety, depression or substance use disorder (SUD) face additional barriers to treatment because of stigma.'').

[96] *See* 29 U.S.C. 705(20) (incorporating ADA definition of disability into Section 504); 42 U.S.C. 12102(1)–(3); 28 CFR 35.108(d)(2)(iii)(J).

[97] *See, e.g.,* ''HHS Office for Civil Rights Secures Corrective Action and Ensures Florida Orthopedic Practice Protects Patients with HIV from Discrimination'' (Oct. 30, 2019), *https://www.hhs.gov/about/news/2019/10/30/hhs-ocr-secures-corrective-action-and-ensures-fl-orthopedic-practice-protects-patients-with-hiv-from-discrimination.html*; ''HHS Office for Civil Rights Enters Into Agreement with Oklahoma Nursing Home to Protect Patients with HIV/AIDS from Discrimination'' (Sept. 8, 2017), *https://www.hhs.gov/about/news/2017/09/08/hhs-office-for-civil-rights-enters-into-agreement-with-oklahoma-nursing-home.html.*

[98] *See* OCR, ''Know the Rights That Protect Individuals with HIV and AIDS,'' *https://www.hhs.gov/sites/default/files/ocr/civilrights/resources/factsheets/hivaids.pdf*; OCR, ''Protecting the Civil Rights and Health Information Privacy Rights of People Living with HIV/AIDS,'' *https://www.hhs.gov/civil-rights/for-individuals/special-topics/hiv/index.html.*

[99] *See* ''Ending the HIV Epidemic: A Plan for America,'' *https://www.hiv.gov/Federal-response/ending-the-hiv-epidemic/overview.*

[100] *See, e.g.,* Alaska Stat. § 09.55.556(a); Ark. Code Ann. § 16–114–206; Del. Code Ann. tit. 18, § 6852; Ga. Code Ann. § 31–9–6.1; Haw. Rev. Stat. § 671–3; Idaho Code Ann. § 39–4304; Ind. Code § 16–36–1.5–7; Ky. Rev. Stat. Ann. § 304.40–320; La. Rev. Stat. Ann. § 40:1299.40; Me. Rev. Stat. Ann. tit. 24 § 2905; Neb. Rev. Stat. § 44–2816; Nev. Rev. Stat. § 449.710; N.Y. Pub. Health Law § 2805–d; N.C. Gen. Stat. § 90–21.13; Or. Rev. Stat. § 677.097; 40 Pa. Cons. Stat. § 1303.504; Tenn. Code Ann. § 29–26–118; Tex. Rev. Civ. Stat. Ann. art. 4590i, § 6.02;

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require, as a condition of participation in Medicare, that patients (or their legal surrogate) have the right to make informed decisions, the right to surgical informed consent policies,[101] and the right to properly executed informed consent forms.[102] Most States' malpractice laws address negligent failure to communicate risks and benefits of medical treatment options. Basic elements of informed consent with respect to participation in a clinical trial, for example, include: (1) Providing information needed to make an informed decision; (2) facilitating the understanding of what has been disclosed; and (3) promoting the voluntariness of the decision about whether or not to participate.[103]

The Department knows of no data showing that the proper enforcement of Federal nondiscrimination law according to statutory text will disproportionately burden individuals on the basis of sexual orientation and/or gender identity. Because the 2016 Rule explicitly declined to make sexual orientation a protected category, and because the Rule's gender identity provision has been legally inoperative since December 31, 2016, to the extent that LGBT individuals suffer future harms, it cannot be attributed to the Department's finalizing this rule, as opposed to other causes.

Comment: Commenters raised concerns that, without the 2016 Rule's provisions, certain insurers, such as those offering short-term limited duration insurance plans, would not offer coverage for conditions that affect only women, such as uterine cancer. Some commenters stated that the underlying Title IX regulatory provisions are insufficient by themselves to address access to insurance coverage of procedures provided to a single sex in healthcare. Some commenters stated that, without the 2016 Rule, women would not be able to afford insurance for medical and hospital care.

Response: The Department is strongly committed to promoting women's health. The Department enforces or implements ACA provisions that protect patient access to obstetrical and gynecological care.[104] The Department also enforces other provisions, both within and outside the ACA, that, for example, provide for maternity and newborn care as essential health benefits,[105] require coverage of women's preventive health services,[106] establish (as a matter of statute) the HHS Office of Women's Health and the Pregnancy Assistance Fund,[107] and promote young women's breast health awareness.[108]

The Department's commitment to women's health also includes vigorous enforcement of Section 1557's prohibition on sex-based discrimination. Under HHS's Title IX regulations, which OCR will use for enforcing Section 1557, covered entities must provide medical insurance benefits, services, policies, and plans without discrimination on the basis of sex. This does not preclude a covered entity's providing a covered benefit or service that is used uniquely by individuals of one sex or the other, such as uterine cancer treatments. However, any plan that includes full-coverage health insurance or services must encompass gynecological care.[109] As discussed in the relevant section below, the Department is bound by applicable law in determining the extent to which Section 1557 covers short-term limited duration insurance.

Comment: Some commenters said that the Department was wrong to claim in the 2019 NPRM that State and local entities are better equipped to address issues of gender dysphoria or sexual orientation, because they say that fifty percent of the LGBT population lives in States without laws prohibiting insurance companies from discriminating based on LGBT status. Others said that, because States like New York explicitly protect persons who identify as LGBT, the new rule will cause confusion for providers and patients about people's rights under Federal and State law. Some commenters suggested that including gender identity and sexual orientation in the Final Rule would reduce ambiguity in its interpretation and implementation.

Response: States and localities do indeed manifest a range of different views on what specific protections should be accorded to the categories of sexual orientation and gender identity in civil rights law, including healthcare civil rights law. That is precisely why, under our Constitutional Federal system, it is appropriate not to preempt States' diverse views on these topics without a clear mandate from Congress to do so. This final rule complies with the federalism-related portions of Executive Orders 12866 and 13132 by avoiding undue interference with State, local, or tribal governments in the exercise of their governmental functions. It leaves them free to balance the multiple competing considerations involved in the contentious and fraught set of questions surrounding gender dysphoria and gender identity, and to adopt protections on the basis of sexual orientation or gender identity to the extent that they see fit (so long as they comply with Federal law).[110]

The Department notes, furthermore, that under the guaranteed issuance and renewal provisions of the ACA, health insurance issuers that offer health insurance coverage in the individual or group market in a state must accept every employer and every individual in that state that applies for such coverage, and must renew or continue in force such coverage at the option of the plan sponsor or the individual. *See* 42 U.S.C. 300gg–1 (guaranteed issuance), 300gg–2 (guaranteed renewability). Federal law similarly limits the bases on which a health insurance issuer can vary premium rates in the individual or small group market; such bases are limited to type of coverage (individual or family), rating area, age, and tobacco use. 42 U.S.C. 300gg. Thus, commenters' concern that LGBT individuals could be denied coverage if the Section 1557 rule does not include gender identity (or sexual orientation) is misplaced.

Comment: One commenter expressed concern that the proposed rule will have an effect beyond the United States by showing the international community that the United States Federal government does not recognize protections for individuals based on gender identity or sexual orientation in healthcare.

Response: The Department is not primarily responsible for the United States' foreign relations. Moreover, the Department has an obligation to implement the statutes according to the plain language of the text passed by Congress (unless unconstitutional), regardless of international implications.

Comment: Some commenters requested that the Department retain all guidance it had issued under the 2016 Rule. Other commenters stated that components of HHS continue to offer

Utah Code Ann. § 78–14–5; Vt. Stat. Ann. tit. 12, § 1909; Wash. Rev. Code Ann. § 7.70.050; Wis. Stat. Ann. § 448.30.

[101] 42 CFR 482.51(b)(2).

[102] 42 CFR 482.24(c)(4)(B)(v).

[103] 45 CFR 46.116–117 (HHS Office of Human Research Subject regulations).

[104] *See, e.g.,* 42 U.S.C. 300gg–19a(d).

[105] 42 U.S.C. 18022(b)(1)(D).

[106] 42 U.S.C. 300gg–13.

[107] 42 U.S.C. 237a; 42 U.S.C. 18202.

[108] 42 U.S.C. 280m.

[109] *See, e.g.,* 45 CFR 86.39.

[110] Ambiguity in the 2016 Rule's provisions regarding gender identity is addressed below. The Department further notes that sexual orientation was explicitly rejected as a protected category under the 2016 Rule. 81 FR 31390 (''OCR has decided not to resolve in this rule whether discrimination on the basis of an individual's sexual orientation status alone is a form of sex discrimination.'').

inconsistent guidance about the legal interpretation of the 2016 Rule.

Response: The Department stated in the preamble to the proposed rule that guidance under the 2016 Rule that conflicted with the proposed rule was suspended until further notice.[111] All such guidance is hereby withdrawn, effective upon publication of this final rule, and is in the process of being removed from the Department's website. Pursuant to Executive Order 13891, the Administration is also undertaking efforts to comprehensively review guidance documents ''to ensure that Americans are subject to only those binding rules imposed through duly enacted statutes or through regulations lawfully promulgated under them, and that Americans have fair notice of their obligations,'' [112] which also requires removal of inconsistent guidance from departmental websites.

ii. Gender Identity, Including Single-Sex Services Under § 92.206 of the 2016 Rule

The Department proposed to repeal the 2016 Rule's definition of ''on the basis of sex'' to encompass gender identity, which the 2016 Rule defined 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.'' [113] The Department also proposed to repeal § 92.206 of the 2016 Rule, which has three elements. First, the section required covered entities not to discriminate ''on the basis of sex'' (as defined in § 92.4 of the 2016 Rule) in providing access to health programs and activities. Second, it required them to ''treat individuals consistent with their gender identity.'' Third, it prohibited covered entities from ''deny[ing] or limit[ing] health services that are ordinarily or exclusively available to individuals of one sex, to a transgender individual based on the fact that the individual's sex assigned at birth, gender identity, or gender otherwise recorded is different from the one to which such health services are ordinarily or exclusively available.'' [114]

Comment: Commenters offered varying views on the state of gender-identity nondiscrimination protections under current Federal law. Some commenters alleged that it is settled law that Section 1557 prohibits gender identity discrimination. Others stated that, in other Federal court decisions on Title VII and Title IX, the text of the Title IX statute and regulation are held to be ''at least susceptible to'' the interpretation that it prohibits anti-transgender bias.[115]

Other commenters disagreed, stating that the courts are not unanimous on the question and pointed to legal precedent saying that gender identity is not encompassed by sex discrimination under Federal civil rights statutes. Commenters stated that the 2016 Rule had departed from existing civil rights law by creating new prohibited conduct unsupported by the text of the statutes. Commenters stated that Title IX has been interpreted by the courts for decades to apply to biological women.[116] Other commenters stated that the fact that the Supreme Court has agreed to consider the legality of the general theory proposed in the 2016 Rule demonstrates it is a novel and contested legal issue.[117] Other commenters stated Congress clearly intended ''sex discrimination'' to be defined with reference to biological classification as male or female, and that is the only understanding that is reasonably supported by the text, history, or structure of the relevant law. Some criticized the 2016 Rule's reliance on the EEOC's opinion in *Macy* v. *Holder,* 2012 EEOPUB LEXIS 1181, 112 FEOR (LRP) 257 (2012) (Title VII).

Response: The Department disagrees with commenters who contend that Section 1557 or Title IX encompass gender identity discrimination within their prohibition on sex discrimination. Some of the cases referenced by such commenters were decided under the Equal Protection Clause of the Constitution,[118] under which courts have applied intermediate levels of scrutiny, permitting governments to adopt ''discriminatory means'' on the basis of sex only insofar as those means are substantially related to the achievement of important governmental objectives and are not ''used to create or perpetuate the legal, social, and economic inferiority of women.'' [119] The Department does not agree that the Equal Protection cases cited by these commenters require Title IX to include a prohibition on gender identity discrimination. Unlike the Equal Protection Clause, Title VII and Title IX broadly forbid covered entities from discriminating on the basis of sex, with limited exemptions expressly provided in statute. Title VII exempts covered entities from the prohibition on sex discrimination where sex is a ''bona fide occupational qualification.'' [120] Title IX exempts covered entities from the prohibition on sex discrimination for admissions to historically single-sex colleges, school father-son and mother-daughter activities (so long as reasonably comparable activities are provided for students of both sexes), beauty pageants, certain boys' or girls' conferences, single-sex voluntary youth service organizations, fraternities and sororities, and military training programs.[121]

The text of Title IX also demonstrates that it is not susceptible to an interpretation under which it would prohibit gender identity discrimination. The statute permits covered entities to maintain ''separate living facilities for the different sexes,'' and it expressly presents this, not as an exemption from the nondiscrimination requirements, but as an ''interpretation'' of them: Separate-sex living facilities are not, as such, discriminatory.[122] The Department's Title IX regulations likewise permit separate-sex housing, intimate facilities, physical education and human sexuality courses, and contact sports.[123] The statute presents these distinctions as being fully compatible with its nondiscrimination requirement. Nondiscrimination requires that separate-sex facilities and programs be (where relevant) comparable to one another, but the existence of separate-sex facilities and programs is not, as such, discriminatory under Title IX. Consequently, the Department does not believe an interpretation of Title IX that would prohibit gender identity discrimination is compatible with the statute's overall approach towards what

[111] 84 FR 27872 (''Upon publication of this notice of proposed rulemaking, the Department will, as a matter of enforcement discretion, suspend all subregulatory guidance issued before this proposed rule that interprets or implements Section 1557 (including FAQs, letters, and the preamble to [the 2016 Rule]) that is inconsistent with any provision in this proposed rule (including the preamble) or with the requirements of the underlying civil rights statutes cross-referenced by Section 1557 or their implementing regulations.'').

[112] ''Promoting the Rule of Law Through Improved Agency Guidance Documents,'' Exec. Order No. 13891, 84 FR 55235 (Oct. 9, 2019).

[113] 81 FR 31387–88, 31467.

[114] 81 FR 31471.

[115] *See G.G. ex rel. Grimm* v. *Gloucester Cty. Sch. Bd.,* 822 F.3d 709 (4th Cir. 2016), *recalling mandate & issuing stay,* 136 S. Ct. 2442 (2016).

[116] *See, e.g., N. Haven Bd. of Ed.* v. *Bell,* 456 U.S. 512, 517–20, (1982); *Cannon* v. *Univ. of Chi.,* 441 U.S. 677, 680 (1979).

[117] Order, *R.G. & G.R. Harris Funeral Homes* v. *EEOC,* No. 18–107 (U.S. Apr. 22, 2019) (granting certiorari).

[118] *See Glenn* v. *Brumby,* 663 F.3d 1312 (11th Cir. 2011).

[119] *United States* v. *Virginia,* 518 U.S. 515, 516 (1996).

[120] 42 U.S.C. 2000e–2(e)(1).

[121] 20 U.S.C. 1681.

[122] 20 U.S.C. 1686.

[123] 45 CFR 86.32–34, § 86.41.

does and does not constitute sex discrimination.

Case law under both Title VII and Title IX has likewise recognized that these statutes do not forbid reasonable and relevant distinctions between the sexes.[124] As the United States Solicitor General recently put it, ''Many commonplace practices that distinguish between the sexes do not violate [Title VII] because they account for real physiological differences between the sexes without treating either sex less favorably.'' [125] No express statutory carve-out is required in order for employers under Title VII to be permitted to impose a sex-specific dress code that burdens men and women equally, nor in order for educational institutions under Title IX to be permitted to require men and women to shower separately from each other. And as compared to the fields of employment and of education, the field of healthcare necessarily may contain many more ''commonplace practices that distinguish between the sexes . . . [by] account[ing] for real physiological differences between the sexes without treating either sex less favorably.'' As discussed in greater detail later in the subsection of this preamble on gender identity, reasonable distinctions between the sexes may be called for in numerous areas within the Department's expertise, including shared hospital rooms,[126] sex-specific protections for patients' modesty,[127] specialized medical practices related to gynecology,[128] and medical treatments or recommendations relying on sex-based generalizations,[129] and other research situations.[130] The biological differences between men and women are not irrelevant to employment law and education, and they are in many ways even more relevant in the health setting.

In general, a covered entity is permitted to make distinctions on the basis of sex that are ''not marked by misconception and prejudice, nor . . . show disrespect for either class.'' [131] In many cases, removing or weakening such reasonable sex-based distinctions could undermine the equality of the sexes by disproportionately harming women.[132] As discussed further below, case law is still developing as to whether covered entities' refusal to draw these distinctions could in some cases violate personal privacy interests and so create a hostile environment under Title IX.[133] ''[N]eutral terms can mask discrimination that is unlawful,'' while ''gender specific terms can mark a permissible distinction.'' [134] Where the ''[p]hysical differences between men and women'' are relevant, sex-neutral policies will in some cases ''undoubtedly require alterations'' to make them sex-specific, in order ''to afford members of each sex privacy from the other sex in living arrangements.'' [135]

Comment: Commenters stated that *Price Waterhouse* v. *Hopkins,* 490 U.S. 228 (1989), and *Oncale* v. *Sundowner Offshore Oil Services, Inc.,* 523 U.S. 75 (1998), fully support or even require the 2016 Rule's gender identity provisions or their equivalent. Commenters asked the Department to address specific court cases that they stated were contrary to the Department's view, such as *Doe* v. *Boyertown Area Sch. Dist.,* 897 F.3d 518 (3d Cir. 2018), *Whitaker* v. *Kenosha Unified Sch. Dist. No. 1 Bd. of Educ.,* 858 F.3d 1034 (7th Cir. 2017), and *Glenn* v. *Brumby,* 663 F.3d 1312 (11th Cir. 2011).

Response: For most of the history of Title IX case law, the ''commonplace practices that . . . account for real physiological differences between the sexes without treating either sex less favorably'' [136] were uncontroversial and not considered discriminatory. In the past five years, two circuit courts have begun to question this long-standing precedent in proceedings arising from motions for preliminary injunctions, although no circuit court has yet done so in a final ruling.[137]

These courts (and some district courts) draw on the Supreme Court's reasoning in *Price Waterhouse* in order to assert that otherwise permissible distinctions on the basis of sex must be applied (if at all) on the basis of an individual's subjective gender identity. But the novel legal theory advanced by these courts represents a serious misreading of *Price Waterhouse* and of Title IX, a reading that has been disputed by the decisions of other courts, including *Franciscan Alliance.*

Price Waterhouse is a Title VII case and establishes that, '' '[i]n forbidding employers to discriminate against individuals because of their sex, Congress intended to strike at the entire spectrum of disparate treatment of men and women resulting from sex stereotypes.' '' [138]

When courts have read *Price Waterhouse* as determining that ''on the basis of sex'' encompasses gender identity, they have done so on the ground that discrimination on the basis of gender identity is, as such, a form of sex stereotyping. But *Price Waterhouse* should be read in light of the Supreme Court definition of a ''stereotype'' about sex ''as a frame of mind resulting from

[124] *See Wittmer* v. *Phillips 66 Co.,* 915 F.3d 328, 334 (5th Cir. 2019) (Ho, J., concurring); *Jespersen* v. *Harrah's Operating Co.,* 444 F.3d 1104, 1109–10 (9th Cir. 2006) (en banc) (collecting cases).

[125] Brief for EEOC, *R.G. & G.R. Harris Funeral Homes* v. *EEOC,* No. 18–107 (U.S. filed Aug. 16, 2019), at 36.

[126] *See Cypress* v. *Newport News General and Nonsectarian Hospital Association,* 375 F.2d 648, 658 (4th Cir. 1967) (''Our holding is simply that race cannot be a factor in the admission, assignment, classification, or treatment of patients in an institution like this, which is state-supported and receives federal funds. Room assignments may be made with due regard to sex, age, type of illness, or other relevant factors, but racial distinctions are impermissible, since the law forbids the treatment of individuals differently or separately because of their race, color, or national origin.''); *cf.* similar statutory requirements at 10 U.S.C. 4319 (Army), 10 U.S.C. 6931 (Navy), and 10 U.S.C. * 9319 (Air Force) (requiring separation of sleeping and latrine areas for ''male'' and ''female'' recruits); 10 U.S.C. 4320 (Army), 10 U.S.C. 6932 (Navy), and 10 U.S.C. 9320 (Air Force) (limiting after-hours access by drill sergeants and training personnel to persons of the ''same sex as the recruits'').

[127] *See, e.g.,* OCR Voluntary Resolution Agreement with Michigan State University, *https://cms-drupal-hhs-prod.cloud.hhs.gov/sites/default/files/vra-between-msu-and-ocr.pdf,* at IV.D.1.d.iii, IV.D.1.d.v.

[128] *See, e.g.,* Women's Preventive Services Guidelines, Health Resources and Services Administration, Dec. 17, 2019 (HRSA) *https://www.hrsa.gov/womens-guidelines-2019.*

[129] *See* the Department's Office of Women's Health, *https://www.womenshealth.gov/.*

[130] *See* NIH Guidance, *Consideration of Sex as a Biological Variable in NIH-funded Research* (2017), *https://orwh.od.nih.gov/sites/orwh/files/docs/NOT-OD-15-102_Guidance.pdf*; NIH, Office of Research on Women's Health, ''Sex & Gender,'' *https://orwh.od.nih.gov/.*

[131] *See Tuan Anh Nguyen* v. *INS,* 533 U.S. 73.

[132] *See* Brief for EEOC, *Harris Funeral Homes,* at 37–38 (citing cases).

[133] *See, e.g., Doe* v. *Luzerne Cty.,* 660 F.3d 169, 176–77 (3d Cir. 2011) (recognizing that an individual has ''a constitutionally protected privacy interest in his or her partially clothed body'' and that this ''reasonable expectation of privacy'' exists ''particularly while in the presence of members of the opposite sex''); *Brannum* v. *Overton Cty. Sch. Bd.,* 516 F.3d 489, 494 (6th Cir. 2008) (''the constitutional right to privacy . . . includes the right to shield one's body from exposure to viewing by the opposite sex''); *Fortner* v. *Thomas,* 983 F.2d 1024, 1030 (11th Cir. 1993) (''[M]ost people have a special sense of privacy in their genitals, and involuntary exposure of them in the presence of people of the other sex may be especially demeaning or humiliating.''). *But see Parents for Privacy* v. *Barr,* No. 18–35708, (9th Cir. Feb. 12, 2020) (no title IX or constitutional privacy violation for school policy allowing student to use bathroom and locker rooms consistent with their gender identity).

[134] *Tuan Anh Nguyen* v. *INS,* 533 U.S. 64.

[135] *United States* v. *Virginia,* 518 U.S. 515, 550 n.19 (1996) (emphasis added) (brackets and citation omitted).

[136] Brief for EEOC, *Harris Funeral Homes,* at 36.

[137] *Whitaker* v. *Kenosha Unified Sch. Dist.,* 858 F.3d 1034, 1039 (7th Cir. 2017); *Dodds* v. *United States Dep't of Educ.,* 845 F.3d 217 (6th Cir. 2016). The ruling in a third related case, *G.G.* v. *Gloucester Co. Sch. Bd.,* 822 F.3d 709 (4th Cir. 2016), was based on *Auer* deference to Department of Education subregulatory guidance and has since been vacated after that guidance was withdrawn.

[138] *Price Waterhouse* v. *Hopkins,* 490 U.S. 228, 251 (1989), quoting *Los Angeles Dept. of Water & Power* v. *Manhart,* 435 U. S. 702, 707, n. 13 (1978).

irrational or uncritical analysis.'' [139] Wherever ''stereotyping play[s] a motivating role in an employment decision,'' according to *Price Waterhouse,* the employer has demonstrated an ''impermissible motive,'' for stereotypes should not even ''play a part in the decisionmaking process.'' [140]

The Department believes that, unlike stereotypes, reasonable distinctions on the basis of sex, as the biological binary of male and female, may, and often must, ''play a part in the decisionmaking process''—especially in the field of health services. A covered entity such as a healthcare provider is not impermissibly stereotyping biological males (notwithstanding their internal sense of gender) on the basis of sex if it uses pronouns such as ''him''; limits access to lactation rooms and gynecological practices to female users and patients; or lists a male's sex as ''male'' on medical forms. Similarly, a covered health care entity is not impermissibly stereotyping biological females (notwithstanding their internal sense of gender) on the basis of sex if it uses pronouns such as ''her''; warns females that heart-attack symptoms are likely to be quite different than those a man may experience; advises women that certain medications tend to affect women differently than men; or lists a female's sex as ''female'' on medical forms. Finally, it is not stereotyping for covered entities to have bathrooms or changing rooms designated by reference to sex, or to group patients in shared hospital rooms by sex.[141] Such practices and actions are not rooted in stereotypes, but in real biological or physiological differences between the sexes. Moreover, none of these examples disadvantages one sex over another, and in fact the failure to take sex into account may in some cases have a disadvantageous effect.

As the Supreme Court has noted, ''to fail to acknowledge even our most basic biological differences . . . risks making the guarantee of equal protection superficial, and so disserving it. Mechanistic classification of all our differences as stereotypes would operate to obscure those misconceptions and prejudices that are real.'' [142] ''[T]here is nothing irrational or improper in the recognition'' of the social and other consequences of real physiological differences between the sexes; ''[t]his is not a stereotype.'' [143] Reasonable distinctions ''may be based on real differences between the sexes . . . so long as the distinctions are not based on stereotyped or generalized perceptions of differences.'' [144] ''Prohibition of harassment on the basis of sex requires neither asexuality nor androgyny.'' [145]

Justice Ginsburg's majority opinion in *U.S.* v. *Virginia* sharply distinguished sex from other protected classes in this regard: ''Supposed 'inherent differences' are no longer accepted as a ground for race or national origin classifications. Physical differences between men and women, however, are enduring: '[T]he two sexes are not fungible; a community made up exclusively of one [sex] is different from a community composed of both.' . . . 'Inherent differences' between men and women, we have come to appreciate, remain cause for celebration.'' [146] This recognition of physical (*i.e.,* biological) differences between men and women is not stereotyping and in some cases will ''undoubtedly require alterations'' to accommodated sex-specific differences.[147]

The lower court decisions referenced by commenters held that a covered entity which required transgender individuals to abide by otherwise permissible distinctions on the basis of sex, such as separate-sex bathrooms, would be impermissibly ''imposing its stereotypical notions of how sexual organs and gender identity ought to align.'' [148] A few lower courts have relied on these holdings in interpreting Section 1557 to require covered entities to override these reasonable distinctions based on sex, in deference to an individual's gender identity.[149] The notion that such distinctions on the basis of sex amount, as such, to impermissible stereotyping, would be lethal to countless reasonable and fully permissible healthcare practices, some of which have been identified above. No court has gone so far: These lower courts have questioned such distinctions only insofar as these distinctions come into conflict with an individual's stated gender identity. But *Price Waterhouse* offers no basis for this regime of individualized exceptions to otherwise reasonable distinctions. If it is impermissible stereotyping of a female employee to demand that she not ''behave aggressively,'' then *Price Waterhouse* (to the extent that it applies) requires companies to stop holding *all* female employees to such a stereotyped standard—not merely to grant exceptions for the occasional female employee who objects to that standard.[150] Similarly, if it is impermissible stereotyping to assume that ''sexual organs . . . ought to align'' with the sex listed on one's hospital bracelet, then *Price Waterhouse* (to the extent that it applies) would invalidate the existence of *all* sex markers on hospital bracelets, not merely of those to which a transgender individual has objected. Where a covered entity has not stereotyped but has only drawn a reasonable distinction, *Price Waterhouse* is irrelevant.

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

[139] *Tuan Anh Nguyen* v. *I.N.S.,* 533 U.S. 53, 68 (2001).

[140] *Price Waterhouse,* 490 U.S. 252–53, 254–55. The Civil Rights Act of 1991 amends the *Price Waterhouse* standard to say that ''an unlawful employment practice is established when the complaining party demonstrates that . . . sex . . . was a motivating factor for any employment practice, even though other factors also motivated the practice,'' but the employer may rebut this claim if he or she ''demonstrates that [the employer] would have taken the same action in the absence of the impermissible motivating factor.'' 42 U.S.C. 2000e–2(m), § 2000e–5(g)(2)(B).

[141] *See* 29 CFR 1910.141(c) (OSHA regulation requiring ''toilet rooms separate for each sex'').

[142] *Tuan Anh Nguyen,* 533 U.S. at 73. In *Sessions* v. *Morales-Santana,* 137 S. Ct. 1678 (2017), the Supreme Court struck down, on intermediate-scrutiny grounds, a statute that granted U.S. citizenship to children born abroad of unwed parents if the child's mother had been a U.S. citizen for one year before the birth, but required five years in the case of a U.S. citizen father. However, the Court did not reject the *Nguyen* analysis recognizing that sex distinctions are real, and that not all such distinctions are based on unlawful stereotypes.

[143] *Id.* at 68.

[144] *Faulkner* v. *Jones,* 10 F.3d 226, 232 (4th Cir. 1993).

[145] *Oncale* v. *Sundowner Offshore Oil Services, Inc.,* 523 U.S. 75, 81 (1998).

[146] *United States* v. *Virginia,* 518 U.S. 515, 533 (1996) (internal citations omitted).

[147] *Id.* at 550 n.19.

[148] *Equal Employment Opportunity Comm'n* v. *R.G. & G.R. Harris Funeral Homes, Inc.,* 884 F.3d 560, 576 (6th Cir. 2018). *See also Whitaker* v. *Kenosha Unified Sch. Dist.,* 858 F.3d 1034, 1051 (7th Cir. 2017) (''the School District treats transgender students like Ash, who fail to conform to the sex-based stereotypes associated with their assigned sex at birth, differently. These students are disciplined under the School District's bathroom policy if they choose to use a bathroom that conforms to their gender identity.''); *Glenn* v. *Brumby,* 663 F.3d 1312, 1316 (11th Cir. 2011) (''A person is defined as transgender precisely because of the perception that his or her behavior transgresses gender stereotypes.'').

[149] *See Rumble* v. *Fairview Health Servs.,* No. 14–cv–037 (SRN/FLN), 2017 WL 401940 (D. Minn. Jan. 30, 2017); *Prescott* v. *Rady Children's Hospital-San Diego,* 265 F. Supp. 3d 1090, 1098–100 (S.D. Cal. 2017)

[150] *See Price Waterhouse,* 490 U.S. at 235, 250–51.

(as under the 2016 Rule).[151] Rather, Title IX prohibits subjecting a person to less favorable treatment because of his or her sex. Thus, if a person claims to have been discriminated against on the basis of his or her sex, that claim is neither weakened nor strengthened by any allegations about his or her ''internal sense of gender.'' Numerous lower courts have held that, like any other man or woman, a transgender individual may sue under Title VII if he or she is harassed, assaulted, terminated, or otherwise discriminated against because of his or her sex.[152] Under Title IX, as under Title VII, ''[t]ranssexuals are not genderless, they are either male or female and are thus protected under Title VII to the extent that they are discriminated against on the basis of sex.'' [153] The Department will vigorously enforce Section 1557's prohibition on sex-based discrimination, but that prohibition cannot be construed as a prohibition on reasonable sex-based distinctions in the health field.

Comment: Commenters offered a variety of views on the role that a patient's sex and/or gender identity ought to play in medical decision-making.

Many commenters spoke of the importance of sex-reassignment surgeries and cited studies that they said show the value of these surgeries in alleviating gender dysphoria. Others cited different studies that they said show the opposite. Some clinicians expressed concerns about consent and medical appropriateness of pre-pubertal sex reassignment with lifelong physical and mental implications (including permanent sterility) when children and adolescents lack the requisite social, emotional, and intellectual maturity, or life experiences necessary for true consent. Commenters also were concerned about coercive, peer, adult, and ideological pressures on children and adolescents to seek cross-sex hormonal treatment, sex reassignment surgery, or other similar services. Some commenters, including parties to lawsuits against the Department on the ground that the 2016 Rule would require gender transition treatments and therapies for children, criticized the 2016 Rule for containing no age limitation. Commenters stated that the ''gender-affirming'' model is the most controversial form of counseling and, as such, is not used by the Dutch national transgender clinic, which they said is considered the international flagship of gender dysphoria treatment.

Some commenters noted that violations of the 2016 Rule are enforceable by termination of Federal financial assistance and that violations of State law with respect to healthcare may involve civil penalties for negligence or malpractice, etc. In light of this, they stated that the 2016 Rule placed providers in an impossible position, where compliance with one law means noncompliance with another, and either choice results in a steep penalty.

Other commenters said that the 2016 Rule's definition of ''on the basis of sex'' could prohibit the way OB/GYN practices specialize in treating females, and raised the concern that specializing in the treatment of female patients could be deemed prohibited discrimination against biological males who identify as women. Commenters stated that because these services are focused on and tailored to females as a single biological sex, they are able to provide a higher quality of care to those patients. They noted that it has long been a permissible sex-based distinction for OB/GYN doctors to not treat any biological males, and this distinction is recognized under HHS Title IX regulations. Such commenters found the 2016 Rule overbroad and inconsistent with day-to-day affairs in how they practice medicine. But other commenters stated that OB/GYNs are not affected by the transgender requirements under the 2016 Rule and that pre-existing OB/GYN practices are justified by reasonable scientific justifications.

Certain providers advocated for removal of the requirement to ''treat individuals consistent with their gender identity,'' as this provision would violate the conscience rights of healthcare providers, and the ethical and foundational convictions that underlie the entire way they practice medicine. Other commenters said that repeal of this provision leaves no clarity about whether such providers will actually provide treatment for transgender patients, and expressed the concern that affirming treatment consistent with gender identity is necessary for high-value transgender healthcare, as is required for all people in the practice of medicine.

Some commenters noted their concern that the 2016 Rule requires doctors to remove healthy reproductive tissue in sex-reassignment surgeries, even if it may be contrary to the patient's medical interest. For example, if a surgeon performs mastectomies as part of a medically necessary treatment for breast cancer, under the 2016 Rule, he or she could also have been required to perform mastectomies for sex-reassignment purposes when recommended by a psychologist, even if the surgeon believes such treatments are not medically indicated in his or her own professional judgment. Similarly, commentators argued that some doctors might be forced to perform hysterectomies not only against their medical judgment but also outside of their expertise. Other commenters contended that certain procedures are not meaningfully different when performed on a transgender versus non-transgender patient, because the mechanics of the procedures are substantially similar. Although genital reassignment surgery is considered a ''gender transition service,'' clinicians commented that somewhat similar procedures are used for genital reconstruction to repair damaged, diseased, or disfigured genital tissue, or in the treatment of disorders of sexual development.

Commenters also stated that the 2016 Rule would force them to provide services damaging to the health of patients, in conflict with their mission as a healthcare provider, instead of using these medical resources to help patients.[154]

Commenters stated that HHS does not have a compelling interest in requiring the medical provision of, or insurance

[151] *See Johnston* v. *Univ. of Pittsburgh of the Commonwealth Sys. of Higher Educ.,* 97 F. Supp. 3d 657 (W.D. Pa. 2015).

[152] *Barnes* v. *City of Cincinnati,* 401 F.3d 729 (6th Cir. 2005); *Smith* v. *City of Salem,* 378 F.3d 566 (6th Cir. 2004). These cases have been cited, by the 2016 Rule and in some recent court cases, in support of the view that sex discrimination encompasses discrimination on the basis of gender identity. This is a serious misreading pointed out at *Johnston* v. *Univ. of Pittsburgh of Com. Sys. of Higher Educ.,* 97 F. Supp. 3d 657, 675n17 (W.D. Pa. 2015) (''In *Smith* v. *City of Salem,* . . . the court did not conclude that ''transgender'' is a protected class under Title VII, but only that a male or female who is also transgender can assert a sex stereotyping claim under Title VII for adverse employment actions that result from the individual's conformity to their gender identity rather than their biological or birth sex. Indeed, the same year that the 6th Circuit issued its opinion in *Smith,* it affirmed, in an unpublished opinion, a district court decision holding that ''Title VII does not prohibit discrimination based on an individual's status as a transsexual,'' in an employment discrimination case involving a transgender women's use of a men's restroom. *Johnson* v. *Fresh Mark, Inc.,* 98 Fed. App'x. 461, 462 (6th Cir.2004).'').

[153] *Tronetti* v. *TLC HealthNet Lakeshore Hosp.,* No. 03–CV–0375E(SC), 2003 WL 22757935, at *4 (W.D.N.Y. Sept. 26, 2003). *See Rosa* v. *Park West Bank Trust Co.,* 214 F.3d 213, 215–16 (1st Cir. 2000) (discrimination against a cross-dressing man is sex-based discrimination if the entity would have treated a ''similarly situated'' woman differently, *i.e.,* if it treats ''a woman who dresses like a man differently than a man who dresses like a woman'').

[154] Commenters cited specific examples of coercion. *See Minton* v. *Dignity Health,* 2017 WL 7733922 (Cal. Super. Ct. Nov. 2017); *Robinson* v. *Dignity Health,* No. 16–cv–3035 YGR, 2016 WL 7102832 (N.D. Cal. Dec. 6, 2016) (on remand from U.S. Supreme Court).

for, gender transition services or procedures. Other commenters stated that access to such services for transgender patients constitutes a compelling interest. Some commenters challenged the idea that an individual born as one biological sex can in actuality be transformed into a person of the other sex, with or without surgeries or hormone treatments.

Response: The Department recognizes that certain single-sex medical procedures, treatments, or specializations are rooted in the binary and biological meaning of sex for valid scientific and medical reasons. The Department believes the 2016 Rule caused significant confusion and cast doubt as to whether such longstanding specialized practices remained lawful, as indicated, for example, by the fact that commenters had diverging views on how the 2016 Rule impacted OB/GYN practices. The Department declines to interfere in these practices, and repeals a mandate that was, at least, ambiguous and confusing.

The Department appreciates the many comments received on the issue of gender identity, gender dysphoria, and the appropriate care for individuals with gender dysphoria. The Department believes providers should be generally free to use their best medical judgment, consistent with their understanding of medical ethics, in providing healthcare to Americans. The wide variation in these comments confirms that the medical community is divided on many issues related to gender identity, including the value of various ''gender-affirming'' treatments for gender dysphoria (especially for minors), the relative importance of care based on the patient's sex, and the compatibility of gynecological practice with a requirement of nondiscrimination on the basis of gender identity.[155]

The Department is also reluctant to pretermit ongoing medical debate and study about the medical necessity of gender transition treatments. The 2016 Rule assumed that, if a covered entity offers a ''categorical coverage exclusion or limitation for all health services related to gender transition,'' then that entity must be relying on medical judgments that are ''outdated and not based on current standards of care.'' [156] But based on its review of the most recent evidence, the Department concludes that this was an erroneous assertion, and that there is, at a minimum, a lack of scientific and medical consensus to support this assertion, as the comments noted above demonstrate. This lack of scientific and medical consensus—and the lack of high-quality scientific evidence supporting such treatments—is borne out by other evidence. For example, on August 30, 2016, CMS declined to issue a National Coverage Determination (NCD) on sex-reassignment surgery for Medicare beneficiaries with gender dysphoria ''because the clinical evidence is inconclusive.'' [157] CMS determined, ''[b]ased on an extensive assessment of the clinical evidence,'' that ''there is not enough high quality evidence to determine whether gender reassignment surgery improves health outcomes for Medicare beneficiaries with gender dysphoria and whether patients most likely to benefit from these types of surgical intervention can be identified prospectively.'' [158] Similarly, in a 2018 Department of Defense (DOD) report on the diagnosis of gender dysphoria, which included input from both transgender individuals and medical professionals with experience in the care and treatment of individuals with gender dysphoria, DOD found that there is ''considerable scientific uncertainty and overall lack of high quality scientific evidence demonstrating the extent to which transition-related treatments, such as cross-sex hormone therapy and sex reassignment surgery—interventions which are unique in psychiatry and medicine—remedy the multifaceted mental health problems associated with gender dysphoria.'' [159] Other research has found that children who socially transition in childhood faced dramatically increased likelihood of persistence of gender dysphoria into adolescence and adulthood.[160] The Department does not believe that the nondiscrimination requirements in Title IX, incorporated by reference into Section 1557, foreclose medical study or debate on these issues. And to the extent that a medical consensus develops on these issues, it is not clear that regulations of the sort encompassed in the 2016 Rule would be necessary to encourage medical professionals to follow such consensus.

The Department believes that its approach in the 2016 Rule inappropriately interfered with the ethical and medical judgment of health professionals. The preamble to the 2016 Rule stated that, under that Rule, ''a provider specializing in gynecological services that previously declined to provide a medically necessary hysterectomy for a transgender man would have to revise its policy to provide the procedure for transgender individuals in the same manner it provides the procedure for other individuals.'' [161] This statement raised the prospect of forcing a provider to perform irreversible, sterilizing, and endocrine-disrupting procedures on what may be, in the provider's view, non-diseased and properly functioning organs—including in children and youth.[162] A medical provider may rightly judge a hysterectomy due to the presence of malignant tumors to be different in kind from the removal of properly functioning and healthy reproductive tissue for psychological reasons, even if the instruments used are identical. For example, OB/GYNs competent and willing to perform dilation and curettage procedures to aid with recovery from a miscarriage should not, and legally cannot,[163] be forced to perform dilation and curettage procedures for abortions, because the regulatory, ethical, and medical frameworks that apply to abortions are radically different from those that apply to recovery from miscarriages. Moreover, commenters who offer transition services made clear that these often involve specialized cross-sex hormonal treatments before and after any sex-reassignment surgeries, and require coordination of care with urologists, psychiatrists, and a variety of other healthcare professionals in different specialized fields. A provider who routinely provides, for example, hysterectomies to address uterine cancer should be able reasonably to choose not to be involved in what may be the much more medically complicated set of procedures involved in sex reassignment.

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[155] Comments referring specifically to providers' conscientious objections to certain forms of treatment are addressed below in the section on ''relation to other laws.''

[156] *Cf.* 81 FR 31472, 31429.

[157] CMS, ''Decision Memo for Gender Dysphoria and Gender Reassignment Surgery'' (CAG–00446N) (Aug. 30, 2016) *https://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=282.*

[158] *Id.*

[159] Department of Defense, ''Report and Recommendations on Military Service by Transgender Persons'' (Feb. 22, 2018), 5.

[160] Thomas D. Steensma, Ph.D., Jenifer K. McGuire, Ph.D. M.P.H., et al. ''Factors Associated with Desistance and Persistence of Childhood Gender Dysphoria: A Quantitative Follow-Up Study,'' 52(6) Journal of the American Academy of Child & Adolescent Psychiatry 582–90 (2013).

[161] 81 FR 31455.

[162] In this regard, the Department distinguishes between the situation created by the requirements of 2016 Rule and the in-program requirements applied within federally funded grant programs where, for example, ''the general rule that the Government may choose not to subsidize speech applies with full force,'' even if the speech concerns what is allegedly required by medical ethics. *See, e.g., Rust* v. *Sullivan,* 500 U.S. 173, 200 (1991).

[163] *See* Church Amendments, 42 U.S.C. 300a–7.

Upon reconsidering this issue, the Department now believes that the 2016 Rule did not offer a sufficient analysis to justify the serious effect of requiring providers to perform certain procedures or provide certain treatments contrary to their medical judgment. The Department does not and need not take a definitive view on any of the medical questions raised in these comments about treatments for gender dysphoria. The question is whether Title IX and Section 1557 require healthcare professionals, as a matter of nondiscrimination, to perform such procedures or provide such treatments. The answer is that they do not. This final rule does not presume to dictate to medical providers the degree to which sex matters in medical decision making, nor does it impose the 2016 Rule's vague and overbroad mandate that they ''treat individuals consistent with their gender identity.''

Nothing in this final rule prohibits a healthcare provider from offering or performing sex-reassignment treatments and surgeries, or an insurer from covering such treatments and procedures, either as a general matter or on a case-by-case basis. The large number of comments received from healthcare providers who perform such treatments and procedures suggests that there is no shortage of providers willing to do so, even without the 2016 Rule's provisions on gender identity (which had been enjoined for over two years by the time of the comment period).

Finally, the *Franciscan Alliance* court held that HHS had not demonstrated a compelling interest in requiring providers with sincerely held religious objections to gender transition services, notwithstanding their objections, to provide these services. The Department sees no compelling interest in forcing the provision, or coverage, of these medically controversial services by covered entities, much less in doing so without a statutory basis.

Comment: Some commenters stated that revising the rule to eliminate the court-vacated provisions on gender identity, in conjunction with other Federal actions related to gender transition-related services, is evidence of animus to transgender individuals, and that the free exercise of religion or conscience claims raised by medical professionals and insurers are merely ''pretext'' for invidious discrimination. Others contended that the proposed rule recognizes the human dignity of all because certain surgical procedures and medications related to gender identity and abortion do not actually serve the health or wellbeing of patients but violate their dignity and physical and psychological integrity, especially of children and women in crisis pregnancies, and that these providers act out of sincere beliefs both as to medical judgment and religious belief in pursuing the best interests of patients regardless of their background or stated identities.

Response: The Department respects the dignity of all individuals. It seeks to further the health and well-being of all, but it can do so only by implementing the laws as adopted by Congress.

Moreover, the Department notes that commenters have provided a number of bases for objections to being forced to provide or cover certain treatments or surgeries contrary to their sincere medical, economic, religious, scientific, ethical, or conscience-based reasons. To presume that religious beliefs on these issues are rooted in bigotry, animosity, or insincerity would risk unlawfully stereotyping people of faith. *See Masterpiece Cakeshop* v. *Colorado Civil Rights Comm'n,* 138 S. Ct. 1719, 1729 (2018) (''To describe a man's faith as 'one of the most despicable pieces of rhetoric that people can use' is to disparage his religion in at least two distinct ways: By describing it as despicable, and also by characterizing it as merely rhetorical—something insubstantial and even insincere.'').[164]

Comment: Commenters expressed various views on whether transgender patients should be treated in accord with their expressed gender identity and/or in accord with their sex.

Some commenters stated that transgender designations conceal real biological sex differences that are relevant to medical risk factors, recognition of which is important for effective diagnosis, treatment, and disease prevention—including effective treatment for patients who identify as transgender. Some added that biological sex differences remain present in numerous bodily systems even after a patient has undergone hormonal and/or surgical transition therapies, and that physicians must be permitted to take these differences into account. Healthcare providers commented that critical decisions are made in the practice of medicine on the basis of objective biological information concerning a person's sex as being male or female because, among other reasons, medications and treatments affect males and females differently, and only females can become pregnant, regardless of stated gender identity. These commenters were concerned that by requiring providers to treat patients consistent with gender identity instead of biological sex, the patients' health is endangered, with both short- and long-term consequences.[165]

Other commenters stated that the Department has not provided sufficient explanation or justification for removing § 92.206 of the 2016 Rule with respect to ensuring equal access to healthcare services without respect to sex, including prohibitions on discriminatory denials of services typically associated with one sex to persons who identify as transgender. The commenters stated that the Department ignored the text of § 92.206 when it asserted in the proposed rule that the 2016 Rule would ''require[e] healthcare entities to code as male all persons who self-identify as male, regardless of biology, [which] may lead to adverse health consequences.''[166] Commenters said § 92.206 properly prohibits, among other things, the arbitrary denial of care based not on clinical considerations but solely on the patient's ''sex as assigned at birth'' or as recorded in medical or insurance records. Others said that while the biological definition of ''sex'' may be appropriate for scientific contexts such as National Institutes of Health (''NIH'') studies, the Department's nondiscrimination provisions should define the term more broadly.

Some commenters commented on a case of a transgender patient with abdominal pains who, as a result of being treated according to a male gender identity, was not diagnosed as being pregnant as part of the triage process and had a stillborn child. Some commenters viewed this set of facts as evidence against the 2016 Rule while others claimed it was evidence for the 2016 Rule.

Response: The Department has long recognized that the practice of medicine and biomedical research routinely involves decisions and diagnoses that legitimately make distinctions based on sex, including decisions made at triage; research studies (including clinical trials); questions of medical history; and requests for a medical consultation. As discussed at length in the NPRM, substantial scientific literature published after the 2016 Rule indicates that sex-specific practices in medicine and research exist because biological

[164] Religious exemptions will be addressed further in the section discussing the final rule's relation to other laws.

[165] Commenters cited texts including William J. Malone, MD, Gender Dysphoria Resource for Providers (3rd Edition); and Michael Laidlaw, MD, ''The Gender Identity Phantom,'' International Discussion Space for Clinicians and Researchers (Oct. 24, 2018) *http://gdworkinggroup.org/2018/10/24/the-gender-identity-phantom.*

[166] *See* 84 FR 27885, n. 55.

(and, derivatively, genetic) differences between males and females are real and matter to health outcomes and research.[167] For example, NIH requires research grant applicants to consider sex as a biological variable ''defined by characteristics encoded in DNA, such as reproductive organs and other physiological and functional characteristics.'' [168] According to an NIH article,

[s]ex as a biological variable (SABV) is a key part of the new National Institutes of Health (NIH) initiative to enhance reproducibility through rigor and transparency. The SABV policy requires researchers to factor sex into the design, analysis, and reporting of vertebrate animal and human studies. The policy was implemented as it has become increasingly clear that male/female differences extend well beyond reproductive and hormonal issues. Implementation of the policy is also meant to address inattention to sex influences in biomedical research. Sex affects: Cell physiology, metabolism, and many other biological functions; symptoms and manifestations of disease; and responses to treatment. For example, sex has profound influences in neuroscience, from circuitry to physiology to pain perception.[169]

Yet the 2016 Rule required covered entities to ''treat individuals consistent with their gender identity'' in virtually every respect. The 2016 Rule's definition of gender identity does not turn on any biological or external indicia of sex, and explicitly disavows any such reliance.[170] Under the 2016 Rule, one can identify as ''male, female, neither, or a combination of male and female.'' A person's gender identity under the 2016 Rule is determined ultimately by what a person says his or her gender identity is, and a covered entity is bound to treat all individuals ''consistent with their gender identity'' the moment it becomes aware of such a declaration (which must be allowed to change under the 2016 Rule). No other Federal statute, agency rule, or guidance has ever gone so far on this question.[171]

In this regard, the 2016 Rule risked masking clinically relevant, and sometimes vitally important, information by requiring providers and insurers to switch from a scientifically valid and biologically based system of tracking sex to one based on subjective self-identification according to gender identity. By eliminating the transgender provisions and definitions from the 2016 Rule, this final rule clarifies that sex, according to the Title IX's plain meaning, may be taken into account in the provision of healthcare, insurance (including insurance coverage), and health research, as was the practice before the 2016 Rule.

Section 92.206 of the 2016 Rule required covered entities to ''treat individuals consistent with their gender identity'' in every respect save one. Namely, ''a covered entity may not deny or limit health services that are ordinarily or exclusively available to individuals of one sex, to a transgender individual based on the fact that the individual's sex assigned at birth, gender identity, or gender otherwise recorded is different from the one to which such health services are ordinarily or exclusively available.'' This confusingly worded exception is premised on the fact that entities may provide specific services to ''one sex'' based on biology, yet must grant transgender individuals access to such single-sex services regardless of how they identify *and* regardless of their sex (''sex assigned at birth''). The 2016 Rule's mandate cannot answer, for example, how a provider is to determine whether or when a transgender individual is entitled by law to be referred to a women's mental health support group, a men's mental health support group, either group, or both at the same time.

Some providers choose to code and track patients according to their biology for some purposes and according to their gender identity for other purposes. Under the 2016 Rule, however, if a transgender patient self-identifies as male in the medical intake process, yet an examining doctor has reason to believe the patient is biologically female, the doctor could reasonably assume that he or she is *prohibited* from changing the person's chart to reflect female sex, because that would not be treating the person ''consistent with'' her stated gender identity.

In the 2019 NPRM, the Department cited a 2019 case from a medical journal article that concluded that a nurse had applied longstanding standards when triaging what the article called a ''man with abdominal pain,'' who identified as male and had been classified as such, but who was in fact a pregnant woman.[172] Because indications of pregnancy were not manifest, and because the patient was treated according to stated gender identity, her pregnancy was not diagnosed early, and the child was stillborn.

This provider was treating the patient according to her stated gender identity (male), just as the 2016 Rule demanded. Indeed, the provider risked liability under the 2016 Rule for not taking that step. The provider did not act unreasonably when, consistent with longstanding medical practice, it did not have a policy of asking every man with abdominal pain whether he is pregnant.

Unlike the many strained hypothetical objections offered in opposition to the proposed rule, this case is not based on speculation. Rather,

[167] *See, e.g.,* NIH Research Matters, Gene Linked to Sex Differences in Autism (Apr. 14, 2020), *https://www.nih.gov/news-events/nih-research-matters/gene-linked-sex-differences-autism;* Wei Yang, Nicole M. Warrington, *et al.,* Clinically Important Sex differences in GBM biology revealed by analysis of male and female imaging, transcriptome and survival data, Science Translational Medicine (Jan. 21, 2019), *https://www.ncbi.nlm.nih.gov/pubmed/30602536S* (identifying sex-specific molecular subtypes of glioblastoma); Ramona Stone and W. Brent Weber, Male-Female Differences in the Prevalence of Non-Hodgkin Lymphoma, 81 Journal of Environmental Health 16 (Oct. 2018); *https://www.ncbi.nlm.nih.gov/pubmed/28065609;* Anke Samulowitz, Ida Gremyr, et al., ''Brave Men'' and ''Emotional Women'': A Theory-Guided Literature Review on Gender Bias in Health Care and Gendered Norms towards Patients with Chronic Pain, Pain Research and Management (Feb. 25, 2018), *https://www.ncbi.nlm.nih.gov/pubmed/29682130* (stating that ''the response to opioid receptor antagonists may generate a difference between men's and women's experiences of pain''); Douglas C. Dean III, E.M. Planalp, *et al.,* Investigation of brain structure in the 1-month infant, Brain Structure and Function 1–18 (Jan. 5, 2018), *https://www.ncbi.nlm.nih.gov/pubmed/29305647* (finding differences between male and female infants at the age of 1 month); Stefan Ballestri, Fabio Nascimbeni, *et al.,* NAFLD as a Sexual Dimorphic Disease: Role of Gender and Reproductive Status in the Development and Progression of Nonalcoholic Fatty Liver Disease and Inherent Cardiovascular Risk, Advances in Therapy (May 19, 2017), *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5487879;* Susan Sullivan, Anna Campbell, *et al.,* What's good for the goose is not good for the gander: Age and gender differences in scanning emotion faces, 72:3 Journals of Gerontology 441 (May 1, 2017), *https://www.ncbi.nlm.nih.gov/pubmed/25969472;* Ester Serrano-Saiz, Meital Oren-Suissa, *et al.,* Sexually Dimorphic Differentiation of a C. Elegans Hub Neuron Is Cell Autonomously Controlled by a Conserved Transcription Factor, 27 Current Biology 199 (Jan. 5, 2017).

[168] NIH Guidance, *Consideration of Sex as a Biological Variable in NIH-funded Research* at 1 (2017), *https://orwh.od.nih.gov/sites/orwh/files/docs/NOT-OD-15-102_Guidance.pdf.*

[169] Janine Austin Clayton (Office of Research on Women's Health, NIH), ''Applying the new SABV (sex as a biological variable) policy to research and clinical care.'' *Physiology & Behavior* 187 (2018), 2.

[170] 81 FR 31467 (''Gender identity means an individual's internal sense of gender'' whose expression ''may or may not conform to social stereotypes associated with a particular gender''); 81 FR 31468 (''[sex] stereotypes can include the expectation that individuals will *consistently identify with only one gender* and that they will act in conformity with the gender-related expressions stereotypically associated with that gender.'') (emphasis added).

[171] *Cf.* 18 U.S.C. 249 (Shepard-Byrd Hate Crimes Act) (defining gender identity as ''actual or perceived gender-related characteristics'').

[172] *See* 84 FR 27855, n. 55, citing Daphne Stroumsa, Elizabeth F.S. Roberts, et al., ''The Power and Limits of Classification—A 32 Year Old Man with Abdominal Pain,'' New England Journal of Medicine (May 16, 2019), *https://www.ncbi.nlm.nih.gov/pubmed/31091369* (a patient with an electronic medical record classification as male did not receive care to treat ''labor, placental abruption, or preeclampsia—urgent conditions presenting a potential emergency'').

it involved the actual death of an unborn child and attendant trauma and anguish for those involved, all potentially because of a misdiagnosis resulting from a reliance on stated gender identity as opposed to sex. Given that life-and-death decisions are frequently made in healthcare settings and often in urgent circumstances, this story serves as an example of the consequences that could result from the confusion caused by the 2016 Rule and its mandate to treat individuals ''consistent with'' stated gender identity.

Comment: Commenters stated that it is clear that characteristics traditionally protected under antidiscrimination law are those inherent, immutable, and readily identifiable. They stated that a binary and biological definition of sex enables consistency and clarity about who is a member of the protected category, what the prohibited conduct is, how covered entities must comply both by inaction and action, and when government enforces a right against discrimination. Commenters stated that changing the definition of the protected category to an identity that is changeable and fluid results in a legal standard that is impractical if not impossible to apply to particular circumstances. Commenters found that those courts that recognize gender identity discrimination apply the prohibitions inconsistently.

Healthcare providers submitted comments stating that ''gender identity'' is a subjective psychological concept that cannot be anatomically located within the brain, and that no MRI or CT scan, autopsy, genetic testing, blood test, or pathology report can localize an ''internal sense'' and verify whether the gender identity of a patient is actually male, female, neither, or a combination of male or female.

Commenters stated that they did not understand the categories in the 2016 Rule's definition of gender identity which are not obviously limited in the number of possible permutations nor anchored in biology. Commenters were concerned that Title IX's prohibitions against disparate treatment of biological women as different from biological males may no longer be prohibited or even enforceable. When a protected category that was binary now becomes a subjective spectrum, commenters did not know what the substantive standard was to establish a facial violation, or how to apply it to particular facts. Some commenters stated that it contradicts Title IX to treat sex as a non-binary concept when the statute explicitly protects persons of either ''one sex'' or ''the other sex.'' Commenters stated the 2016 Rule retained the words male or female—two categories which have long formed the biological and binary concept of sex—but eliminated their substantive content. The breadth of the definition of gender identity included both exterior (''expression'') and interior (''internal'' sense) characteristics; mental (''identity'') and physical (''body characteristics''); variable over time (at birth vs. after birth), feminine or masculine (binary), both (''some combination''), and androgyny (''neither''). Commenters stated that they did not have clarity as to how to assess claims of ''either/or'' disparate treatment as well as ''both/and.'' Commenters also noted the text also included an expansive catchall provision stating that the definition of gender identity ''is not limited to'' what was in that enumerated list.

Response: The Department agrees that gender identity is difficult to define, in some cases difficult to categorize, and frequently very difficult to determine with objective certainty. For these and reasons stated elsewhere, the 2016 Rule's provisions on gender identity were confusing facially and in application. This final rule eliminates that confusion by returning to the plain meaning of the underlying statutes, relying as it does on the plain meaning of ''sex'' as biologically binary.

Comment: The Department received comments stating that the proposed rule would harm the privacy interests of children with gender dysphoria who seek to use restrooms according to gender identity and would otherwise encourage bullying. Commenters also alleged that in Federal court cases concerning gender identity unrelated to health services, courts have rejected arguments about competing privacy concerns of non-transgender individuals with respect to bathroom access for transgender individuals.

Response: These comments show that, although the preamble to the 2016 Rule had stated that it was not intended to overrule ''existing Federal, State and local laws, rules or regulations'' such as Title IX or its regulations, under which ''certain types of sex-specific facilities such as restrooms may be permitted'' such as bathrooms or intimate facilities,[173] even the 2016 Rule's supporters can reasonably interpret its provisions as doing precisely that.

The Department acknowledges that there is new and developing case law on the intersection of privacy concerns of non-transgender individuals and bathroom access for transgender individuals.[174] As commenters pointed out, there have been recent Title IX complaints regarding access to intimate facilities and associated case law. One complaint alleged a sexual assault by a male who identifies as female and had been granted access to a single-sex (female) facility based on stated gender identity.[175] Another incident involved dueling discrimination and privacy complaints concerning the use of communal shower facilities. After filing a complaint, a male who identifies as female was granted an exception to live as a female. A group of females filed complaints that their privacy rights were violated.[176] At least one Title IX complaint similar to these was denied by a court because of the specific facts of the case.[177] But the case law on such complaints is very new and still developing.

The Department notes that, regardless of whether Title IX *requires* covered entities to maintain sex-specific bathrooms, the Title IX regulations continue to *permit* policies that regulate intimate facilities based on sex. These regulations are consistent both with the ordinary, biological understanding of the word ''sex'' as reflected throughout the text of Title IX and the ordinary understanding of discrimination. Indeed, as the U.S. government has noted, the provisions in Title IX stating that nothing in that statute prohibits educational institutions from ''maintaining separate living facilities *for the different sexes*'' ''could not sensibly function if 'the term 'sex' includes 'gender identity,' which, unlike 'sex,' may not be limited to two categories.'' [178] Moreover, it has long been understood that, although ''separate bathrooms are obviously not blind to sex, they do not discriminate because of sex . . . so long as they do not treat men or women disadvantageously compared to the opposite sex.'' [179] In light of experience, including experience since the 2016 Rule was promulgated, the Department concludes that this final rule, by

[173] 81 FR 31409.

[174] *See, e.g., Soule* v. *Conn. Ass'n of Schools,* No. 3:20–cv–00201 (D. Conn. filed Feb. 12, 2020).

[175] Moriah Balingit, ''After Alleged Sexual Assault, Officials Open Investigation of Transgender Bathroom Policy,'' *The Washington Post* (Oct. 9, 2018), *https://www.washingtonpost.com/local/education/after-alleged-sexual-assault-officials-open-investigation-of-transgender-bathroom-policy/2018/10/09/431e7024-c7fd-11e8-9b1c-a90f1daae309_story.html.*

[176] *See* Department of Defense, ''Report and Recommendations,'' 37.

[177] *See Doe* v. *Boyertown Area Sch. Dist.,* 897 F.3d 518, 531–33 (3d Cir. 2018).

[178] Statement of Interest for DOJ, *Soule* v. *Conn. Ass'n of Schools,* 3:20–cv–00201–RNC (D. Conn., filed March 27, 2020) at 5.

[179] Brief for EEOC, *Harris Funeral Homes,* at 36.

removing the possibility that the Section 1557 regulations could be read as overruling Title IX's regulatory permission to maintain certain sex-segregated facilities (a permission consonant with Title IX's prohibition on sex discrimination, as explained above), will better permit covered entities to balance relevant privacy interests. The Department declines to retain a provision that could reasonably be read to prohibit covered entities from recognizing the difference between men and women or acting to protect men's and women's privacy interests in HHS-funded health programs or activities.[180]

Comment: Some commenters challenged the requirement under the 2016 Rule that medical professionals must use a patient's preferred pronouns based entirely on self-identification, regardless of biological sex or the presence or absence of surgery or the use of masculinizing or feminizing hormone treatments. Some commenters disagreed with any requirement that forces providers to treat patients in a manner other than according to their biological sex, including through coerced use of pronouns. Others stated that social transition treatment required providers to use the preferred pronouns or preferred names of patients, and to identify patients according to their preferred sex effectively at all times.

Response: The 2016 Rule preamble held out a provider's ''persistent and intentional refusal to use a transgender individual's preferred name and pronoun and insistence on using those corresponding to the individual's sex assigned at birth'' as a potential example of hostile-environment sex discrimination under Section 1557.[181] At least one district court has held similarly that when a provider allegedly ''continuously referred to'' a transgender patient ''with female pronouns'' in accordance with her sex, this could be sufficient grounds for a sex discrimination claim under Section 1557 in light of the *Price Waterhouse* ''stereotyping'' theory discussed above.[182] This view, again, rested on a misreading of Title IX.

Pronouns are not stereotypes. Pronouns reflect the most elementary sex-based classification in the English language. They are routinely used in scientific contexts to refer to humans as well as any other animals that are either male or female. They identify an individual's sex, which is an essential element of determining sex-based discrimination under Title IX. This final rule does not interfere with the medical judgment of any covered entity in treating gender dysphoria, but Title IX cannot be used to require covered entities to ignore or override the underlying distinctions of sex that Title IX itself is premised upon.

The Department thus does not believe that Title IX requires participants in covered entities to use a pronoun other than the one consistent with an individual's sex and does not believe it otherwise appropriate to dictate pronoun use or force covered entities to recognize a conception of sex or gender identity with which they disagree for medical, scientific, religious, and/or philosophical reasons. This final rule does not prevent covered entities from maintaining or adopting pronoun policies, or endorsing a variety of theories of gender identity, to the extent otherwise allowed by statutory and constitutional law. This rule also does not prevent State and local jurisdictions from imposing such policies to the extent allowed by statutory and constitutional law.

Comment: A commenter contended that the Department exceeded its authority by proposing to roll back protections for transgender individuals, noting that a 2012 letter from OCR stated that Section 1557 protections included gender identity.[183]

Response: Consistent with the position taken by the Executive Branch on Title IX since 2017, the Department has concluded that the position stated in the 2012 OCR letter reflected an incorrect understanding of Title IX, as incorporated into Section 1557. The Department indefinitely suspended the sub-regulatory guidance contained in the 2012 letter in light of the proposed changes to the rule. 84 FR 27872 n.175. Having considered the matters raised fully, the Department disavows the views expressed in the 2012 letter that concern the coverage of gender identity and sex discrimination under Section 1557. Similarly, the Department disavows the views expressed in a voluntary resolution agreement entered into with The Brooklyn Hospital Center in 2015 resolving allegations of gender identity discrimination under Section 1557.[184] To the extent that those views were integrated or incorporated into the 2016 Rule with respect to gender identity, they are rescinded in this final rule.

Comment: Many commenters asserted that the proposed rule removes legal protections for transgender individuals and would allow or encourage providers to deny basic healthcare to individuals who identify as transgender. Commenters pointed to what they said were instances of discrimination on the basis of the identity of the patient as a transgender individual, where providers allegedly used excessive precautions, avoided touching the patient, engaged in unnecessary physical roughness in pelvic examinations, made insensitive jokes, intentionally concealed information about options for different treatments, asked unnecessarily personal questions, referred to transgender patients by pronouns and terms of address based on their biological sex rather than their gender identity, and/or disclosed a patient's medical history without authorization. Others cited 15 closed cases handled by OCR of alleged discrimination against transgender individuals in which providers had refused sex-specific care or coverage on the basis of discrepancies between the individual's sex and stated gender identity.

Response: The Department believes that all people should be treated with dignity and respect, regardless of their characteristics including their gender identity, and they should be given every protection afforded by the Constitution and the laws passed by Congress. The Department is committed to fully and vigorously enforcing all of the nondiscrimination statutes entrusted to it by Congress. For reasons explained above, the term ''on the basis of . . . sex'' in Section 1557 does not encompass discrimination on the basis of gender identity. Unprofessional conduct such as inappropriate jokes or questions, excessive precautions, or concealment of treatment options, may be covered under State medical malpractice, tort, or battery laws.

Commenters' concern about denial of basic healthcare to transgender

[180] *See* OCR Voluntary Resolution Agreement with The Brooklyn Hospital Center (requiring assignment of persons to shared patient rooms according to gender identity) (2015), sub-regulatory guidance contained therein since *abrogated,* as discussed above, *https://www.hhs.gov/sites/default/files/ocr/civilrights/activities/agreements/TBHC/vra.pdf.*

[181] 81 FR 31406.

[182] *See Prescott* v. *Rady Children's Hospital-San Diego,* 265 F. Supp. 3d 1090, 1098–100 (S.D. Cal. 2017) (''As other courts have recognized, '[b]y definition, a transgender individual does not conform to the sex-based stereotypes of the sex that he or she was assigned at birth. '. . . The Complaint alleges that the RCHSD staff discriminated against Kyler by continuously referring to him with female pronouns, despite knowing that he was a transgender boy and that it would cause him severe distress. . . . Accordingly, Ms. Prescott's claim on behalf of Kyler survives under [Section 1557 of] the ACA.'').

[183] *See* Letter from Leon Rodriguez, Director, U.S. Dep't of Health & Human Servs., Office for Civil Rights, to Maya Rupert, Federal Policy Director, National Center for Lesbian Rights (Jul. 12, 2012), *available at https://perma.cc/RB8V-ACZU.*

[184] *See* OCR Voluntary Resolution Agreement with The Brooklyn Hospital Center.

individuals appears to be based largely on unsubstantiated hypothetical scenarios. Although some rare instances have been reported, they are not recent, and the Department is unaware of a significant number of cases where a transgender individual who has accurately identified his or her (biological) sex to a provider has nonetheless been denied relevant, non-transition-related healthcare on the basis of his or her gender identity. The Department is not aware of any providers claiming that they see a need for or wish to make broad, identity-based denials of care. To the contrary, many providers who specifically object to the 2016 Rule's mandates with respect to sex-reassignment treatments and/or elective abortion procedures explicitly affirmed in comments their commitment to treat all patients without regard to self-identification, inclusive of gender identity or sexual orientation. In the anecdotes of discrimination reported by commenters, what is often being alleged is poor care or insensitive treatment rather than outright denial of care, and is often lacking documentation. This lack of substantial evidence supports the Department's understanding, in contrast to the allegations of some commenters, that denial of basic healthcare on the basis of gender identity is not a widespread problem in the U.S. Moreover, to the extent that the 2016 Rule provided against denial of basic healthcare on the basis of gender identity, those provisions of the rule have been preliminarily enjoined since December 2016 and have since been vacated; any future mistreatment hypothesized by commenters would not, then, be the result of this final rule.

Additionally, several of the behaviors alleged by commenters would be unlawful even if Title IX and Section 1557 had never been enacted. Unnecessary roughness in a pelvic examination, or any other medical procedure or examination without a medical basis or appropriate informed consent, may be a case of battery or malpractice, which should be reported to local law enforcement and/or licensing authorities. If such conduct willfully causes bodily injury because of gender identity, and is in or affecting interstate commerce, then it could be a Federal hate crime.[185] When OCR becomes aware of any crimes that may violate Federal law, it may be required to make a referral to the Department of Justice.[186] The Emergency Medical Treatment and Labor Act (EMTALA) also requires stabilization in certain emergency medical situations.

OCR also continues to enforce Federal health information privacy laws to ensure the confidentiality of all individuals' protected medical information, including information concerning gender dysphoria diagnosis or treatment, sexual orientation, or HIV status.[187]

The Department, through its Offices of Minority Health, supports outreach to diverse populations and those facing particularized or disproportionate health challenges.

Comment: Commenters alleged that removing the definitions of ''gender identity'' and ''on the basis of sex'' (which includes gender identity) from the rule would ''erase'' transgender individuals from the *Code of Federal Regulations.*

Response: The Department denies that removal of definitional terms in one regulation has the wide-ranging impact that commenters allege. Under this final rule, transgender individuals remain protected by the same civil rights laws as any other individual, and the Department will vigorously enforce their statutory and regulatory civil rights. This final rule also does not and cannot erase explicit statutory protections for individuals on the basis of gender identity, such as in hate crimes laws that bar violence committed on the basis of an individual's gender identity.[188]

iii. Termination of Pregnancy

Comment: Commenters reacted to the proposed rule's elimination of the 2016 Rule's language that had encompassed ''termination of pregnancy'' within the definition of ''on the basis of sex.'' Commenters stated that the Department's declining to take a position about the full scope of the meaning of ''termination of pregnancy'' in the 2019 NPRM was confusing, and that the point merited clarification. Some providers objected to the inclusion of ''termination of pregnancy'' under the 2016 Rule to the extent that it referred to elective abortions. Other providers interpreted ''termination of pregnancy'' to mean both elective abortion and natural termination of pregnancies. Others stated that all forms of termination of pregnancy should be encompassed in the prohibition on discrimination on the basis of sex.

Some commenters stated that removing the 2016 Rule's definition of ''on the basis of sex'' will allow discrimination against women based upon their abortion history. Commenters also identified a variety of other women's healthcare services related to pregnancy that may be implicated, including prenatal and postpartum services, tubal ligations, and birth control (both as a contraceptive and when used to treat other medical conditions). They also referred to infertility treatments including in vitro fertilization, and pointed to *Benitez* v. *North Coast Women's Care Medical Group, Inc.*[189] as a real-world example of discrimination in this regard. Commenters said that the proposed rule would or could permit discrimination against women through denial or restriction of access to treatments such as these, as well as treatments prior to, during, or after a miscarriage.

Response: Under this final rule, the Department will interpret Section 1557's prohibition on sex-based discrimination consistent with Title IX and its implementing regulations. This final rule ensures that the Department's Section 1557 regulations are implemented consistent with the abortion neutrality and statutory exemptions in Title IX. The regulations are subject to the text of the Title IX statute, so they cannot be ''construed to require or prohibit any person, or public or private entity, to provide or pay for any benefit or service, including the use of facilities, related to an abortion.'' 20 U.S.C. 1688. As explained below, this final rule also incorporates that statutory text explicitly into the Title IX regulations for the sake of clarity, to ensure those regulations are

[185] 18 U.S.C. 249(c)(4) (prohibiting hate crimes that are based on ''actual or perceived religion, national origin, gender, sexual orientation, gender identity, or disability'').

[186] *See* 34 U.S.C. 41303 (''All departments and agencies within the Federal government . . . shall report details about crime within their respective jurisdiction to the Attorney General''); 28 U.S.C. 535(b) (''any information, allegation, or complaint received in a department or agency of the executive branch of government relating to violations of title 28 involving Government officers and employees shall be expeditiously reported to the Attorney General by the head of the department or agency'').

[187] *See* U.S. Department of Health and Human Services, ''Careless handling of HIV information jeopardizes patient's privacy, costs entity $387k'' (May 23, 2017), available at *https://www.hhs.gov/about/news/2017/05/23/careless-handling-hiv-information-costs-entity.html* (OCR enforcement under HIPAA); *see also* U.S. Department of Health and Human Services, ''HHS Office for Civil Rights Secures Corrective Action and Ensures Florida Orthopedic Practice Protects Patients with HIV from Discrimination'' (Oct. 30, 2019), *https://www.hhs.gov/about/news/2019/10/30/hhs-ocr-secures-corrective-action-and-ensures-fl-orthopedic-practice-protects-patients-with-hiv-from-discrimination.html* (OCR enforcement under Section 504 and Section 1557).

[188] *See* 18 U.S.C. 249(c)(4) (prohibiting hate crimes that are based on ''actual or perceived religion, national origin, gender, sexual orientation, gender identity, or disability'').

[189] *Benitez* v. *N. Coast Women's Care Med. Grp., Inc.,* 106 Cal. App. 4th 978 (Mar. 4, 2003).

implemented consistent with the statute.

The *Franciscan Alliance* court vacated the ''termination of pregnancy'' language in the 2016 Rule because it failed to incorporate the abortion-neutrality language from the Title IX statute.[190] The Court held that ''Congress intended to incorporate the entire statutory structure, including the abortion and religious exemptions,'' [191] and concluded that by failing to include these exemptions, the Department unlawfully ''expanded the 'ground prohibited under' Title IX that Section 1557 explicitly incorporated.'' [192]

The Department is committed to enforcing vigorously the prohibition on discrimination on the basis of sex, through its implementing regulations (which include provisions on termination of pregnancy), as interpreted consistent with the text of Title IX. OCR will fully enforce its statutory authorities concerning any discriminatory denial of access to women's health services, including those related to pregnancy. The Department, however, declines to speculate on particular hypotheticals related to termination of pregnancy, and will proceed based on the specific facts and circumstances of each case that may arise.

Comment: Some commenters stated that without the 2016 Rule, there would be serious and/or life-threatening results because hospitals would not provide abortion care on the basis of religious beliefs, referencing *ACLU* v. *Trinity Health Corporation,* 178 F. Supp. 3d 614 (E.D. Mich. 2016), and *Means* v. *U.S. Conference of Catholic Bishops,* No. 1:15–CV–353, 2015 WL 3970046 (W.D. Mich. 2015). Some alleged that the proposed rule does not comply with constitutional law regarding abortion or the applicable standard of scrutiny for sex discrimination and imposes undue burdens on women. Some stated that the proposed rule would hurt women's health by denying or encouraging denial of access to abortion.

Others submitted evidence challenging the idea that the termination of pregnancy provision, if retained (and not enjoined by a court), would materially increase abortion access for the average person. Specifically, they state that the overwhelming majority of abortions in America are performed at high-volume abortion clinics, and that there is no reason to suspect that retaining the 2016 Rule would lead to a significant increase in hospitals or other institutions willing to perform abortions when compared to abortion providers as a whole. According to commenters, this is in part because many hospitals and medical institutions that do not have a formal position objecting to abortion are free to engage in them now yet do not perform them or do so only to a limited extent.[193] Additionally, commenters said that the relative dearth of doctors willing to perform abortions at institutions appears largely to be a result of independent physician choices, not of the policies of institutions that object to abortions.

Some commenters were concerned that the 2016 Rule's provisions on termination of pregnancy devalue human life, both with respect to unborn children who lose their lives, and with respect to mothers, as many abortions are dangerous and lead to life-threatening complications for women. Other commenters stated that HHS has a compelling interest in defending the sanctity of innocent human life at all stages. Some institutional providers who object to abortion stated that they can and do treat women who have had miscarriages, even using techniques that are commonly used in abortion (such as dilation and curettage), so long as the procedure itself is not intended to and does not result in the taking of a human life.

Response: The Department appreciates all comments related to the highly controversial matter of abortion. The strong views that Americans hold on various sides of this question are an important policy reason supporting the Congressionally-enacted abortion-neutrality language in Federal statutes such as Title IX. Because Section 1557 expressly incorporated Title IX—therefore including the abortion-neutrality provision—the Department likewise incorporates that provision for purposes of the covered entities under Section 1557. This final rule also does not add any abortion-related conscience protections beyond those that Congress has set down in statute. Those statutes have not been held to be unconstitutional. The Department will vigorously enforce these and all other Federal civil rights statutes under its jurisdiction.

This final rule also does not abrogate other longstanding Federal laws that may apply to situations related to pregnancy, including EMTALA and the Pregnancy Nondiscrimination Act. The Department will read all applicable laws and exemptions harmoniously.[194] In addition, the termination of pregnancy provisions of the 2016 Rule have been enjoined since December 2016 and are now vacated. Finally, this rule does not change the legal ability of providers to offer abortions. The Department therefore disagrees with commenters who predict that the finalization of this rule will significantly reduce abortion access or cause resulting health consequences.

iv. Sexual Orientation

Comment: Some commenters stated that the 2016 Rule's § 92.209 should be removed because Title VII and Title IX do not include sexual orientation in their prohibition of sex discrimination. They used as an example the fact that the previous Administration treated sex, sexual orientation, and gender identity as different concepts in an executive order that prohibited discrimination on the basis of sex, sexual orientation, and gender identity in Federal hiring, contracting, and employment.[195] They added that Congress has rejected the sexual orientation and gender identity provisions in the Employment Non-Discrimination Act, the Equality Act, and the Student Non-Discrimination Act.

Others said that sexual orientation is a foundational trait of an individual and that cannot be separated and/or isolated from his or her being and that the proposed rule would enable discrimination based on sexual orientation. Other commenters cite a general fear of discrimination; abuse or neglect related to sexual orientation; a

[190] *Franciscan Alliance,* 227 F. Supp. 3d 660, 690–91 (N.D. Tex. 2016) (''Title IX prohibits discrimination on the basis of sex, but . . . . categorically exempts any application that would require a covered entity to provide abortion or abortion-related services. 20 U.S.C. 1688. . . . Failure to incorporate Title IX's religious and abortion exemptions nullifies Congress's specific direction to prohibit only the ground proscribed by Title IX. That is not permitted.''); *Franciscan Alliance,* 414 F. Supp. 3d 928, 945, 947 (N.D. Tex. 2019) (adopting reasoning from preliminary injunction and vacating the portions of the rule it deemed unlawful).

[191] *Franciscan Alliance,* 227 F. Supp. 3d at 690–91.

[192] *Id.* (citing *Corley* v. *U.S.,* 556 U.S. 303, 314 (2009)).

[193] As one commenter wrote, ''A 2018 study in the journal *Contraception* found that only 7% of obstetrician-gynecologists in private practice had performed an abortion in 2013 or 2014. An older study published in 2011 in *Obstetrics and Gynecology* found that 97% of practicing obstetrician-gynecologists encountered patients seeking an abortion, though only 14% performed them. Finally, a 2014 study published in *Perspectives on Sexual and Reproductive Health* found that just 5% of abortions take place in hospitals or physicians' offices, demonstrating that the vast majority of abortions are not performed by healthcare providers at hospitals or physicians' offices.''

[194] *See* 42 U.S.C. 13955dd(c)(1)(ii) (EMTALA); Public Law 95–555, 92 Stat. 2076 (Oct. 31, 1978) (Pregnancy Nondiscrimination Act).

[195] Exec. Order No. 13672, 79 FR 42971–72 (July 21, 2014), *https://www.govinfo.gov/content/pkg/FR-2014-07-23/pdf/2014-17522.pdf.*

lack of inclusive services; social isolation; a sense of invisibility; lack of educated providers; and distrust of the healthcare system. They argue that these burdens lead to inadequate care, including preventive care, and require a Federal response. In support of these claims, commenters cited a survey stating that 8% of lesbian, gay, and bisexual respondents allege they have been refused care from a healthcare provider due to their sexual orientation.[196] Other commenters, however, cited a survey showing that 97% of responding faith-based medical professionals attest that they ''care for all patients in need, regardless of sexual orientation, gender identification, or family makeup, with sensitivity and compassion, even when [they] cannot validate their choices.'' [197] Thus, some commenters argue, the issue is not one of refusing to care for certain patients based on identity, but instead a matter of declining to participate in a discrete set of morally controversial procedures and treatments that are available elsewhere.

Others said that discrimination because of an individual's sexual orientation is plainly a species of sex stereotyping that is impermissible under Section 1557's sex discrimination prohibition and cite *Baldwin* v. *Foxx,* an EEOC decision,[198] in support of the idea that the final rule should cover sexual orientation.

Response: OCR may only enforce laws that Congress has enacted and the regulations that were promulgated pursuant to that statutory authority. The plain meaning of ''sex'' under Title IX encompasses neither sexual orientation nor gender identity. Concerning commenters' discussion of Congress's failure to add sexual orientation and gender identity to contexts encompassed by Title IX or Title VII, the Department is guided primarily by its understanding of the plain meaning of the statute.[199] This final rule does not change the status quo with respect to sexual orientation, because, as the Department stated in the 2019 NPRM preamble, sexual orientation was not explicitly included in the 2016 Rule text,[200] and the Department has concluded that it is a category separate from sex and does not fall within the ambit of discrimination ''on the basis of sex.''

The U.S. Attorney General and Solicitor General have persuasively argued that *Price Waterhouse* does not elevate sexual orientation to a protected category using a sex stereotyping theory under Title VII, just as it fails to make gender identity a protected category under Title IX.[201] Much as the reasonable distinctions on the basis of sex discussed above (in the subsection on gender identity) are not illegitimate sex stereotypes, so too, distinctions on the basis of sexual orientation do not as such constitute sex stereotyping. As an initial matter, 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. The Eleventh Circuit has recently rejected the application of *Price Waterhouse* to expand ''sex'' to include ''sexual orientation,'' citing an abundance of case law in support.[202] Additionally, as the Solicitor General has argued, distinctions made on the basis of sexual orientation are not necessarily based on stereotypes, as they may instead be based on ''moral or religious beliefs about sexual, marital, and familial relationships.'' [203] ''There is nothing irrational or improper'' in such beliefs.[204]

The Department notes that in *Baldwin* v. *Foxx,* the EEOC reversed its long-held position that sexual orientation discrimination was not protected under Title VII.[205] The United States government has since rejected the

[196] *See* Shabab Ahmed Mirza and Caitlin Rooney, Discrimination Prevents LGBTQ People from Accessing Health Care, *Center for American Progress* (January 18, 2018), *https://www.americanprogress.org/issues/lgbt/news/2018/01/18/445130/discrimination-prevents-lgbtq-people-accessing-health-care/.*

[197] *See* Freedom2Care, ''Conscience in healthcare: 2019,'' *https://www.freedom2care.org/polling.*

[198] *Baldwin* v. *Foxx,* EEOC Appeal No. 0120133080, 2015 WL 4397641 (July 15, 2015).

[199] The Department agrees that Congressional inaction on this issue is supportive of the conclusion that Title IX does not encompass sexual orientation or gender identity, although it does not rely on this Congressional inaction in interpreting Title IX.

[200] 81 FR 31390 (''OCR has decided not to resolve in this rule whether discrimination on the basis of an individual's sexual orientation status alone is a form of sex discrimination.'').

[201] *See Bostock* v. *Clayton Cty. Bd. of Commissioners,* 2019 WL 4014070 at *26 (U.S. 2019) (Brief for the United States as *Amicus Curiae* Supporting Affirmance in No. 17–1618 (*Bostock* v. *Clayton Cty. Bd. of Commissioners*) and Reversal in No. 17–1623 (*Altitude Express Inc.* v. *Zarda*)) (''Title VII prohibits disparate treatment of men and women regardless of sexual orientation. Gay, lesbian, and bisexual employees, no less than straight employees, may invoke *Price Waterhouse* if they are subjected to gender-based stereotypes; a gay man who is fired for being too effeminate has just as strong a claim as a straight man who is fired for that reason.''). *See also Etsitty* v. *Utah Transit Authority,* 502 F.3d 1215, 1224–25 (10th Cir. 2007) (explaining that the legal issue ''is whether members of one sex are exposed to disadvantageous terms or conditions of employment to which members of the other sex are not exposed'').

[202] *Evans* v. *Georgia Reg'l Hosp.,* 850 F.3d 1248, 1256–57 (11th Cir. 2017) (''*Price Waterhouse* and *Oncale* are neither clearly on point nor contrary to *Blum* [v. *Gulf Oil Corp.,* 597 F.2d 936 (5th Cir. 1979) (''Discharge for homosexuality is not prohibited by Title VII. . . .'')]. These Supreme Court decisions do not squarely address whether sexual orientation discrimination is prohibited by Title VII.'') *Id.* at 1256–57 (''Finally, even though they disagree with the decisions, [the plaintiffs] acknowledge that other circuits have held that sexual orientation discrimination is not actionable under Title VII. *See, e.g., Higgins* v. *New Balance Athletic Shoe, Inc.,* 194 F.3d 252, 259 (1st Cir. 1999) (''Title VII does not proscribe harassment simply because of sexual orientation.''); *Simonton* v. *Runyon,* 232 F.3d 33, 36 (2d Cir. 2000) (''Simonton has alleged that he was discriminated against not because he was a man, but because of his sexual orientation. Such a claim remains non-cognizable under Title VII.''); *Bibby* v. *Phila. Coca Cola Bottling Co.,* 260 F.3d 257, 261 (3d Cir. 2001) (''Title VII does not prohibit discrimination based on sexual orientation.''); *Wrightson* v. *Pizza Hut of Am.,* 99 F.3d 138, 143 (4th Cir. 1996), *abrogated on other grounds by Oncale* v. *Sundowner Offshore Servs.,* 523 U.S. 75, 118 S. Ct. 998, 140 L.Ed.2d 201 (1998) (''Title VII does not afford a cause of action for discrimination based upon sexual orientation. . . .''); *Vickers* v. *Fairfield Med. Ctr.,* 453 F.3d 757, 762 (6th Cir. 2006) (''[S]exual orientation is not a prohibited basis for discriminatory acts under Title VII.''); *Hamner* v. *St. Vincent Hosp. & Health Care Ctr., Inc.,* 224 F.3d 701, 704 (7th Cir. 2000) (''[H]arassment based solely upon a person's sexual preference or orientation (and not on one's sex) is not an unlawful employment practice under Title VII.''); *Williamson* v. *A.G. Edwards & Sons, Inc.,* 876 F.2d 69, 70 (8th Cir. 1989) (''Title VII does not prohibit discrimination against homosexuals.''); *Rene* v. *MGM Grand Hotel, Inc.,* 305 F.3d 1061, 1063–64 (9th Cir. 2002) (''[A]n employee's sexual orientation is irrelevant for purposes of Title VII. It neither provides nor precludes a cause of action for sexual harassment. That the harasser is, or may be, motivated by hostility based on sexual orientation is similarly irrelevant, and neither provides nor precludes a cause of action.''); *Medina* v. *Income Support Div.,* 413 F.3d 1131, 1135 (10th Cir. 2005) (''Title VII's protections, however, do not extend to harassment due to a person's sexuality. . . . Congress has repeatedly rejected legislation that would have extended Title VII to cover sexual orientation.'') (internal quotations omitted). *Evans* and the EEOC question these decisions, in part, because of *Price Waterhouse* and *Oncale.* Whether those Supreme Court cases impact other circuit's decisions, many of which were decided after *Price Waterhouse* and *Oncale,* does not change our analysis that *Blum* is binding precedent that has not been overruled by a clearly contrary opinion of the Supreme Court or of this Court sitting *en banc.*'').

[203] *Bostock* v. *Clayton Cty. Bd. of Commissioners,* 2019 WL 4014070 at *25 (U.S. 2019) (Brief for the United States as *Amicus Curiae* Supporting Affirmance in No. 17–1618 (*Bostock* v. *Clayton Cty. Bd. of Commissioners*) and Reversal in No. 17–1623 (*Altitude Express Inc.* v. *Zarda*)).

[204] *See Tuan Anh Nguyen* v. *INS,* 533 U.S. 68. *See also Obergefell* v. *Hodges,* 135 S. Ct. 2585, 2602 (2015) (referring to opinions that are ''based on decent and honorable religious or philosophical premises'' and are therefore not ''disparaged here''); *See Masterpiece Cakeshop* v. *Colorado Civil Rights Comm'n,* 138 S. Ct. 1719, 1729 (2018) (''To describe a man's faith as 'one of the most despicable pieces of rhetoric that people can use' is to disparage his religion in at least two distinct ways: by describing it as despicable, and also by characterizing it as merely rhetorical—something insubstantial and even insincere.'').

[205] *See e.g., Angle* v. *Veneman,* EEOC Decision No. 01A32644, 2004 WL 764265, at *2 (Apr. 5, 2004) (recognizing that the EEOC had ''consistently held that discrimination based on sexual orientation is not actionable under Title VII''), *Marucci* v. *Caldera,* EEOC Decision No. 01982644, 2000 WL 1637387, at *2–*3 (Oct. 27, 2000).

EEOC's novel position.[206] Given Congress's decision not to extend civil rights protections on the basis of sexual orientation 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.

v. Scrutiny for Sex-Based Classifications (Repeal of § 92.101(b)(3)(iv) of the 2016 Rule)

The Department proposed to repeal 92.101(b)(3)(iv) of the 2016 Rule, which forbids covered entities from operating a health program or activity restricted to members of one sex unless they can ''demonstrate an exceedingly persuasive justification, that is, that the sex-specific health program or activity is substantially related to the achievement of an important health-related or scientific objective.'' [207]

Comment: Commenters stated that the 2016 Rule's provisions would pose an unjustified burden on, and lead to excessive scrutiny of, entities operating single-sex facilities in healthcare, as well as entities or persons who would claim religious or abortion exemptions under Title IX.

Response: The Department agrees that the 2016 Rule placed an unjustified burden on sex-specific health programs and activities conducted by private entities. The ''exceedingly persuasive justification'' legal standard under Equal Protection jurisprudence sets a limit to *governmental* actions that discriminate on the basis of sex, such as the military draft.[208] This standard is foreign to Title IX jurisprudence.[209] The 2016 Rule cited no case law in support of its decision to import a significantly modified version of this standard from constitutional law into its interpretation of ''on the basis of sex'' as defined by Title IX.[210] The express statutory exemptions to Title IX's nondiscrimination provisions, such as for fraternities and sororities, do not require individual covered entities to provide an ''exceedingly persuasive justification'' before being able to benefit from the exemption. Title IX also does not require religious entities to provide such a justification to qualify for the religious exemption from Title IX nondiscrimination provisions. To require such a justification in the enforcement of Section 1557 would be to impose a significant burden on private entities that the statutory text does not contemplate. Government actors are routinely subjected to levels of judicial scrutiny that private parties (even private parties receiving Federal funds) are not, such as where constitutional provisions restrict government action, or where statutes allow civil rights actions against State actors. *See, e.g.,* 1st Am., U.S. Const.; 42 U.S.C. 1983; 42 U.S.C. 2000bb, *et seq.* It would be inappropriate to constrain medical professionals' best judgment by requiring them to meet the governmental burden of proof every time they seek to draw a reasonable distinction on the basis of sex in providing healthcare or separate programs or activities for the two sexes.[211] As stated above, such distinctions are not inherently discriminatory: It is not discriminating against men to exclude them from, for example, gynecological services, because men are not similarly situated to women for purposes of such services. Providers accordingly should not be required to present an ''exceedingly persuasive justification'' for providing gynecological services only to women. OCR will, however, evaluate, and respond appropriately to, any allegations that a covered entity's sex-specific health programs or activities have in fact discriminated unlawfully on the basis of sex, including sexual harassment.[212]

vi. Disparate Impact Under § 92.101(b)(3)(iii) of the 2016 Rule

The Department proposed to repeal 92.101(b)(iii) of the 2016 Rule, which prohibited selection of sites or facilities that have an effect of discriminating on the basis of sex.[213]

Comment: Some commenters opposed repealing language that affirmed a disparate impact theory under grounds of nondiscrimination encompassed by Section 1557, contending that the civil rights statutes cited in Section 1557 authorize disparate impact claims.

One commenter asserted that the very existence of Section 1557 indicates that the ACA intends to extend protections against disparate impact discrimination to private rights of action: Title VI already applied in the context of healthcare programs and activities, so Section 1557 would have been meaningless if it did not also allow for private rights of action for disparate impact discrimination. The same commenter also took issue with the proposed rule's elimination of monetary damages for disparate impact claims.

Response: Case law has indicated that certain civil rights statutes incorporated by Section 1557 do authorize disparate impact claims: Namely, claims with respect to discrimination on the basis of race, color, national origin, and disability.[214] Title IX, however, authorizes no such claims regarding discrimination on the basis of sex. Similarly, provisions relating to site or facility selection based on race, color, national origin, or disability are found in HHS's Title VI and Section 504 regulations, but are not found in HHS's Title IX regulations.[215] Insofar as the 2016 Rule added new grounds of prohibited discrimination not found in the statute, the Department believes it is necessary to revert to the underlying statutes and their implementing regulations. As a result, to the extent any of the underlying statutes authorize disparate impact claims, this final rule will recognize such claims by virtue of its reliance on the governing statutes, regulations, guidance and case law applicable to such claims, without needing to delineate the availability or lack of availability of all possible claims in this final rule. In reviewing all complaints that raise a disparate impact claim, the Department will consider the circumstances of each complaint and will independently apply each statute and underlying regulation, according to its text and any applicable court precedents, to the health context under Section 1557.[216]

Comment: Some commenters stated that that the proposed rule's removal of protections against disparate impact discrimination, especially concerning race, color, and national origin, will lead to more instances of discrimination and fewer means of recourse.

[206] *See* Brief for United States, *Bostock* v. *Clayton Cty. Bd. of Commissioners,* No. 17–1618 (U.S. filed Aug. 23, 2019).

[207] 81 FR 31470.

[208] *See Rostker* v. *Goldberg,* 453 U.S. 57, 69–70 (1981).

[209] *See, e.g.,* the clear distinction at *Whitaker* v. *Kenosha Unified Sch. Dist.,* 858 F.3d 1034, 1046–50 (7th Cir. 2017) (''Title IX Claim''), and 1050–54 (''Equal Protection Claim,'' encompassing the ''exceedingly persuasive justification'' test).

[210] *Cf.* 81 FR 31408–09.

[211] *See* 2016 Rule, 81 FR 31409 (''In all cases, . . . OCR will expect a covered entity to supply objective evidence, and empirical data if available, to justify the need to restrict participation in the program to only one sex.'').

[212] *See* U.S. Department of Health and Human Services, ''HHS OCR Secures Agreement with MSU to Resolve Investigation into Sexual Abuse by Larry Nassar'' (2019), *https://www.hhs.gov/about/news/2019/08/12/hhs-ocr-secures-agreement-msu-resolve-investigation-sexual-abuse-larry-nassar.html.*

[213] 81 FR 31470.

[214] *See* 45 CFR 84.4(b)(4) (Title VI); 80.3(b)(2) (Section 504).

[215] *See* 45 CFR 80.3(b)(3) (Title VI); 84.4(b)(5) (Section 504).

[216] The Department responds to comments on private rights of action and damages below in the section on the enforcement mechanisms of the 2016 Rule.

Commenters cited data about health disparities in LGBT and female populations that they asserted were caused by discrimination on the basis of gender identity or termination of pregnancy, and stated that disparate impact analysis under the 2016 Rule is the appropriate way to address such discrimination. Another commenter questioned the persuasiveness of assessing the relative proportion of health disparities between racial, transgender, and/or female populations and other populations. The commenter stated that the available data did not provide conclusive evidence that the health disparities were caused by discriminatory conduct against LGBT persons and individuals seeking abortions, because correlations are not definite evidence of causation. The commenter contended that the proposed rule's approach causes ambiguity by blurring the distinctions between the two.

Response: As an initial matter, the Department wishes to reiterate that it will enforce Section 1557 in light of its regulations that already protect against disparate impact on the basis of race, color, or national origin. With respect to concerns regarding disparate impact on LGBT and abortion-seeking populations, the Department notes that this final rule conforms the Section 1557 Rule to HHS's Title IX regulations, under which the disparate impact standard does not apply. This conformity provides a clearer standard for covered entities, which are no longer required to have legally sufficient knowledge of the causes of statistically disproportionate health disparities on the basis of sex or gender identity.

vii. Insurance Coverage in § 92.207 of the 2016 Rule

The 2016 Rule prohibited insurers from ''hav[ing] or implement[ing] a categorical coverage exclusion or limitation for all health services related to gender transition.'' [217] Its preamble explained that this encompasses a ''range of transition-related services'' to treat gender dysphoria that are ''not limited to surgical treatments and may include, but [are] not limited to, services such as hormone therapy and psychotherapy, which may occur over the lifetime of the individual,'' and that may be required even if not ''strictly identified as medically necessary or appropriate'' insofar as the entity covers other types of similarly ''elective'' procedures.[218]

[217] 81 FR 31472, 31435–36.

[218] *Id.*

Comment: Commenters indicated support for the 2016 Rule's insurance coverage requirements, claiming that the Rule has led to increased access to gender transition services for transgender patients, and that these services will be lost if the proposed rule is finalized. In comments, clinicians provided information about the specific procedures, services, or treatments they perform or offer with respect to gender identity. Among those who offer medical interventions under the category of ''gender transition,'' there was a consensus that such interventions included genital sex reassignment surgeries, cross-sex hormonal treatment, counseling, and often psychological or psychiatric support. Some clinicians stated that only patients with longstanding identification as the opposite sex and distress with their biological sex sought these services. Beyond these, some (but not all) clinicians indicated that gender transition procedures could also include surgery for feminization or masculinization of the entire body, which could include reduction, augmentation, removal, or transplant of tissue, skin, hair, or body fat, as well as ''social transition'' services such as voice training.[219]

Some commenters regard transition services (which they said may include counseling, hormone therapy, and/or a variety of possible surgical treatments) as the governing standard of care. They directed the Department to studies on the matter including those cited in the 2016 Rule preamble, and cited what they said is a consensus of major American medical associations [220] about sex-reassignment surgery, cross-sex hormones, and affirmation counseling.

[219] Examples of procedures identified were rhinoplasty, blepharoplasty, septoplasty, rhytidoplasty, abdominoplasty, electrolysis, liposuction, jawline modifications, scalp advancement, cheek and chin contouring, fat transfer, pectoral implants, forehead or brow lifts, or breast, buttocks, breast, waist, or lip augmentation/reduction. *See* Whitman-Walker Health; Philadelphia Transgender Center. HHS–OCR–2019–0007–138335 (Whitman-Walker Health). *http://www.thetransgendercenter.com/index.php/femaletomale1/ftm-price-list.html; http://www.thetransgendercenter.com/index.php/maletofemale1/mtf-price-list.html.*

[220] Commenters cited Jason Rafferty, ''Ensuring Comprehensive Care and Support for Transgender and Gender-Diverse Children and Adolescents,'' 142 *Pediatrics* no. 4 (Oct. 2018) (American Academy of Pediatrics policy statement), and noted that the American Medical Association, the American College of Physicians, the American Psychological Association, the American Psychiatric Association, the American Academy of Family Physicians, the Endocrine Society the American College of Obstetricians and Gynecologists, and the American Academy of Pediatrics, among others, support transition-related treatments.

Commenters urged the Department to follow the 2016 Rule in relying on the standards promulgated by the World Professional Association for Transgender Health (WPATH).[221]

Commenters stated that, under the WPATH standards and other protocols, treatment for gender dysphoria may require transition-related care.[222] Commenters asserted specific benefits from transition-related care in treating gender dysphoria.[223] For example, commenters said that access to transition services leads to decreased health disparities, such as lower levels of depression and suicide attempts.[224]

With respect to adolescents, some commenters promoted approaches that affirm or encourage gender identity variation, including sex reassignment, citing data that they said showed it resulted in fewer mental health concerns.[225] Some medical professionals also stated in comments that hormone blockers are a safe and reversible way to delay puberty, noting

[221] *See* 81 FR 31429.

[222] Commenters cited, for example, Wylie C. Hembree et al., *Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline,* 102 The Journal of Clinical Endocrinology & Metabolism 3869 (2017); Am. Medical Ass'n, *AMA Policies on GLBT Issues, Patient-Centered Policy H–185.950, Removing Financial Barriers to Care for Transgender Patients* (2008), *http://www.imatyfa.org/assets/ama122.pdf;* and Am. Psychiatric Ass'n, *Position Statement on Discrimination Against Transgender and Gender Variant Individuals* (2012); *http://www.dhcs.ca.gov/services/MH/Documents/2013_04_AC_06d_APA_ps2012_Transgen_Disc.pdf* (citing WPATH *Standards*); Am. Psychological Ass'n, *Policy on Transgender, Gender Identity & Gender Expression Non-Discrimination* (2008), *http://www.apa.org/about/policy/transgender.aspx.*

[223] Commenters cited, for example, Ashli A. Owen-Smith, et al., *Association Between Gender Confirmation Treatments and Perceived Gender Congruence, Body Image Satisfaction, and Mental Health in a Cohort of Transgender Individuals.* J Sexual Medicine (Jan. 17, 2018); Gemma L. Witcomb et al., *Levels of Depression in Transgender People and its Predictors: Results of a Large Matched Control Study with Transgender People Accessing Clinical Services,* J. Affective Disorders (Feb. 2018); and Cecilia Dhejne et al., *Mental Health and Gender Dysphoria: A Review of the Literature,* 28 Int'l Rev. Psychiatry 44 (2016).

[224] Commenters cited, for example, Lily Durwood, Katie A. McLaughlin, & Kristina R. Olson, *Mental Health and Self-Worth in Socially Transitioned Transgender Youth,* 56 J. Am. Acad. Child Adoles. Pyschiatry 116 (2017); Kristina R. Olson et al., *Mental Health of Transgender Children Who Are Supported in Their Identities,* 137 Pediatrics (2016); and Stephen T. Russel et al., *Chosen Name Use Is Linked to Reduced Depressive Symptoms, Suicidal Ideation, and Suicidal Behaviors Among Transgender Youth,* 64 J. Adolescent Health 503 (2018), *https://www.jahonline.org/article/S1054-139X(18)30085-5/fulltext.*

[225] Commenters cited Hill DB, Menvielle E, Sica KM, Johnson A. *An affirmative intervention for families with gender variant children: parental ratings of child mental health and gender.* J Sex Marital Ther. 36(1):6–23 (2010).

they have been used historically for children experiencing precocious puberty, or puberty at a younger age.

Other commenters disagreed as to whether sex reassignment treatments or surgeries, or gender-affirming therapies, are the proper care for gender dysphoria, or even whether they are ever medically indicated. Instead of surgery, hormones, or cross-sex affirmation counseling, some healthcare providers recommended watchful waiting, talk therapy that affirms a person's biological sex, or psychological or psychiatric treatment of comorbid conditions, as distinct from permanent surgical or hormonal interventions.[226] These providers explained that patients with gender dysphoria can work with a psychiatrist or counselor to better understand their feelings and emotions, and how the incongruence between their psychological identity and biological sex causes them distress. Some clinicians stated that reinforcing a patient's perception that there is something wrong with their body is damaging both to mental and physical health of transgender patients.

Some medical professionals discussed the long-term and irreversible physical effects of cross-sex hormones and puberty blockers, pointing to permanent deepening of voice, clitoromegaly, jaw enlargement, permanent sterility, and sexual dysfunction.[227] Doctors also commented that clinical data have not shown that such hormonal treatments improve the long-term psychological functioning of gender dysphoric persons. Clinicians stated that certain hormone treatments given to persons with gender dysphoria result in glucose and lipid metabolism disorders and cardiovascular conditions. Some clinicians were critical of the research supporting transition services, stating that it does not adequately assess such long-term health consequences and ignores a particularly vulnerable population of patients, namely the growing population of transitioned individuals who wish to transition back but are being ignored or impeded from receiving services affirming their biology.[228] They cited research indicating that patients did not need surgical or hormonal transition services when less drastic interventions would have been effective.[229] Clinicians stated that transition services were burdensome on these patients on several levels—financially, physically, and psychologically. Commenters concluded that repeal of the 2016 Rule would relieve the burden on these transgender individuals by letting providers decide, based on their assessment of individuals, what surgeries or treatments are appropriate according to their medical judgment and without coercive regulatory pressure.

Some medical providers raised concerns that prescription of sex-reassignment procedures and treatments had risked the health of young patients under their care due to lack of capacity at young ages to fully consent to treatments, difficulties with proper diagnosis during changes undergone in adolescence, and the negative impacts on bone mass and growth, emotional development, and sexual function.[230] Some clinicians stated that gender dysphoria is not an immutable mental health condition and, as such, the appropriate treatment is not physical and permanent. Some clinicians stated that current care for gender dysphoria includes accommodation counseling, the ''wait and see'' approach, and (where indicated) detransition therapy, because dysphoria, particularly in children, has a high rates of resolving without other interventions. They said that in their medical judgment, sex reassignment, cross-sex hormones, and affirming counseling are new and controversial treatments with known permanent and negative health consequences. Some medical clinicians criticized the WPATH standards[231] for coming to policy conclusions without adequate clinical evidence and recommending treatments that are still experimental.[232] Other commenters criticized the 2016 Rule for relying on the policy recommendations of an international advocacy group to

[226] Commenters cited sources including Monique Robles, ''Observations in a Gender Diversity Clinic,'' 44 Ethics & Medics 2 (Feb. 2019); and Devita Singh, Ph.D., ''A Follow-up Study of Boys with Gender Identity Disorder,'' Department of Human Development and Applied Psychology, Ontario Institute for Studies in Education, University of Toronto (2012).

[227] Commenters cited sources including Talal Alzahrani, M.D., et al., ''Cardiovascular Disease Risk Factors and Myocardial Infarction in the Transgender Population,'' *Circulation: Cardiovascular Quality and Outcomes* 12:4 (Apr. 2019), *https://www.ncbi.nlm.nih.gov/pubmed/30950651;* and Darios Getahun, M.D., et al., Cross-sex Hormones and Acute Cardiovascular Events in Transgender Persons, *Annals of Internal Medicine* (July 10, 2018), *https://www.ncbi.nlm.nih.gov/pubmed/29987313.*

[228] Commenters cited, for example, Miroslav L. Djordjevic et al., Reversal Surgery in Regretful Male-to-Female Transsexuals After Sex Reassignment Surgery, 13 J. of Sexual Med., 1000, 1006 (2016).

[229] Commenters cited, for example, Joe Shute, ''Sex change regret: Gender reversal surgery is on the rise, so why aren't we talking about it?'' *The Telegraph* (Oct. 1, 2017), *https://www.telegraph.co.uk/health-fitness/body/gender-reversal-surgery-rise-arent-talking.*

[230] Commenters cited, for example, Lieke Josephina Jeanne Johanna Vrouenraets, M.Sc., *et al.,* ''Early Medical Treatment of Children and Adolescents With Gender Dysphoria: An Empirical Ethical Study,'' *Journal of Adolescent Health* (Jan. 12, 2015), *https://www.ncbi.nlm.nih.gov/pubmed/26119518;* and Guido Giovanardi, ''Buying time or arresting development? The dilemma of administering hormone blockers in trans children and adolescents,'' *Porto Biomedical Journal* (2017).

[231] *See* Standards of Care for the Health of Transsexual, Transgender, and Gender Nonconforming People 16 (7th ed. 2011), *https://www.wpath.org/publications/soc.*

[232] Clinicians stated that the WPATH Standards ignored research evidence in support of a ''wait and see'' approach that gender dysphoria during childhood has a desistance rate, without drastic surgical or medical intervention for sex-reassignment or affirmation for social transition. They cited studies including Singh, D., ''A Follow Up Study of Boys with Gender Identity Disorder,'' doctoral dissertation submitted at University of Toronto (2012); Drummond, K. D., Bradley, S. J., Badali-Peterson, M., & Zucker, K. J., ''A follow-up study of girls with gender identity disorder,'' *Developmental Psychology* 44:1 (2008), 34–45; Wallien, M. S. C., & Cohen-Kettenis, P. T., ''Prediction of adult GID: A follow-up study of gender-dysphoric children,'' paper presented at the meeting of the World Professional Association of Transgender Health, Chicago, IL (2007); and Smith, Y.L., Van Goozen, S.H., & Cohen-Kettenis, P. T., ''Adolescents with gender identity disorder who were accepted or rejected for sex reassignment surgery: A prospective follow-up,'' *Journal of the American Academy of Child & Adolescent Psychiatry,* 40:4 (2001), 472–81.

interpret U.S. nondiscrimination laws and develop policy in the American healthcare sector. Other commenters disputed the conclusions of medical professional associations referenced above, stating that they had mischaracterized the medical data, and that life-altering transition interventions are not medically necessary, effective, or safe.[233]

Several commenters who expressed objections to the 2016 Rule clarified that they do not exclude patients from access to healthcare on the basis of the patient's gender identity, but rather objected to the rule requiring that they provide treatment that would be detrimental to the health and well-being of their patients. Part of their medical profession involves recommendations on which treatments will appropriately treat medical conditions to improve the health of their patients, and the choice not to provide transition surgery or abortion is part of those judgments. Some providers indicated that the options for treatment they recommend for patients with gender dysphoria are therapeutic and accommodative counseling to improve long-term health outcomes, particularly of young patients.

Other commenters said the Department should rely on the recent reviews of the clinical data on sex-reassignment surgery and cross-sex hormonal treatment by science and healthcare professionals at HHS and DOD.

Response: These comments further reinforce the Department's conclusion, discussed above in the section on gender identity, that there is no medical consensus to support one or another form of treatment for gender dysphoria. In the Department's current view, the 2016 Rule did not give sufficient evidence to justify, as a matter of policy, its prohibition on blanket exclusions of coverage for sex-reassignment procedures. The Department shares commenters' judgment that the 2016 Rule relied excessively on the conclusions of an advocacy group (WPATH) rather than on independent scientific fact-finding—such as the fact-finding that CMS undertook in deciding to not issue a National Coverage Determination with respect to sex-reassignment surgeries (as discussed above) due to insufficient proof of medical necessity. In addition, commenters identify a lack of clarity in the 2016 Rule's mandate, because of the lack of medical consensus as to what is even encompassed within ''gender transition procedures'' (*e.g.,* whether they include facial reconstruction or hair transplants). All these are further reasons why, as a matter of policy, Federal civil rights law should not be used to override providers' medical judgments regarding treatments for gender dysphoria. But as stated above, even if it were appropriate policy, such an end could not be achieved through application of Section 1557 and Title IX. There is no statutory authority to require the provision or coverage of such procedures under Title IX protections from discrimination on the basis of sex.

Comment: Some commenters state that the provisions in § 92.207(b)(3) through (5) of the 2016 Rule were confusing, overbroad, unclear, and inconsistent. Commenters stated that specificity in this area is necessary for efficient and transparent operation of the health insurance coverage to work for all involved. Commenters expressed concerns that the 2016 Rule did not address whether insurers are required to pay for all such surgeries, including without prior approval; approve them absent some standard of medical necessity; or approve them even over concerns of later malpractice lawsuits by the patient. A commenter reiterated his comments on the 2015 NPRM that the 2016 Rule's requirements related to gender transition were confusing for covered entities. The commenter said the regulatory requirement did not address which healthcare providers must provide these surgeries: *e.g.,* plastic surgeons, thoracic surgeons, general surgeons, or physicians whether or not they ordinarily perform major surgery. Others stated that although the 2016 Rule preamble characterized the categorical exclusion provision as a ''limited'' exception, the provisions on gender transition-related services were very broad and could include facial feminization or masculinization surgeries. Some commenters interpreted ''gender dysphoria'' as only affecting transgender individuals who seek sex re-assignment services, but other commenters cited clinical data indicating that men who had genital combat injuries and women who had removal of cancerous tissue in breasts and have received the diagnosis may also experience body dysmorphia.[234]

Other commenters stated that surgical sex reassignment (which may also include cross-sex hormonal treatment) may cost up to $22,025 on average for those covered by insurers. Still others said that the definition of ''gender dysphoria'' itself has changed rapidly and unpredictably over the years, leading to confusion, and point to its shifting conception as an experience of distress or a personal characteristic, to different and changing terms used for diagnosis of gender dysphoria in the DSM, and to the varied use of both clinical medical terms and sociological identity terms concerning the topic. The American Psychiatric Association justified the abandonment of the term ''gender identity disorder'' and its replacement with ''gender dysphoria'' in the Diagnostic and Statistical Manual of Mental Disorders to reduce stigmatization of the particular mental condition, but commenters noted that the DSM–5 made no changes to remove the classification of ''disorder'' for suicidal ideation, other body dysmorphias, or substance use disorder, which mental health advocates commented are also stigmatizing and may be comorbid with gender dysphoria.

Response: The Department agrees that the 2016 Rule made confusing and overbroad demands on covered entities, including insurance providers, and left unclear to what extent it was requiring providers to provide, or health insurance issuers to cover, treatments such as facial feminization, Adam's apple reduction, and hair transplants as part of ''health services related to gender transition.'' This final rule seeks to handle issues involving the exercise of legitimate medical judgment (including determinations relating to medical necessity and coverage decisions) with greater care, and to provide covered entities with greater clarity regarding their regulatory obligations.

Comment: Some commenters who identified as transgender patients opposed the proposed rule on the grounds that they had budgeted and planned with the expectation that there would be a limited or no cost for transition services due to the 2016 Rule, but they were surprised when they had an out-of-pocket cost not covered by their selected insurance company or plan. A much higher cost for these services resulted in the inability to receive or delay in receiving such services. They described surprise billing at multiple steps of the process, from reviewing health insurance coverage plans to waiting for reimbursements. These commenters stated that they anticipated and relied on OCR's 2016

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[233] *See* Michelle Cretella, ''Gender Dysphoria in Children'' (November 2018) (American College of Pediatricians policy statement); *see also* James Cantor, ''American Academy of Pediatrics Policy and Trans- Kids: Fact-Checking,'' *Sexology* (Oct. 2018).

[234] Commenters cited M. Jocelyn Elders, et al., ''Medical Aspects of Transgender Military Service,'' Armed Forces and Society 41(2) (Mar. 2014): 199–220.

Rule as guaranteeing them insurance coverage because it is provided to other patients, and that this was their understanding of the Affordable Care Act and their civil rights protections. Other commenters contended that the 2016 Rule had caused the reduction of blanket exclusions for gender transition in health insurance coverage over the past three years.[235] Others stated that short-term limited duration insurance plans do not provide coverage of gender transition-related services, and therefore if transgender individuals are covered by such plans, they would not be able afford medically necessary services.

Response: With respect to coverage for gender transition services, the Department notes that this final rule makes no changes to what has been the status quo since December 2016, when the Department was enjoined from enforcement of the gender identity provisions of the 2016 Rule; such provisions have now been vacated by a court. Any recent decrease in blanket exclusions for sex-reassignment coverage is therefore more likely to be attributable to health insurance issuer or plan sponsor choice. State-level legal requirements concerning gender identity coverage have also come into effect in recent years, such as State statutes, regulations, guidance,[236] and court orders [237]—this final rule does not affect those changes in any way. But to the extent that provisions in the 2016 Rule did pressure any insurers to cover services on the basis of gender identity that they previously had not covered, such provisions did so without statutory authority, which is why they were preliminarily enjoined and vacated.

As a policy matter, the Department recognizes that surprise billing is a serious problem, but that topic is not a subject of this rulemaking. As for short-term limited duration insurance, for reasons discussed below, it is generally not regulated under this final rule and so is generally not affected by the rule's nondiscrimination requirements in any case.

e. Discrimination on the Basis of Association, Repeal of § 92.209 of the 2016 Rule

The Department proposed to repeal § 92.209 of the 2016 Rule, which included a prohibition on discrimination against an individual or entity on the basis of being known to or believed to have a relationship or association.

Comment: Commenters opposed the repeal of prohibitions against discrimination based on association with a protected category. These commenters contended that removing such protections would cause confusion, both for covered entities who will be unsure of their responsibilities and for individuals who will be unsure of their rights, especially in light of other Federal nondiscrimination laws that the Department enforces. For example, the Department enforces Title II of the ADA and its implementing regulation, which prohibits discrimination against an individual based on his or her association with another individual with a disability, as do Titles I and III of the ADA.[238] Commenters said that this also shows that it would defy Congressional intent, and cause inconsistency among different regulations that covered entities are subject to, if the Department were to withdraw associational discrimination protections from patients seeking healthcare. Commenters also expressed concern that the proposed rule would make it more difficult for those experiencing discrimination by association to enforce their rights. Other commenters stated that the lack of reference to associational discrimination in the proposed rule is inconsistent with existing case law that validates prohibitions on associational discrimination, particularly in employment discrimination cases brought under Title VII pertaining to race, sex, and religion. Others argued that it is incorrect to assume that by referencing the grounds protected under previous civil rights laws, Section 1557 automatically incorporates the limitations found in those laws.

Some commenters contended that specific protected populations are more susceptible to associational discrimination. In particular, commenters stated that deaf and hard-of-hearing patients frequently use hearing companions, especially in hospital settings, and may be subject to associational discrimination. Commenters also identified potential instances of associational discrimination, including an entity's refusing to provide medical services to a white individual due to association with an African American individual, refusing to provide medical services to a child because his parents speak a different language, or refusing to provide services to an individual because her family members have a specific disability.

Response: This final rule neither abrogates nor withdraws any protections available under the incorporated civil rights statutes or their implementing regulations. It simply declines to use the Section 1557 regulation to identify protections beyond those specifically identified in the text of the relevant statutes and regulations. Protections against discrimination on the basis of association will be available under this final rule to the extent that they are available under those statutes and regulations. As stated above, the Department regards this as the best way to decrease confusion. As the *Franciscan Alliance* court noted, the executive branch is obligated to implement Section 1557, with the civil rights statutes it incorporates, by ''giving the statutory text its plain and ordinary meaning, construing the statute as a whole, and giving effect to every word of the statute.'' [239] Courts have held that Section 1557 incorporates the limitations of the civil rights statutes referenced in Section 1557.[240]

Some instances discussed by commenters would appear to constitute discrimination against a person under the underlying civil rights statutes even without the 2016 Rule's prohibition on associational discrimination. For example, if a covered entity refused to provide meaningful access for LEP parents who are legally entitled to make medical decisions on behalf of their child, it could constitute discrimination on the basis of national origin.

f. Multiple Protected Statuses

The Department received many comments about individuals who may have protected status or face discrimination on multiple grounds.

[235] Commenters cited sources including, *e.g.*, Out2Enroll, Summary of Findings: 2019 Marketplace Plan Compliance with Section 1557 (finding that 18.5% of insurers in 2017, 28% of insurers in 2018, and 94% of the insurers did not include blanket exclusions in their plans).

[236] *See, e.g.*, Calif. Health and Safety Code 1365.5; Colo. Insurance Bulletin No. B–3.49; Conn. Insurance Bulletin IC–34; 79 Del. Laws Ch. 47; DC Code 31–2231.11; Haw. Rev. Stat. 431:10A–118.3, 432:1–607.3, 432D–26.3; 50 Ill. Adm. Code 2603.35; Mass. Insurance Bulletin 2014–03; Nev. Rev. Stat. 651.070; Nev. Admin. Code 686A.140(7); 11 New York Codes Rules and Regulations 52.16; New York Insurance Code 2607, 3243, 4330; Ore. Rev. Stat. 746.015; Ore. Admin. Rules 836–080–0055; 46 Pa. Bulletin 2251; Rhode Island Health Insurance Bulletin 2015–3; 8 Va. Stat. Ann. 4724; Vt. Insurance Bulletin 174; Wash. Rev. Code 48.30.300.

[237] *See, e.g., Outfront* v. *Piper*, No. 62–cv–15–7501 (Minn. D. Ct. Nov. 14, 2016) (interpreting the state Constitution as applied to MinnesotaCare); *Good* v. *Iowa Dept. of Human Services*, No. 18–1158 (Iowa S. Ct. Mar. 8, 2019) (interpreting the Iowa Civil Rights Act as applied medical assistance).

[238] 28 CFR 35.130(g) (Title II); 42 U.S.C. 12112(b)(4) (Title I); 42 U.S.C. 12182(b)(1)(E) (Title III).

[239] *Franciscan Alliance, Inc.* v. *Burwell*, 227 F. Supp. 3d 660, 690 (N.D. Tex. 2016).

[240] *See, e.g., Condry* v. *UnitedHealth Group*, 2018 WL 3203046 (N.D. Cal. Jun 27, 2018) (''disparate impact claims on the basis of sex are not cognizable under section 1557'').

Comment: One commenter stated that because the 2016 Rule covers discrimination based on multiple protected statuses, the proposed rule would create a confusing mix of legal standards and available remedies and therefore could limit claims of intentional discrimination, while the 2016 Rule makes it easier for members of the public to file complaints of intersectional discrimination in one place.

Response: OCR has long accepted complaints alleging discrimination based on more than one protected status. OCR has handled those complaints, and will continue to handle them, under the implementing regulations of each of its applicable civil rights laws. Nothing in this final rule changes that. OCR's complaint form provides the public with the option to select multiple forms of prohibited discriminatory practices, such as both race and disability. OCR continues to encourage the public to file complaints about potentially unlawful discrimination, whether on one prohibited basis or on multiple prohibited bases.

Comment: Commenters stated that the proposed rule would compound discrimination faced by individuals with multiple protected characteristics, such as people of color who are also LEP or disabled. Some commenters said that African Americans are more likely to live with disabilities and chronic conditions, and thus would be disproportionately affected by relaxing discrimination restrictions for health insurance plans.

Response: The Department commits itself, in this final rule, to fully enforce Section 1557 according to its text and the text of the underlying statutes, as well as under the Department's implementing regulations for those statutes, as applied to the health context. Although the Department is proposing to repeal the nondiscrimination provision of the 2016 Rule at § 92.101, this final rule replaces it with a general provisions section at § 92.2. The new section will maintain the nondiscrimination requirements required by Title VI, Title IX, the Age Act, and Section 504. As such, individuals with multiple protected characteristics, such as race and disability, would be protected under the Department's enforcement of Section 1557 to the extent those statutes and regulations apply. Those statutes and regulations explain which characteristics are protected.

With respect to LEP and disability, this final rule additionally contains specific sections clarifying those protections. The underlying regulations and guidance for enforcing these statutes establish standards that are well-known by covered entities. The Department will continue to robustly enforce these statutes, and believes this final rule provides appropriate language to ensure that enforcement occurs.

Comment: Commenters contend that African American, Asian American and Pacific Islander, and Native American women are more likely to die from pregnancy-related complications and will be disproportionately affected by changes to the interpretation of sex discrimination in the proposed rule. Others contend that LGBT people of color will be harmed by the proposed regulation; they also state that LGBT people of specific national origins, including Native American and Middle Eastern, experience high rates of negative experiences in healthcare settings related to gender identity. Commenters alleged the proposed rule would disproportionately harm Native American women, women of color, and transgender individuals who are minorities.

Response: As discussed above, the 2016 Rule's definition of ''on the basis of sex'' is not included in this final rule because it exceeded the Department's statutory authority. In addition, with respect to gender identity and termination of pregnancy, the court's longstanding preliminary injunction and eventual *vacatur* of that language means that the results some commenters fear from removing such language would not be the result of this final rule. The Department is not aware of data supporting commenters' assertion that this change will have a disparate impact on the basis of race or national origin, although even if it did, that disparate impact would be attributable to the statutes rather than to this final rule. To the extent that the Department learns that individuals suffer barriers to healthcare on the basis of race, national origin, or any other protected characteristic, it will work to address those barriers within the limits of its statutory authority.

g. Examples of Discriminatory Practices (Repeal of § 92.207 of the 2016 Rule)

The Department proposed to repeal § 92.207 of the 2016 Rule, which stipulated that covered entities must not discriminate on the prohibited bases in providing or administering health-related insurance or other health-related coverage, and listed examples of such prohibited discrimination. Comments pertaining to § 92.207(b)(3)–(5) related to gender identity are discussed above in the section on discrimination on the basis of sex.

Comment: Commenters opposed repealing the explicit provisions of § 92.207 that prohibit covered entities from discriminating in health insurance or other health coverage. Commenters argued that the proposed rule did not provide any reasoned legal or policy basis for the repeal, which precluded the opportunity to provide public comment on the Department's justifications and so violated the APA. While the proposed rule discussed repealing provisions that may be duplicative, inconsistent, or confusing, commenters argued that the Department did not explain under which of these grounds it was repealing § 92.207, and that the proposed rule's supporting footnote [241] listed comparator regulatory citations that did not duplicate or contradict the provisions of § 92.207.

Commenters also expressed concern that repealing this section would allow health insurance issuers to discriminate, particularly with regard to benefit design, and could make it harder for people who experience discrimination to enforce their rights through administrative and judicial complaints. Commenters asserted that, prior to the ACA, health insurance issuers avoided covering costly individuals by employing the discriminatory practices prohibited by § 92.207, and that repealing these explicit prohibitions would allow health insurance issuers to again discriminate in a variety of ways, including by excluding or denying benefits, applying age limits, increasing costs for sicker enrollees, imposing utilization management limitations, and designing discriminatory prescription drug formularies. Commenters also argued that the ACA was intended to increase administrative oversight of private health insurance plans and to prevent discrimination in health insurance, particularly in light of the underlying civil rights laws' historically limited application to private health insurance and benefit design prior to the ACA.

Several commenters argued that the removal of specific nondiscrimination provisions under § 92.207 would make the regulation vague, eliminate guidance for covered entities, and create confusion about what is prohibited conduct, thereby increasing legal

[241] 84 FR at 27869 n.147 (comparing 45 CFR 92.207 with ''45 CFR 80.5 (health benefits under Title VI), 84.43 (health insurance under Section 504), 84.52 (health benefits under Section 504), 84.33 (rule of construction of Section 504 vis-à-vis validly obligated payments from health insurer); 86.39 (health insurance benefits and services under Title IX).'').

uncertainty and risk. This argument was reiterated by some State government regulators, who said that the specificity in the law provides clarity for both covered entities and the State, with State regulators often relying upon the standards in the 2016 Rule to ensure nondiscrimination in health insurance. Other commenters said that the repeal of § 92.207, compounded with the repeal of language access and taglines requirements, would open the door to discrimination based on national origin by healthcare providers.

Response: The number, breadth, and depth of comments received and discussed in this preamble indicate that the public was given an adequate opportunity to provide comment on the Department's justifications for this final rule.

Commenters are correct to note that the ACA has significantly expanded the applicability of Federal civil rights laws to private health insurance plans. That is why, under this final rule, all health insurance programs that remain covered by Section 1557 remain prohibited from discriminating on the grounds specified by the statute. This final rule has a section on scope at § 92.3, and the Department does not believe the rule needs an additional or separate section on health insurance in order to make this clear. OCR will examine carefully any allegations of discrimination by health insurance issuers, including through benefit design, and will vigorously enforce Section 1557's prohibitions. The Department also notes that certain health insurance issuers remain subject to similar nondiscrimination requirements under statutory provisions implemented and the regulations issued by CMS's Center for Consumer Information and Insurance Oversight (CCIIO). Commenters' specific concerns about national origin discrimination are addressed above and below in the relevant sections.

The 2019 NPRM listed § 92.207 among passages of the 2016 Rule that ''are duplicative of, inconsistent with, or may be confusing in relation to the Department's preexisting Title VI, Section 504, Title IX, and the Age Act regulations.'' [242] As the footnote referenced by commenters shows, the Department specifically pointed there to preexisting HHS regulations under those statutes regarding health benefits and health insurance.[243] The substantive overlap between these regulations and § 92.207 is sufficient to show that the latter either duplicates them, or is inconsistent with them, or may be confusing as to whether it is duplicating them or contradicting them. Because Section 1557 does not require a regulation, the Department prefers to enforce the relevant statutes, to the extent possible, through their existing regulations. The changes in the 1557 regulation made by this final rule advance the Administration's goal of reducing the regulatory burden of the ACA and of administrative action in general.[244]

The 2016 Rule's list of examples of prohibited conduct by insurers at § 92.207(b) was followed by a catchall provision at § 92.207(c) stipulating that the enumeration of those specific forms of discrimination was no limitation on the general prohibition on insurers' discriminating on the prohibited grounds. That catchall provision made § 92.207 no less vague, and gave it no less potential to cause confusion, than this final rule's general prohibition on discrimination by covered entities. The Department declines in this preamble to give guidance of this kind to State regulators, who must each work within their own State's regulatory framework for health insurance. The Department notes that State regulators may also rely upon regulations issued by CCIIO, as applicable.

h. Summary of Regulatory Changes

For the reasons discussed herein, and considering the comments received, the Department finalizes its proposed new § 92.2 without change, its repeal of § 92.4 without change, its repeal of the notice requirement in § 92.8(d) and Appendix B without change, and its repeal of § 92.101, 92.206–92.207, and 92.209 without change.

(5) Assurances in Proposed § 92.4, and Repeal of § 92.5 of the 2016 Rule

The Department proposed that the 2016 Rule's provision at § 92.3 requiring an assurance of compliance with Section 1557 be retained and redesignated § 92.4. 84 FR at 27863. Here, as throughout the proposed rule, the Department also updated the 2016 Rule's term ''State-based Marketplace℠'' to read ''State Exchange,'' in conformity with current CMS regulations. 84 FR at 27871.

Comment: Comments contended it is unclear whether submitting assurances required under this provision at § 92.4 would also fulfill the assurance requirements of Section 504 at 45 CFR 84.5.

Response: As under the 2016 Rule, the application package for all HHS grant-making agencies continues to include a requirement that the applying entity submit a signed assurance form (Form 690), which specifically references Section 1557 along with Title VI, Title IX, Section 504, and the Age Act. That form is available at *https://www.hhs.gov/sites/default/files/forms/hhs-690.pdf.* All recipients of Federal financial assistance from HHS are required to submit the consolidated form that satisfies the assurance requirements for both Section 1557 and these four other civil rights statutes.

The Department requested comment on whether this proposal struck the proper balance by retaining the assurance provisions from the 2016 Rule, and whether the benefits of these provisions exceed the burdens imposed by them.

Comment: Some commenters expressed their support for maintaining the current assurance of compliance requirement, noting that an assurance of compliance is an important step towards ensuring that covered entities know their obligations under Section 1557 and remain compliant. Additionally, questions were raised regarding which entity would be responsible for oversight, enforcement, and corrective action should a covered entity violate Section 1557 despite assuring its compliance.

Response: OCR is responsible for enforcing Section 1557 and will provide oversight, enforcement, and corrective action should a covered entity violate its obligations under Section 1557. The Department agrees that assurances of compliance provide valuable services by alerting covered entities of their obligations, and will retain these provisions under § 92.4 of this final rule.

Summary of Regulatory Changes: For the reasons given in the proposed rule, and having considered comments received, the Department finalizes its proposed § 92.4, and repeal of § 92.5 of the 2016 Rule, without change.

(6) Enforcement Mechanisms in Proposed § 92.5, and Repeal of §§ 92.6, 92.7, 92.8, 92.101, 92.301, 92.302, 92.303, and Appendices A and C of the 2016 Rule

The Department proposed provisions on enforcement of Section 1557 at the new § 92.5, 84 FR at 27863, and proposed to repeal §§ 92.6, 92.7, 92.8, 92.101, 92.301, 92.302, 92.303, and

[242] 84 FR 27869.

[243] *See* 84 FR at 27869 n.147.

[244] Executive Order 13765 on Minimizing the Economic Burden of the Patient Protection and Affordable Care Act Pending Repeal, 82 FR 8351 (Jan. 20, 2017); Executive Order 13771 on Reducing Regulation and Controlling Costs (Jan. 30, 2017); Executive Order 13777 on Enforcing the Regulatory Reform Agenda (Feb. 24, 2017); Executive Order 12866 on Regulatory Planning and Review, 58 FR 190 (Oct. 4, 1993), at § 1(b)(10).

Appendices A and C of the 2016 Rule, which also provided for enforcement mechanisms and notices.

a. Enforcement Procedures and Underlying Regulations in § 92.5(a) (Repeal of § 92.302 and § 92.6(a) of the 2016 Rule)

Proposed § 92.5(a) applies the enforcement mechanisms provided for, and available 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, with their respective implementing regulations, to Section 1557.

Comment: Various commenters expressed opposition to the Department's proposal to replace § 92.301 with § 92.5, and requested that the Department retain § 92.301. Others expressed the view that by adopting § 92.5, the Department would be incorrectly limiting the remedies available under Section 1557. Several commenters asserted that enforcement would be more difficult under the proposed rule because, they said, it creates a patchwork of legal standards—unlike the 2016 Rule, which used a single standard that permitted disparate impact claims. They said this would create confusion, hamper enforcement, and dilute the protections provided to individuals.

Response: This final rule properly limits the remedies available under Section 1557. The text of the 2016 Rule, at § 92.301(a), stated that the enforcement mechanisms available and provided for under Title VI, Title IX, Section 504 and the Age Act shall apply for the purposes of Section 1557.[245] But upon reconsideration of these issues, the Department concludes the 2016 Rule applied these mechanisms in a confusing and inconsistent manner. For certain covered entities, it applied Title VI mechanisms, not only to grounds of discrimination prohibited under Title VI, but also to those prohibited under Title IX and Section 504, while leaving Age Act mechanisms in place for the grounds of discrimination it prohibits; for other covered entities, it applied Section 504 mechanisms, not only to grounds of discrimination prohibited under Section 504, but also to those prohibited under Title VI, Title IX, and the Age Act.[246] The 2016 Rule's regulatory structure blended new standards and preexisting standards from underlying civil rights regulations, and imposed those standards alongside the underlying regulations, which were left in place. In contrast, this final rule adopts the enforcement mechanisms for these four statutes and their implementing regulations *respectively,* each for its own statute. The Department believes this minimizes the patchwork effect of the 2016 Rule by using a familiar regulatory regime under those four statutes. The Department also believes this approach is what the statutory text contemplates. Moreover, because OCR has significant experience enforcing civil rights claims using these civil rights statutes' regulations, the Department expects this change to improve enforcement of Section 1557 and, by removing possible confusion, to make it easier for both individuals and covered entities to know their rights and responsibilities.

Comment: One commenter said that the Department's proposal to remove the 2016 Rule's single standard for enforcing claims is inconsistent with the Minnesota District Court's finding in *Rumble* v. *Fairview Health Services* that ''Congress intended to create a new, health-specific, anti-discrimination cause of action that is subject to a singular standard, regardless of a plaintiff's protected class status.'' [247]

Response: The Department disagrees with this commenter's suggestion that it is inappropriate to finalize the proposed rule's repeal of provisions containing certain enforcement mechanisms. The Minnesota District Court found the language of the Section 1557 statute to be ''ambiguous, insofar as each of the four statutes utilize[s] different standards for determining liability, causation, and a plaintiff's burden of proof,'' [248] and concluded that the Department's interpretation of Section 1557 was permissible. However, the Minnesota District Court view is the minority view and has subsequently been rejected by multiple other court rulings that postdate the 2016 Rule.[249] The Department agrees with these latter courts' reasoning. To the extent that the statutory language could be ambiguous, as the Minnesota district court concluded, the Department believes that its new interpretation is a better and reasonable interpretation of the statute, and is at least an equally permissible statutory interpretation, and therefore is entitled to *Chevron* deference, *Chevron U.S.A., Inc.* v. *NRDC,* 467 U.S. 837 (1984). That the Department's interpretation represents a break with a previous interpretation does not preclude the Department from reinterpreting the statute and receiving *Chevron* deference for its new interpretation, *see, e.g., Rust* v. *Sullivan,* 500 U.S. 173, 186–87 (1991). Here, the Department believes that this final rule's approach is the one best suited to reducing confusion and robustly enforcing Section 1557's nondiscrimination provisions.

b. Compensatory Damages (Repeal of § 92.301(b) of the 2016 Rule)

The Department proposed to repeal § 92.301(b) of the 2016 Rule, which provided for compensatory damages for any and all claims under Section 1557.

Comment: Some commenters opposed the changes to the enforcement mechanisms under the proposed rule and asserted that Section 1557 makes available to all individuals any of the enforcement mechanisms available under any of the four civil rights statutes, including but not limited to compensatory damages.

Response: Although the 2016 Rule stated that compensatory damages are available in appropriate administrative and judicial actions under the Section 1557 regulation, the Department has concluded that its enforcement of Section 1557 should conform to the Department of Justice's Title VI Manual. 84 FR at 27851. The manual states that, under applicable Federal case law, compensatory damages are generally unavailable for claims based solely on a Federal agency's disparate impact regulations.[250] Consequently, the Department considers it most appropriate to finalize this rule by eliminating § 92.301(b) and reverting to enforcement under the regulations applicable to Title VI, Title IX, the Age Act, or Section 504. To the extent compensatory damages are, or are not,

[245] 81 FR 31472.

[246] *Id.*

[247] 2015 WL 1197415, at *11 (D. Minn. Mar. 16, 2015).

[248] *Id.* at *10.

[249] *See Briscoe* v. *Health Care Svc. Corp.,* 281 F. Supp. 3d 725, 738 (N.D. Ill. 2017) (''Taken together, the first two sentences of § 1557 unambiguously demonstrate Congress's intent 'to import the various different standards and burdens of proof into a Section 1557 claim, depending upon the protected class at issue.' ''), quoting *Southeastern Pennsylvania Transp. Auth.* v. *Gilead Sciences Inc.,* 698–99 (E.D. Pa. 2015); *York* v. *Wellmark, Inc.,* 2017 WL 11261026, at *18 (S.D. Iowa Sept. 6, 2017) (''Congress clearly intended to incorporate the statutes' specific enforcement mechanisms rather than create a general catch-all standard applicable to all discrimination claims.''). *See also Galuten on Behalf of Estate of Galuten* v. *Williamson Med. Ctr.,* 2019 WL 1546940, at *5. (M.D. Tenn. Apr. 9, 2019) (same); *E.S. by and through R.S.* v. *Regence BlueShield,* 2018 WL 4566053, at *4 (W.D. Wash. Sept. 24, 2018); *Doe* v. *BlueCross BlueShield of Tennessee, Inc.,* 2018 WL 3625012, at *6 (W.D. Tenn. July 30, 2018).

[250] *See* DOJ Title VI Manual, *https://www.justice.gov/crt/fcs/T6Manual9* (citing *Alexander* v. *Sandoval,* 532 U.S. 275, 282–83 (2001), *Barnes* v. *Gorman,* 536 U.S. 181, 187 (2002), and *Gebser* v. *Lago Vista Indep. Sch.,* 524 U.S. 274, 87 (1998)).

available under those regulations, the regulations will provide for enforcement of Section 1557 in applicable circumstances in the same way.

This approach is consistent with both the best interpretation of the text and the court decisions (cited above) indicating that Section 1557 does not impose a single standard but instead incorporates the distinct enforcement mechanisms of each of the four civil rights statutes described in Section 1557.[251]

c. Implied Private Rights of Action (Repeal of § 92.302(d) of the 2016 Rule)

The Department proposed to repeal § 92.302(d) of the 2016 Rule, which stated that an individual or entity may bring a civil action in a United States District Court to challenge a violation of Section 1557 or the 2016 Rule.

Comment: Some commenters opposed repeal of this language. Several commenters argued that the existence of a private right of action is clear from the statutory language in Section 1557, which they say explicitly references and incorporates the enforcement mechanisms of the four civil rights laws listed, including a private right of action. They cited cases that allow for Section 1557 to include enforcement mechanisms separate from the mechanisms in underlying statutes.[252] Commenters said that the creation of a private right of action within Section 1557 is consistent with Congress's intent that civil rights laws be broadly interpreted to effectuate the remedial purposes of those laws, and that removing Section 1557's private right of action is inconsistent with precedent of the United States Supreme Court, which has upheld private rights of action under the preexisting civil rights laws.

Response: Upon reconsideration of this issue, the Department no longer intends to take a position in its regulations on the issue of whether Section 1557 provides a private right of action. To the extent that Section 1557 permits private rights of action, plaintiffs can assert claims under Section 1557 itself rather than under the Department's Section 1557 regulation.

Comment: Commenters requested that the Department adopt a regulatory framework for Section 1557 where there is a requirement for exhaustion of administrative remedies before a party can bring a private right of action.

Response: Because the Department is eliminating the language specifying a right to sue, the Department does not consider it necessary to establish a framework and a requirement for exhaustion of administrative remedies before filing suit in court.

d. Voluntary Action (Repeal of § 92.302(c) and § 92.6(b) of the 2016 Rule)

The Department proposed to repeal § 92.302(c) of the 2016 Rule, as well as § 92.6(b), which set forth provisions concerning voluntary cooperation with requests for information, and voluntary action beyond the requirements of Section 1557. These provisions have parallels in the regulations implementing Title VI, Section 504, Title IX, and the Age Act,[253] which the Department will use to enforce Section 1557.

The Department did not receive comments specific to these sections.

e. Access to Records of Compliance (Repeal of § 92.303(c) of the 2016 Rule)

The Department proposed to repeal § 92.303(c) of the 2016 Rule, which set forth the Department's obligations to permit access by OCR to review records and sources of information, and to otherwise comply with OCR investigations under the 2016 Rule.

Comment: Commenters expressed concern that the proposed rule undermines the Department's enforcement authority concerning compliance with Section 1557 by programs and activities administered by the Department.

Response: The regulations implementing Section 1557's four underlying statutes already contain provisions addressing access to review of covered entities' records of compliance.[254] The language in the 2016 Rule to this effect was unnecessary, as OCR has the tools to review records and sources of information under existing regulations.

f. Prohibitions on Intimidation and Retaliation (Repeal of § 92.303(d) of the 2016 Rule)

The Department proposed to repeal § 92.303(d) of the 2016 Rule, which concerns intimidation and retaliation provisions that pertain to the Department.

Comment: Several commenters contended that under the proposed rule, those bringing Section 1557 claims would no longer be explicitly protected from retaliation and discrimination.

Response: The regulations implementing Section 1557's four underlying statutes already contain provisions against intimidation and retaliation as appropriate.[255] The language in the 2016 Rule to this effect was unnecessary. Moreover, OCR ensures the confidentiality of complainants under all the statutes it enforces, to the extent permitted by law and consistent with OCR's investigative needs. In some cases, the Freedom of Information Act, the APA, or other laws may require disclosure of certain information provided by complainants.

g. Perpetuating Discrimination by Assistance and Utilizing Criteria or Methods of Administration (Repeal of § 92.101(b)(1)(ii), (b)(3)(ii), and (b)(4)(ii) of the 2016 Rule)

The Department proposed to repeal § 92.101(b)(1)(ii) and § 92.101(b)(4)(ii), which prohibited significant assistance to any agency, organization, or person that discriminates on the basis of race, color, national origin, or age. The Department also proposed to repeal § 92.101(b)(3)(ii), which prohibited utilization of criteria or methods of administration that have the effect of subjecting individuals to discrimination on the basis of sex.

Comment: One commenter objected to repealing the prohibition on the utilization of criteria or methods of administration that have the effect of subjecting individuals to discrimination on the basis of sex. Arguing that Section 1557 is its own authority, the commenter stated that it is irrelevant that the Title IX regulations do not

[251] *See Galuten,* 2019 WL 1546940, at *5 n.8 (because ''the Age Discrimination Act would not authorize [ ] compensatory damages,'' ''it appears that a Federal court with jurisdiction would be constrained to dismiss Plaintiff's claims for compensatory . . . damages under the ACA'').

[252] Commenters cited *Edmo* v. *Idaho Dep't of Corr.,* No. 1:17–cv–00151–BLW, 2018 WL 2745898, at *9 (D. Idaho June 7, 2018) (''[C]ross-referencing the statutes and the express incorporation of the enforcement mechanisms from those statutes is probative of Congressional intent to provide both a private right and a private remedy for violations of Section 1557.''); *Esparza* v. *Univ. Med. Ctr. Mgmt. Corp.,* No. 17–4803, 2017 WL 4791185, at *5 (E.D. La. Oct. 24, 2017) (concluding it was ''abundantly clear to the Court that Congress intended to create a private right of action to enforce § 1557''); *Doe One* v. *CVS Pharmacy, Inc.,* 348 F. Supp. 3d 967, 982 (N.D. Cal. 2018) (finding plaintiffs had not sufficiently alleged disparate impact); *see also Cannon* v. *Univ. of Chi.,* 441 U.S. 677, 703 (1979) (recognizing that Congress intended to create Title IX remedies comparable to those available under Title VI, including a private cause of action for victims of the prohibited discrimination, and finding that age and advanced degrees criteria had a disparate impact on women); *Rumble* v. *Fairview Health Servs.,* 2015 WL 1197415.

[253] *See* 45 CFR 80.7(d), § 80.8(c)(1) (Title VI); § 84.6(b) (Section 504); proposed § 86.71 (Title IX incorporating 45 CFR 80.7(d)); § 90.49(c) (Age).

[254] *See* 45 CFR 90.45, § 91.31 (Age Act) and § 80.6(c) (Title VI); 45 CFR 84.61 (Section 504 incorporating 45 CFR 80.6(c)); § 86.71, as finalized here (Title IX incorporating 45 CFR 80.6(c)).

[255] *See* 45 CFR 80.7(e) (Title VI); § 91.45 (Age Act); 45 CFR 84.61 (Section 504 incorporating 45 CFR 80.7(e)); § 86.71, as finalized here (Title IX incorporating 45 CFR 80.7(e)).

contain a disparate impact provision. Some commenters also contended that removing the ''significant assistance'' provision would undermine enforcement.

Response: The prohibition on perpetuating discrimination by providing significant assistance to any agency, organization, or person that discriminates is identified only in the Title IX and Section 504 regulations, as applied to sex and disability discrimination claims; [256] the 2016 Rule applied it also to claims on the basis of race, color, national origin, or age. Similarly, as discussed above in the section on discrimination on the basis of sex, there is no disparate impact language in the Department's Title IX regulations, but the 2016 Rule made such language applicable to sex discrimination claims brought under Section 1557. For the reasons given earlier in this section, the Department considers it appropriate to rely on the enforcement mechanisms appropriate to each underlying civil rights statute, rather than to create a new and confusing civil rights regulatory framework specific to the enforcement of Section 1557.

h. Notices of Nondiscrimination Rights and Statement of Nondiscrimination Under the 2016 Rule (Repeal of § 92.8 of the 2016 Rule)

The Department proposed to repeal § 92.8 of the 2016 Rule, which required a notice informing individuals about nondiscrimination and accessibility requirements, such as the sample notice and nondiscrimination statement at Appendix A to Part 92.

Comment: Some commenters contended that HHS did not consider how the removal of the 2016 Rule's notice provisions may result in decreased access to, and utilization of, healthcare by people with disabilities, people with LEP, older adults, people who are LGBT, and other vulnerable populations. These commenters argued that with the notice provision's removal, these protected populations will be limited in knowing their rights under Federal civil rights laws, and in knowing how to file complaints with OCR if faced with discrimination in a healthcare setting. Others stated that the Department did not provide an evidentiary basis for what it deemed would be a ''negligible'' impact on people with LEP or ''additional societal costs'' as a result of removing the notice provisions. Commenters proposed that instead of eliminating the notice provision, the Department should consider requiring covered entities to provide notice on an annual basis, when updated, and upon request, in order to harmonize with the Health Insurance Portability and Accountability Act (HIPAA)'s annual notice requirements. Other commenters similarly proposed that the Department should consider specifying a number of times that a covered entity should send notice to individuals over the course of a year.

Response: The regulations implementing Section 1557's four underlying statutes already contain notice provisions.[257] The language in the 2016 Rule to this effect was unnecessary.

Individuals belonging to any protected category under Section 1557, including those with disabilities or LEP, remain covered under existing standards regarding notice. The Department is unaware of data suggesting that those regulations have been or are inadequate to their purpose of making individuals aware of their civil rights. To the extent that it discovered such data, it would consider revising each regulation as appropriate.

Each of the relevant underlying regulations has its own unique standards on providing notice, tailored to the purposes of each civil rights statute.[258] Compressing these into a single standard under the 2016 Rule has led to an unjustifiable burden and understandable confusion. The Department's estimates of regulatory burden are discussed in the RIA.

Comment: Some commenters stated the Department should clarify when the notice and taglines requirements will no longer be effective with respect to timeframes such as open enrollment for Exchanges, employer-sponsored plans, and Medicare. Most of these communications are subject to the current notice and taglines requirements under the 2016 Rule. Commenters sought clarification from the Department as to whether OCR will enforce the notice and taglines requirement against any covered entity from the date of the proposed rule (June 14, 2019).

Response: The changes made in this final rule will be effective 60 days from the publication of this final rule in the **Federal Register**. The 2016 Rule is in effect until that time, except as enjoined or vacated by courts.

Comment: Several commenters requested that the Department retain parts of § 92.8 of the 2016 Rule that require the designation of a responsible employee and grievance procedures, and the text of sample grievance procedures in Appendix C to Part 92. They said that retaining these provisions would increase access to healthcare and retain uniform responsible employee and grievance procedures.

Response: The Department believes it is appropriate to rely on the regulatory framework that has already been set forth for Section 1557's four underlying statutes. To the extent that those implementing regulations have responsible employee and grievance procedures, they are sufficient for enforcement of Section 1557.

i. Summary of Regulatory Changes

For the reasons described in the proposed rule and considering the comments received, the Department finalizes § 92.5, and the proposed repeal of §§ 92.6, 92.7, 92.8, 92.101, 92.301, 92.302, 92.303, and Appendices A and C of the 2016 Rule, without change.

(7) Relationship to Other Laws in Proposed § 92.6, and Repeal of § 92.2(b) and 92.3 of the 2016 Rule

The Department proposed to repeal §§ 92.2(b) and 92.3 of the 2016 Rule, which addressed the application and relationship of Section 1557 and the 2016 Rule to other laws. The Department proposed instead a new § 92.6. The new § 92.6(a) states that nothing in the 1557 regulations shall be construed to invalidate or limit the rights, remedies, procedures, or legal standards applicable under Title VI, Title VII, Title IX, the Age Act, or Section 504, or to supersede State laws that provide additional protections against discrimination on any basis described in § 92.2. The new § 92.6(b) states that insofar as the application of any requirement under the Section 1557 regulations would violate, depart from, or contradict definitions, exemptions, affirmative rights, or protections provided by any of the statutes cited in paragraph (a) of this section or provided

[256] *See* 45 CFR 84.4(b)(1)(v) (Section 504); § 86.31(b)(6), as finalized here (Title IX).

[257] *See* 45 CFR 80.6 and Appendix to Part 80 (Title VI), § 84.8 (Section 504), § 86.9 (Title IX) and § 91.32 (Age Act).

[258] Title VI, 45 CFR 80.6(d), and the Age Act, 45 CFR 91.32, contain general requirements to provide notice. Section 504 requires more: A covered entity must ''take appropriate initial and continuing steps to notify [individuals] that it does not discriminate on the basis of [disability]'' and include this information in its ''recruitment materials and publications.'' 45 CFR 84.8. Title IX goes even further: A covered entity must ''prominently'' display its notice of nondiscrimination in ''each announcement, bulletin, catalog, or application form which it makes available to any [covered person], or which is otherwise used in connection with the recruitment of students or employees'' and not ''distribute a publication . . . which suggests, by text or illustration, that such [covered entity] treats applicants, students, or employees differently on the basis of sex except as such treatment is permitted by [Title IX].'' 45 CFR 86.9.

by the Architectural Barriers Act of 1968 (42 U.S.C. 4151 *et seq.*); the Americans with Disabilities Act of 1990, as amended by the Americans with Disabilities Act Amendments Act of 2008 (42 U.S.C. 12181 *et seq.*); Section 508 of the Rehabilitation Act of 1973, as amended (29 U.S.C. 794d); the Coats-Snowe Amendment (42 U.S.C. 238n); the Church Amendments (42 U.S.C. 300a–7); the Religious Freedom Restoration Act (42 U.S.C. 2000bb *et seq.*); Section 1553 of the Patient Protection and Affordable Care Act (42 U.S.C. 18113); Section 1303 of the Patient Protection and Affordable Care Act (42 U.S.C. 18023); the Weldon Amendment (Consolidated Appropriations Act, 2019, Pub. L. 115–245, Div. B sec. 209 and sec. 506(d) (Sept. 28, 2018)); or any related, successor, or similar Federal laws or regulations, such application shall not be imposed or required.

a. Conscience Laws

Comment: Some commenters supported revising the Section 1557 Rule to explicitly identify the Federal public consensus that conscience statutes reflect, in order to ensure appropriate protection for all civil rights. Some noted that the Coats-Snowe and Church Amendments were passed by Congress and signed into law on a bipartisan basis, reflecting explicit protections from discrimination on the Federal, State, or local level if healthcare providers or hospitals seek to be exempted from participation in the performance or training for abortions.

Some commenters supported including references to conscience and religious freedom laws in § 92.6(b), stating that protecting the conscience rights of healthcare providers also protects patients by protecting trust between patients and providers, and allowing providers who entered healthcare on the basis of moral convictions to serve those who are ill consistent with that ethic. They also stated that providers must exercise professional judgment as to what constitutes the best interest of the patient. Commenters stated that respect for the autonomy of the patient should not be misconstrued to create coercive obligations on providers overriding the best interest of the patient. Some stated that the 2016 Rule resulted in a ''Hobson's choice'' of options for certain providers, who were required under the rule to either violate their ethical pledges to Do No Harm or their longstanding oaths as physicians, or comply with the 2016 Rule and be forced to perform abortions. Some commenters also suggested that if those providers complied with laws like Title VII and conscience laws that require religious accommodation, they could risk noncompliance with the 2016 Rule, or vice versa. Some of those commenters contended that coercing providers to compromise their moral integrity negatively impacts both provider and patient, and ultimately hurts the provider's ability to provide patient care. If facing the threat of coercion, such commenters said, providers will continually face escalating moral dilemmas in the practice of their job, resulting in stress and burnout in a time when physician shortages are already increasing.

Other commenters opposed the language in § 92.6(b), saying that the proposed rule construes the Federal conscience protections more broadly than existing law allows. They contended conscience protections and religious liberty are meant for individuals, not entities, and that healthcare systems and entities cannot have the right of conscience, because the notion of conscience is limited to individuals. Some commenters also recommended that instead of removing gender identity and termination of pregnancy language and having the language in § 92.6(b) concerning conscience and religious freedom statutes, the Department should merely insert a narrow religious exemption, for they asserted that preventing discrimination on the basis of gender identity or termination of pregnancy is more critical than religious freedom rights, which should be more heavily scrutinized for pretextual discrimination. Other commenters stated that conscience and religious protections under the current statutes are sufficient and incorporating conscience or religious exemptions is unnecessary. Some opposed referring to the Coats-Snowe Amendment in § 92.6(b), saying that it would allow healthcare providers to decline to make medical care available to any patient based on personal beliefs. Some added that the Department does not have the authority to interpret statutes such as the Coats-Snowe Amendment to limit or supersede Section 1557, which should be seen as controlling law. One commenter stated that Federal conscience statutes are not applicable to the ACA because they are not mentioned in the ACA.

Response: Section 1557 and the ACA did not repeal any Federal conscience law. Indeed, ACA § 1303 specifically provides that ''[n]othing in [the ACA] 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. 8023(c)(2). At the time of its passage, the President stated that ''[u]nder the [ACA], longstanding Federal laws to protect conscience (such as the Church Amendment, 42 U.S.C. 300a–7, and the Weldon Amendment, section 508(d)(1) of Pub. L. 111–8) remain intact and new protections prohibit discrimination against healthcare facilities and healthcare providers because of an unwillingness to provide, pay for, provide coverage of, or refer for abortions.'' [259] New law is to be interpreted consistently with existing law wherever possible, and the Department sees no conflict between Section 1557 and preexisting Federal conscience statutes.

This final rule emphasizes that the Section 1557 regulation will be implemented consistent with various statutes enacted by Congress, including conscience and religious freedom statutes. This should not be a controversial statement, nor should it even be necessary to add, as the Department is always obligated to comply with relevant Federal statutes. But the fact that so many commenters found this provision objectionable is itself a reminder of why such a provision is needed. The fact that the 2016 Rule was the subject of litigation and injunctive relief, in part because of plaintiffs' claim that the 2016 Rule did not clearly state that it would be enforced consistent with conscience and religious freedom statutes, is also a reason the Department believes it is appropriate to make the issue clearer in this final rule. This final rule does not purport to construe the statutes referenced in this section, so it cannot be construing them too broadly (or too narrowly). It would be inappropriate to replace § 92.6(b)'s language with a religious exemption, whether narrow or broad, because § 92.6(b) neither adds to nor takes away from the conscience and religious freedom statutory language that Congress has enacted.

Commenters who discuss the gender identity and termination of pregnancy provisions of the 2016 Rule in this context are confusing two different issues. As stated above, this final rule eliminates the 2016 Rule's provisions related to gender identity for numerous

[259] Executive Order 13535, ''Patient Protection and Affordable Care Act's Consistency with Longstanding Restrictions on the Use of Federal Funds for Abortion'' (March 24, 2010).

legal and policy reasons that have nothing to do with conscience protection, and it eliminates the 2016 Rule's provisions on termination of pregnancy because they failed to incorporate Title IX's abortion-neutrality language (which goes much farther than any mere protection for individual conscientious objectors). In neither case could the Department's concerns have been adequately addressed by permitting individuals to claim a conscientious exemption from those objectionable provisions.

Comment: Many providers with conscientious or religious concerns stated that their medical judgment is based upon a review of the clinical evidence, and that medical ethics requires that they act in accordance with their best medical judgment. For example, some commenters contended that they have practices, such as in the obstetrics and gynecology field, which are specialized to the biological sex of females based on a binary distinction between males and females. Others had objections because of their moral and religious convictions concerning specific procedures that they sincerely believed, both in their medical judgment and ethically, would endanger the health and wellbeing of a person.

Response: By respecting medical professionals' judgment, the Department protects their right and responsibility to follow medical ethics in treating patients to the best of their ability. In their objections to abortion, sex-reassignment procedures, or other treatments covered by the 2016 Rule, some providers assert that not only their medical judgment but also their conscientious or religious beliefs would be burdened by such procedures. The Department believes that the best way to avoid such burdens on conscience is, instead of requiring individual objectors to assert claims under RFRA or other applicable laws, to avoid regulatory requirements that would have forced them to provide such procedures in the first place, as well as to ensure that remaining requirements are interpreted consonant with the applicable Federal conscience statutes.[260] This will protect both providers' medical judgment and their consciences, thus helping to ensure that patients receive the high-quality and conscientious care that they deserve.

Comment: Some commenters argued that religious or conscience exemptions were used as a pretext to conceal animus against LGBT individuals. Commenters expressed concerns that the proposed rule would improperly prioritize conscience and religious freedom rights over LGBT rights or civil rights in general. However, others, such as hospital associations that expressed support for care regardless of gender identity and sexual orientation, explained that they also support appropriate protections for the reasonable accommodation of a nurse or other provider who may assert a sincere conscientious objection to participating in a particular medical procedure. Other providers stated that the exemption they seek is from providing certain treatments, not from treating certain patients. Some submitted their hospital nondiscrimination policies, contending those policies do not include blanket denial of healthcare treatment for LGBT individuals, and in many cases expressly prohibit discrimination on the basis of gender identity or sexual orientation, but that they nonetheless seek limited exemptions on the basis of sincerely held religious and moral convictions. Some individual, institutional, and religious groups affiliated with healthcare providers also provided comments stating that both in policy and in practice, they have never refused to care for a patient on the grounds of their identity as an LGBT individual. They stated that they object to being required to perform services that violate sound medical judgment, ethical convictions, or religious beliefs about the dignity of human beings. Commenters also submitted surveys finding healthcare professionals experienced pressure, coercion or punishment for not participating in training, performing a procedure, or writing a prescription when they had medical or scientific objections.

Response: The Department recognizes that members of the public hold different opinions concerning conscience and religious freedom laws and their interplay with various health contexts, including with respect to LGBT concerns. This final rule does not, however, create any new conscience or religious freedom exemptions beyond what Congress has already enacted.

Comment: Some commenters contend that women of color are more likely to rely on religious hospitals to receive care, and thus women of color will be more likely to be affected by religious exemptions that allow religious hospitals to deny certain reproductive care. Others opposed inclusion of references to conscience and religious freedom laws, stating that the danger of losing Federal funds is the only incentive for covered entities to offer more abortion, contraception, sterilization, gender identity affirming, or sex reassignment services. Other commenters stated that conscience laws were intended to protect health professionals from precisely that form of government coercion.

Some commenters stated that the proposed rule, in particular concerning the Church Amendments, 42 U.S.C. 300a–7, is inconsistent with EMTALA, because the conscience exemptions would deny emergency and stabilizing care, including with respect to abortion or sterilization. Other commenters stated that the rule is consistent with EMTALA, because EMTALA requires protection of the ''unborn child.''

Response: The Department is not aware of any instance to date where a facility required to provide emergency care under EMTALA was unable to do so because of objections protected by the Church Amendments. This final rule does not adopt any stance on how hypothetical conflicts between the Church Amendments and EMTALA ought to be resolved. The Department intends to read every law passed by Congress in harmony to the fullest extent possible, so that all laws are given their fullest possible effect. Commenters' other policy concerns about the possible healthcare effects of the conscience laws are among the many complicated factors that Congress had to balance in the texts of the separate statutes, and it is not the Department's job to overturn the results of that legislative process.

Comment: One commenter compared the proposed rule with the 2019 Conscience Rule and alleged that the Department's recent actions of decreasing protections for patients and increasing protections for providers run contrary to actual public sentiment. The commenter alleged that between 2008 and January 2018, the Department received fewer than 50 complaints regarding violations of Federal religious or conscience statutes while receiving 30,000 complaints of other civil rights discrimination in 2017 alone. Other commenters stated that the 2019 Conscience Rule violates EMTALA, and results in the denial of transition-related surgeries or abortion services in emergencies, because conscience statutes allow exemptions from performance of sterilizations or abortions. Commenters also recommended that the Department delay finalizing the proposed rule pending the outcome of litigation challenging the 2019 Conscience Rule, in order to provide clarity and finality, and to reduce litigation risk as regards the construction of Section 1557 with conscience statutes.

[260] *See California* v. *Azar,* at *24 (''HHS acted well within its authority in deciding how best to avoid conflict with the Federal conscience laws.'').

Response: This final rule is separate from the 2019 Conscience Rule. It does not implement that rule, and it does not implement the statutes implemented by that rule. Several courts have vacated the 2019 Conscience Rule before its effective date, but none of those courts issued any order against the conscience statutes themselves,[261] which the Conscience Rule sought to implement and which this final rule references. Because this final rule does not refer to or rely on the 2019 Conscience Rule, there is no reason to delay finalization of this rule pending further litigation over the 2019 Conscience Rule.

b. Religious Freedom Restoration Act

Comment: Some commenters said that the proposed rule's inclusion of the Religious Freedom Restoration Act (''RFRA'') in § 92.6(b) was unclear and confusing. Others said that it should be excluded because it would allow providers to deny needed healthcare. Other commenters supported inclusion of RFRA, agreeing that it is an important protection for religious conscience from government-imposed burdens. Commenters also pointed out that the Federal government has clearly articulated its commitment to RFRA and religious freedom laws under a recent executive order[262] and the subsequent Attorney General Memorandum[263] to executive departments and agencies that ''Congress has taken special care with respect to programs touching on abortion, sterilization, and other procedures that may raise religious conscience protections.''[264] One commenter supported the Department's explicit acknowledgment that Section 1557 is subject to RFRA, stating that religious organizations have had to repeatedly go to court to vindicate their conscience rights against the Department's enforcement of the 2016 Rule. Others said that referring to RFRA accurately reflects statutory text and Congressional intent, and would correct a legal misinterpretation of Section 1557 that has been recognized as such by the *Franciscan Alliance* court.

Response: Congress explicitly stated that RFRA applies to ''all Federal law, and the implementation of that law, whether statutory or otherwise, and whether adopted before or after November 16, 1993 . . . unless such law explicitly excludes such application by reference to this chapter.''[265] Section 1557 does not explicitly exclude such application, so the Department is bound to enforce Section 1557 in compliance with RFRA. The Department agrees with the court in *Franciscan Alliance* that particular provisions in the 2016 Rule violated RFRA as applied to private plaintiffs.[266] In order to ensure that Section 1557 regulations are now interpreted consistently with, and implemented in compliance with, RFRA, the Department considers it appropriate to specify this explicitly.

Comment: Some commenters stated that the text of the Section 1557 statute does not contain a religious exemption, and therefore asked the Department not to include a religious exemption, either explicitly or by reference in § 92.6(b). Other commenters stated that exemptions on religious bases should be blanket exemptions, not case-by-case exemptions as outlined in RFRA.

Response: This final rule does not craft a religious exemption to Section 1557. Congress has already created various religious and conscience protections in healthcare by enacting several statutes, including RFRA, healthcare conscience statutes, and the religious organization exception in Title IX. This final rule simply states that the Section 1557 regulation will be implemented consistent with those statutes.

c. Title IX

Comment: Some commenters opposed including reference to the Title IX statutory religious exemption in § 92.6(b). They said that Section 1557 does not require or authorize Title IX religious or abortion exemptions, because these are limited to educational institutions, and are improper in the healthcare context. Others expressed concern that Section 1557 and Title IX would be subject to exemptions that HHS does not apply to its rules enforcing Title VI.

Other commenters stated that it is unnecessary and unwise to change the standard for the religious exemption under Title IX, and pointed to the legislative history of Title IX, where the Conference Committee rejected an amendment proposed by Senator Hatch to loosen the standard for the religious exemption. Commenters stated that § 92.101(c) of the 2016 Rule took an inconsistent analysis by failing to incorporate Title IX's religious and abortion exemptions, despite incorporating exemptions from the other three Federal civil rights laws referenced in Section 1557.

Still other commenters stated that the Title IX exemption should not apply broadly to large religious institutional healthcare facilities, or that conscience protections and religious liberty cannot apply to institutions like hospitals or healthcare systems because they cannot have the right of conscience: They suggested that conscience is limited to individuals and that an institution is not a person. Other commenters disagreed and pointed to legislative history to recognize that the protections under Title IX's religious exemption are not just for individuals but for institutions.

Response: The text of Title IX applies its religious exemption to institutions, so there should be no question that religious exemptions can apply to institutions as well as individuals.[267] As discussed above regarding termination of pregnancy, the *Franciscan Alliance* court vacated portions of the 2016 Rule for failing to incorporate Title IX's exemption for religious institutions. More generally, the Supreme Court in *Burwell* v. *Hobby Lobby* held that RFRA can apply to for-profit corporations. 573 U.S. 682 (2014). And that holding parallels other Supreme Court precedent making clear that organizations may engage in exercises of religion protected by the First Amendment. *See, e.g., Masterpiece Cakeshop, Ltd.* v. *Colo. Civil Rights Comm'n,* 138 S. Ct. 1719, 1732 (2018); *Hosanna-Tabor Evangelical Lutheran Church & Sch.* v. *EEOC,* 565 U.S. 171, 199 (2012); *Church of the Lukumi Babalu Aye, Inc.* v. *City of Hialeah,* 508 U.S. 520, 525–26, 547 (1993).

Under the Civil Rights Restoration Act amendments to Title IX, the Title IX religious exemption is no longer limited to educational institutions controlled by religious organizations: Any educational operation of an entity may be exempt from Title IX due to control by a religious organization.[268] Section 1557

[261] *See New York* v. *United States Dep't of Health & Human Servs.,* 414 F. Supp. 3d 475 (S.D.N.Y. 2019); *City & Cty. of San Francisco* v. *Azar,* 411 F. Supp. 3d 1001 (N.D. Cal. 2019); *Washington* v. *Azar,* No. 2:19–CV–00183–SAB, 2019 WL 6219541 (E.D. Wash. Nov. 21, 2019).

[262] Executive Order 13798 on Promoting Free Speech and Religious Liberty, 82 FR 21675 (May 4, 2017).

[263] Memorandum of the Attorney General (Oct. 6, 2017), *https://www.justice.gov/opa/press-release/file/1001891/download.*

[264] *Id.*

[265] 42 U.S.C. 2000bb–3.

[266] *Franciscan Alliance,* 2019 WL 5157100 at *9 (''[T]he Court holds that the Rule, which expressly prohibits religious exemptions, substantially burdens Private Plaintiffs' religious exercise in violation of RFRA.'')

[267] *See* 20 U.S.C. 1681(a)(3) (''this section shall not apply to an educational institution which is controlled by a religious organization if the application of this subsection would not be consistent with the religious tenets of such organization''); 20 U.S.C. 1687(4) (excluding ''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'').

[268] *Id.*

incorporates the statutory scope of Title IX, so it is appropriate for this rule to incorporate the Title IX statutory language concerning religious institutions and abortion neutrality. Although much of Title VI case law can be applied to Title IX situations, the parallel is not perfect because Title IX contains several important statutory exemptions that are absent from Title VI. These are mentioned above in the section on discrimination on the basis of sex.[269]

Comment: Commenters stated that adding the Title IX exemption for religious entities violates the Establishment Clause, because it would force third parties to subsidize or bear the costs of religious exercise, citing *Cutter* v. *Wilkson,* 544 U.S. 709 (2005), *Lee* v. *Weisman,* 505 U.S. 577 (1992), and *Estate of Thornton* v. *Caldor, Inc.* 472 U.S. 703 (1985). Commenters indicated that religious exemptions must take an adequate account of the burdens a requested accommodation may impose on nonbeneficiaries. Commenters similarly suggested that the rule's requirement that the Section 1557 rule be implemented consistent with RFRA would violate the Establishment Clause and should be limited to instances where no third party is harmed by application of RFRA.

Response: Neither RFRA (as applied to Federal government actions), nor Title IX's statutory exemptions, have ever been held unconstitutional by the Supreme Court. The Court has upheld Title VII's statutory exemption for religious organizations,[270] and has denied that statutory exemptions of this type violate the Establishment Clause.[271] The Department will comply with all relevant court rulings.

d. Other Laws and Cases

Comment: The Department received comments supporting the express mention of Section 1303 of the ACA[272] in proposed § 92.6. These commenters contended that this helps clarify the prohibition on mandating QHPs to provide abortions, and that it could not have been Congress's intent to mandate abortion coverage in Section 1557. Section 1303 expressly leaves it up to issuers of health plans to decide not to cover abortion. Other comments stated that Section 1303 should not be expressly mentioned in this rule and that termination of pregnancy should remain as a prohibited basis of discrimination under the Section 1557 rule, notwithstanding Section 1303.

Response: In Section 1303, Congress specified that nothing in the ACA (therefore including Section 1557) ''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 willingness or refusal to provide, pay for, cover, or refer for abortion or to provide or participate in training to provide abortion'' (emphasis added). The Department considers it appropriate to finalize § 92.6 to indicate that the Section 1557 regulation will be implemented consistent with Section 1303, as that provision is relevant to the interpretation of the Federal laws that Section 1557 incorporates by reference.

Comment: The Department received comments from State public officials raising concerns about the 2016 Rule's constitutionality. State public officials contended that the 2016 Rule violated the Spending Clause because the Federal government did not provide adequate notice by clear statement and opportunity to agree to the Section 1557 Rule's new conditions on receipt of Federal financial assistance. States also raised objections under the Eleventh Amendment to the Department-initiated Section 1557 enforcement actions. States identified their obligation to protect the First Amendment rights to free exercise of religion of their citizenry. However, these State commenters noted that the proposed rule's removal of the definition of ''on the basis of sex,'' and the addition of the religious and abortion exemptions, would address these concerns.

Other commenters stated that when the Department said in the 2019 NPRM that State and local entities are better suited than the Federal government to address gender identity discrimination, this was contrary to constitutional law principles and undermined the right to be free from discrimination.

Response: The Department is not aware of any Supreme Court precedent that would call into question the constitutionality of its reasoning about federalism as laid out in the 2019 NPRM.[273] The Department believes that this final rule resolves the concerns States had about the 2016 Rule's constitutionality.

Comment: Some comments from State public officials stated that the 2016 Rule conflicted with State laws on religious accommodations and independent medical judgment of healthcare providers. A different group of State public officials submitted a separate joint comment stating that their States' civil rights legislation and/or regulations prohibited discrimination on the basis of gender identity or sexual orientation, and that the proposed rule would remove the consistency of their laws with the 2016 Rule. They argued that State insurance agencies acted first to promulgate regulations after passage of Section 1557 in 2010, assuming that Section 1557 prohibited gender identity discrimination. Some States also said that the proposed rule's incorporation of Federal conscience statutes would result in conflict with State laws, or with other Department rules requiring covered entities to provide care to all (*e.g.,* vaccination care).

Some States said that as employers they had difficulty resolving religious accommodation laws with Section 1557. Others stated they had no difficulties resolving consumer complaints of discrimination on the basis of gender identity.

Response: The Department agrees that States have a public interest in enforcement of their statutes, including conscience and religious freedom statutes. This final rule respects Federalism: It neither interferes with State laws on conscience protections and medical judgment, nor does it interfere with State laws that provide additional protections (so long as these do not violate other Federal statutes). The rule also explicitly provides that Section 1557 will not be taken to supersede State laws that provide additional protections against discrimination on the enumerated grounds. The Department is not aware of actual, as opposed to hypothetical, conflicts between the statutes incorporated here and other laws or

[269] 20 U.S.C. 1681(a)(6)(B); 34 CFR 106 *et seq.*

[270] *Corporation of the Presiding Bishop of the Church of Jesus Christ of Latter-Day Saints* v. *Amos,* 483 U.S. 327, 338–40 (1987); *see also Walz* v. *Tax Commn. of City of New York,* 397 U.S. 664 (1970) (upholding the constitutionality of a state's statutory property tax exemption for religious organizations); *Id.* at 675 (''The grant of a tax exemption is not sponsorship since the government does not transfer part of its revenue to churches but simply abstains from demanding that the church support the state. No one has ever suggested that tax exemption has converted libraries, art galleries, or hospitals into arms of the state or put employees 'on the public payroll.' There is no genuine nexus between tax exemption and establishment of religion.'').

[271] *Corporation of the Presiding Bishop of the Church of Jesus Christ of Latter-Day Saints* v. *Amos,* at 336–37 (''We agree with the District Court that this purpose does not violate the Establishment Clause. . . . A law is not unconstitutional simply because it allows churches to advance religion, which is their very purpose.''); *Id.* at 339 (''It cannot be seriously contended that [Title VII's statutory exemption] impermissibly entangles church and state; the statute effectuates a more complete separation of the two and avoids the kind of intrusive inquiry into religious belief that the District Court engaged in in this case.'').

[272] 42 U.S.C. 18023.

[273] *See* 84 at 27857 (2019 NPRM discussion of ''Sensitive Balancing of Competing Interests at the Local Level'' at Part g).

regulations that the Department enforces.

Comment: A commenter supported including the reference to Section 1553 of the ACA in § 92.6 in order to protect nurses who have objections to participating in assisted suicide, promote trust in the nurse-patient relationship, and keep the profession open to candidates who want to serve as nurses but object to participation in assisted suicide.

Commenters supported the proposal's specification that the proposed regulation not be applied in a manner that conflicts with or supersedes exemptions, rights, or protections contained in several civil rights statutes, such as the Architectural Barriers Act of 1968, the Americans with Disabilities Act of 1990 (as amended by the Americans with Disabilities Act Amendments Act of 2008), and Section 508 of the Rehabilitation Act of 1973.

Some commenters requested that the word ''obligations'' be added in order to specify that the proposed regulation not be applied in a manner that conflicts with or supersedes the exemptions, rights, protections or obligations contained in several civil rights statutes. This addition would help clarify that this consideration is intended to help reduce redundancy, compliance burdens, and confusion for healthcare providers.

Response: The Department appreciates all these comments in support of the proposed rule. The Department declines to add the word ''obligations,'' as the final rule's language adequately addresses its interaction with other civil rights statutes.

Comment: One commenter noted that a number of provisions in the proposed rule seem to contradict portions of the recent Conscience Rule published by the Department.[274] In particular, this proposed rule eliminates and narrows definitions advanced by the 2016 Rule, while the Conscience Rule expands definitions and protections. This proposed rule seeks to drastically cut costs of enforcement by eliminating notice and taglines requirements and other costs for providers, while the Conscience Rule will impose new costs on providers and individuals. Finally, this proposed rule and the Conscience Rule use different definitions to define health programs and activities.

Response: The 2019 Conscience Rule and this final rule rely on different statutes, and different underlying regulations for those statutes, so it is not surprising that there should be differences between their respective definitions and protections. The four civil rights statutes underlying Section 1557 have implementing regulations containing appropriate definitions, protections, and enforcement mechanisms. As explained herein, the Department has now deemed most of the parallel provisions in the 2016 Rule to be unnecessary, superfluous, or unduly burdensome. Therefore the Department considers it appropriate to finalize a Section 1557 rule that is shorter than the 2016 Rule and relies more substantially on those underlying regulations. In contrast, the 2019 Conscience Rule (which has been vacated and is subject to pending litigation) modified previous regulations that are only three sentences long, and that lack the kinds of definitions and enforcement mechanisms found in regulations implementing other civil rights laws enforced by the Department. In promulgating the 2019 Conscience Rule, the Department concluded more extensive regulations were needed in the absence of existing regulations containing such provisions.

Comment: One commenter stated that the proposed rule's changes to the relationship to other laws section at § 92.6 are contrary to the requirements of Section 1557, because the 2016 Rule stated that neither it nor Section 1557 would apply a lesser standard than Title VI, Title IX, Section 504, or the Age Act. In contrast, the proposed rule expressly states that application of the proposed rule will not be required if the proposed rule violates, departs from, or contradicts a number of other Federal civil rights laws.

Response: The Department seeks to give all laws their fullest possible effect. It does not believe that the other laws referenced at § 92.6 are generally in conflict with Title VI, Title IX, Section 504, or the Age Act, except to the extent that some of them (*e.g.,* RFRA) may be specifically designed to limit the applicability of other Federal laws and governmental actions.

e. Summary of Regulatory Changes

For the reasons described in the proposed rule and having considered the comments received, the Department finalizes § 92.6 and repeals §§ 92.2(b) and 92.3 of the 2016 Rule without change.

C. Section 1557 Regulation, Subpart B: Specific Applications to Health Programs or Activities (Sections 92.201–92.205 of the 2016 Rule)

The Department requested comment on the proposed retention and modification of the provisions in Subpart B of the Section 1557 regulation, which imposes specific requirements on covered entities as regards individuals with LEP or disabilities.

(1) Meaningful Access for Individuals With Limited English Proficiency (45 CFR 92.101)

The Department proposed § 92.101(a), which states that any entity operating or administering a health program or activity subject to the Section 1557 regulation is obligated to take reasonable steps to ensure meaningful access to such programs or activities by LEP individuals. It also proposed § 92.101(b), which states that OCR may assess how an entity balances the following four factors:

(1) The number or proportion of LEP individuals eligible to be served or likely to be encountered in the eligible service population;

(2) the frequency with which LEP individuals come in contact with the entity's health program, activity, or service;

(3) the nature and importance of the entity's health program, activity, or service; and

(4) the resources available to the entity and costs.

Section § 92.101(b) retains many of the 2016 Rule's provisions related to access for LEP individuals. It removes definitions of the terms ''qualified bilingual/multilingual staff'' and ''individual with limited English proficiency,'' but the 2019 NPRM expressed the Department's commitment to interpreting those terms naturally and consistently with the 2016 Rule.[275] It also repeals the 2016 Rule's definition of ''national origin.''

The Department requested comment on whether the proposed retention of some provisions that impose requirements on covered entities under the Section 1557 Regulation (which govern health programs or activities), but not on entities that only receive HHS funding for human services, would cause problems or confusion, and (if so) whether this might warrant amendments to the Department's Title VI regulation.

Comment: In response to the Department's request for comment concerning possible amendments to the underlying civil rights regulations, some commenters said that they were unable to provide meaningful comments without HHS first providing explanations and rationale for any proposed changes, and that unanticipated changes could not be

[274] 45 CFR part 88.

[275] 85 FR 27860–61, 27866.

made in a final rule without first giving the public an opportunity to comment on those proposed changes.

Response: The Department did not propose changes to regulations other than those finalized here, but simply invited comment on whether to consider doing so. In this final rule, the Department does not implement any such changes, and in this respect finalizes the proposed rule without change. The Department here finalizes only those changes proposed in the 2019 NPRM (with minor and primarily technical changes to these).

Comment: Some commenters opposed the proposed rule's revisions to the requirements for meaningful access for LEP individuals, arguing that they weaken nondiscrimination requirements. These commenters noted that instead of requiring covered entities to take reasonable steps to provide meaningful access for *each* ''LEP individual eligible to be served or likely to be encountered,'' the proposed rule only requires covered entities to take steps to ensure meaningful access for ''LEP individuals'' generally. These commenters contend that this change will result in a number of LEP individuals unable to access healthcare, and will contribute to discrimination and to healthcare disparities for LEP individuals. Many commenters stated that lack of understanding in a medical setting could cause harm and possibly death to patients with LEP. One commenter emphasized the facilitative role that interpreters play to decrease risk associated with miscommunication between patients and providers. A commenter expressed concerns that healthcare services would dramatically decrease for individuals with LEP who are unable to access an interpreter. Another commenter objected to the notion that oral interpretation for patients would not be required. Some commenters also oppose the replacement of the 2016 Rule's two-factor test with a four-factor test. One commenter recommended replacing the term ''reasonable'' in the Department's LEP Guidance meaningful access standard with the term ''all,'' saying that the word ''reasonable'' leaves too much room for ambiguity in its application.

Response: The 2016 Rule imposed a stringent requirement on covered entities to take reasonable steps to provide meaningful access to each LEP individual eligible to be served or likely to be encountered. This provision could potentially be interpreted to require a covered entity to provide language assistance services to every LEP individual it comes into contact with. This final rule instead follows DOJ's longstanding LEP guidance (under Executive Order 13166), and HHS's corresponding LEP guidance from 2003, by saying that a covered entity under Title VI must take reasonable steps to ensure meaningful access to its programs or activities by LEP individuals.[276] Adopting this language would apply the same standard to both health and human services programs within the Department, and would conform to the other Federal agencies that follow DOJ's LEP Guidance, consistent with its civil-rights coordinating authority. Because Section 1557 incorporates the enforcement mechanisms available under Title VI (which encompasses LEP status under *Lau* v. *Nichols*),[277] it is appropriate for this final rule to adopt the Title VI standard requiring reasonable steps to ensure meaningful access.

This final rule also incorporates the four-factor test found in the DOJ LEP Guidance and reiterated in the Department's own 2003 LEP Guidance. That test is ''designed to be a flexible and fact-dependent standard,'' [278] and is meant to strike a balance that ensures meaningful access by LEP individuals to critical services while not imposing undue burdens on small businesses, small local governments, or small nonprofits. As the 2019 NPRM made clear, an individualized case-by-case assessment of the four factors is the starting point for exercising the Department's enforcement discretion in language access cases.[279]

This final rule retains, and the Department will vigorously enforce, the underlying legal standard of Title VI: Recipients are prohibited from utilizing criteria or methods of administration which have the effect of subjecting individuals to discrimination on the basis of their race, color, or national origin, or have the effect of defeating or substantially impairing accomplishment of the program with respect to individuals on the basis of their race, color, or national origin. Entities that utilize such criteria or methods of administration have failed to take reasonable steps to ensure meaningful access to their programs by individuals with LEP and are operating their programs in violation of this final rule's prohibition against discrimination on the basis of national origin. All covered entities remain obligated to submit assurances that they will comply with Title VI and all other relevant civil rights law.[280]

The language access provisions in this final rule are consistent with Title VI enforcement mechanisms and with the Department's longstanding guidance. Title VI enforcement mechanisms are broadly known to the regulated community, and the HHS LEP Guidance has been effective in helping covered entities comply with the statute and implementing regulations. The Department regards the four-factor test, employed since 2003, as the best way of balancing the relevant factors in ensuring nondiscrimination on the basis of national origin. Under this final rule, the Department's LEP Guidance will help covered entities assess their programs using the four factors to ensure meaningful access to their programs by individuals with LEP. By eliminating confusion, inconsistency, redundancy, and unnecessarily burdensome compliance costs, this final rule applies proven enforcement mechanisms and guidance to ensure access to covered programs by individuals with LEP.

Comment: Commenters stated that the proposed rule significantly reduces the administrative burden placed on providers. For example, the proposed rule will allow retail pharmacies to provide patients with better quality of care in a more efficient manner. Another comment emphasized that under the 2016 Rule, providers are required to physically post the information at their facilities, on their websites, and in any ''significant'' publications and communications. This example underscored that the term ''significant'' has never been defined by OCR, which has resulted in providers using taglines notices in nearly every document provided to patients. This practice was described as administratively burdensome and counterproductive, because patients already receive numerous notices mandated by the Department. Another commenter expressed support for the proposed rule's empowerment of individual entities to take reasonable steps to ensure meaningful access.

Response: The Department agrees, and recognizes the burdens imposed by the 2016 Rule's requirement to post notices and taglines in all significant communications and publications, as well as by the difficulty of determining the meaning of ''significant'' with

[276] *See* 67 FR 41455 (June 18, 2002) (DOJ Guidance to Federal Financial Assistance Recipients Regarding Title VI Prohibition Against National Origin Discrimination Affecting Limited English Proficient Persons).

[277] 414 U.S. 563 (1974).

[278] 68 FR 47314 (Aug. 8, 2003) (HHS Guidance to Federal Financial Assistance Recipients Regarding Title VI Prohibition Against National Origin Discrimination Affecting Limited English Proficient Persons).

[279] 84 FR 27865 (June 14, 2019).

[280] *See* 84 FR 27860.

respect to the numerous and diverse types of programs covered by this final rule. These requirements were difficult for covered entities to implement due to different and overlapping language access requirements imposed by the Federal government and by many States.[281] Stakeholders have informed the Department that the repetitive nature of these requirements dilutes the messages contained in significant communications to the point that some recipients may be disregarding the information entirely.[282] In addition, many beneficiaries do not want to receive extra pages of information they have seen many times before, due to environmental concerns or annoyance.[283] Most significantly, the Department has found scant evidence to demonstrate that repeatedly mailing all beneficiaries of Federal and other health programs taglines with 15 or more languages is an efficient use of covered entities' language access resources when the overwhelming majority of beneficiaries speak English.[284] Savings from the notice and taglines requirements changes are described in more detail in the Regulatory Impact Analysis.

Comment: Some commenters stated that the notices and taglines requirements of the 2016 Rule are burdensome, but that the Department should consult with stakeholders to determine how to most effectively and efficiently communicate with LEP individuals, rather than repeal the requirements.

Response: The Department consulted with the public before and since issuing policy guidance to recipients on compliance with the Title VI obligation to take reasonable steps to ensure meaningful access to their programs by individuals with LEP. The Department also provided stakeholders with an opportunity to comment on the proposed rule during the public comment period.

Comment: The Department received comments opposing the proposed rule's revised § 92.101, which requires covered entities to take reasonable steps to ensure meaningful access to its programs or activities by individuals with LEP. Commenters asserted that the proposed change is contrary to congressional intent because the language in Section 1557 is clear that ''an individual shall not'' be subject to discrimination on the prohibited grounds. Others stated that the proposed § 92.101 inappropriately changes the Section 1557 regulation language and shifts the focus of the regulation from an individual's rights to the covered entity's programs or activities, thus weakening meaningful access and running contrary to the text of Section 1557.

Still others recommended that—through sub-regulatory guidance—the Department should communicate to providers the flexibility of the LEP access requirement.

Response: This final rule fully retains all protections offered by Section 1557, and it does not shift any focus from an individual's rights to the covered entity's programs or activities. It ensures that covered entities do not use their programs or activities to discriminate on the basis of any individual's national origin, which includes (under *Lau'*s disparate impact analysis) requiring those entities to provide reasonable access to LEP individuals.

Comment: The Department received comments asserting that language assistance is necessary for individuals with LEP to access Federally funded programs and activities in the healthcare system. Several commenters argued that adequate translation services are a civil right and an important tool for informing individuals with LEP of their healthcare rights. One commenter also expressed concern that informed consent is compromised when a language barrier prevents a patient from understanding what he or she is consenting to. Many commenters also said that individuals with LEP face unique challenges in healthcare that are mitigated by language access services, and that the proposed rule might weaken access by patients with LEP to quality healthcare, resulting in patients' avoiding or postponing the medical care they require out of fear of discrimination or mistreatment due to their national origin or the language they speak.

Response: The Department strongly agrees that language assistance is often vital for ensuring access to Federally funded programs and activities in the healthcare system by individuals with LEP. The Department believes this final rule highlights its commitment to ensuring that individuals with LEP receive language access services that are appropriate under the circumstances and consistent with longstanding enforcement mechanisms and guidance. Accordingly, this final rule clarifies throughout § 92.101 that where language assistance services are required to be offered by a covered entity, they must be no-cost, timely, and accurate; that translators or interpreters provided in order to comply with the law must meet specific minimum qualifications, including ethical principles, confidentiality, proficiency, effective interpretation, and the ability to use specialized terminology as necessary in the healthcare setting; and that a covered entity may not require an individual with LEP to bring his or her own interpreter or rely on a minor child or accompanying adult to facilitate communication, except under limited exceptions. In addition, the Department expects that the cost savings estimated below resulting from repeal of notice and taglines requirements will, where applicable, free up resources that entities can use to provide more access to LEP individuals.

Comment: A commenter said that the proposed rule weakens system-wide standards governing access to language assistance services and will

[281] *E.g.,* 42 U.S.C. 300gg–15(b)(2) and 300gg–19(a)(1)(B) (requiring standards for ensuring that the Summaries of Benefits and Coverage and certain notices are provided in a culturally and linguistically appropriate manner); 42 U.S.C. 1396d(p)(5)(A) (requiring HHS to distribute to States an application form for Medicare cost-sharing in English and 10 non-English languages); 26 CFR 1.501(r)–4(a)(1), (b)(5)(ii) (requiring a hospital organization to translate certain documents, among other requirements, to qualify for a tax-exempt status with respect to a hospital facility); 42 CFR 422.2262(a)(1)–(2) and 422.2264(e) (setting forth Medicare Advantage marketing requirements, which include requiring Medicare Advantage organizations to translate marketing materials into non-English languages spoken by 5% or more of individuals in a plan service area), § 423.2262(a)(1)–(2) and § 423.2264(e) (setting forth Medicare Part D marketing requirements, which include requiring Part D plan sponsors to translate marketing materials into non-English languages spoken by 5% or more of individuals in a plan service area); 45 CFR 155.205(c)(2)(iii)(A) (Marketplaces must post taglines on their websites and include taglines in documents ''critical for obtaining health insurance coverage or access to health care services through a QHP''); 68 FR 47318 (Aug. 8, 2003)—Guidance to Federal Financial Assistance Recipients Regarding Title VI Prohibition Against National Origin Discrimination Affecting Limited English Proficient Persons (setting forth guidance on translating ''vital'' documents).

[282] *See* Aetna, ''Member Reactions to 1557 Taglines'' (Apr. 2017), available at *https://www.regulations.gov/document?D=HHS-OCR-2019-0007-0002;* American Health Insurance Plans and Blue Cross Blue Shield Association (May 5, 2017), available at *https://www.regulations.gov/document?D=HHS-OCR-2019-0007-0003;* Pharmaceutical Care Management Association (May 2, 2017), available at *https://www.regulations.gov/document?D=HHS-OCR-2019-0007-0006.*

[283] *See* Aetna (May 1, 2017), available at *https://www.regulations.gov/document?D=HHS-OCR-2019-0007-0005;* Pharmaceutical Care Management Association (Mar. 27, 2017), available at *https://www.regulations.gov/document?D=HHS-OCR-2019-0007-0007;* American Health Insurance Plans and Blue Cross Blue Shield Association (May 5, 2017), available at *https://www.regulations.gov/document?D=HHS-OCR-2019-0007-0003.*

[284] *See* Pharmaceutical Care Management Association (Mar. 27, 2017), available at *https://www.regulations.gov/document?D=HHS-OCR-2019-0007-0007;* American Health Insurance Plans and Blue Cross Blue Shield Association (May 5, 2017), available at *https://www.regulations.gov/document?D=HHS-OCR-2019-0007-0003.*

disincentivize the broader system from embedding and institutionalizing LEP services.

Response: The Department knows of no evidence to support this assertion and considers it an improbable one, as this final rule simply applies the longstanding and well-known enforcement mechanisms of Title VI that have proven effective over time in ensuring access by individuals with LEP to covered programs.

Comment: Commenters said that it would be beneficial if the Department contacted providers with educational documents outlining the requirements under the proposed rule.

Response: It is not Department practice to reach out to all covered entities individually upon every regulatory change. At the same time, OCR does engage in various kinds of outreach to the regulated community. The proposed rule was published in the **Federal Register** and publicized on OCR's website, and this final rule will be publicized similarly. The Department expects its changes to reduce confusion among covered entities. If OCR sees evidence that this final rule's changes are causing any new confusion, OCR will consider issuing relevant guidance and education.

Comment: The Department received comments opposing the elimination of the provision requiring the Director to consider, if relevant, whether an entity has developed and implemented an effective written language access plan appropriate to its particular circumstances. Commenters stated that language access plans are important for evaluating compliance with Section 1557 and for planning efforts to address the needs of LEP individuals.

Response: The HHS LEP Guidance continues to encourage recipients to produce language access plans, but does not require them, and offers assistance to help ensure that implementation provides meaningful access by individuals with LEP. DOJ's LEP Guidance also does not require entities to produce such a plan. This final rule brings the Department's LEP regulations into closer conformity with the DOJ guidance, while Departmental guidance continues to encourage covered entities to go beyond minimum regulatory requirements.

Comment: One commenter argued that the justifications related to costs and resource availability do not supersede the right to meaningful access for individuals with LEP. Another commenter objected to cost's being the primary determinant for compliance with the proposed rule.

Response: Cost is not the primary factor in the four-factor analysis; no single factor is determinative. The four-factor analysis does not supersede the right to meaningful access but rather helps determine when an entity has taken reasonable steps to secure that right.

Comment: Some commenters believe the four-factor analysis under § 92.101(b) is too broad, lacks clarity, does not ensure that translation and other language services are available under important medical circumstances, may require recipients to provide unnecessarily expensive services, and/or weakens recipient language access obligations to serve persons who speak infrequently encountered languages. Others said that the proposed rule does not require a medical provider to make any effort to secure translation services when a patient faces a dire medical condition. Others supported the proposed rule's changes, indicating they would provide more flexibility for covered entities while ensuring that LEP persons have meaningful access to services. Some indicated that covered entities should not be required to provide expensive forms of language assistance, such as video remote interpreting services.

Response: The Department agrees with commenters who state that the four-factor analysis is an appropriate way to allow flexibility for covered entities while ensuring meaningful access for LEP individuals. As to the specific hypothetical situations described by commenters, OCR will evaluate such situations as they are presented to OCR on a case-by-case basis. The fact-dependent nature of Title VI analysis makes it impossible to make pronouncements on such situations without all the relevant facts.

Comment: Some commenters requested that this final rule stipulate that health insurance plans are in compliance with the four-factor test if they incorporate either State LEP requirements or items 4–7 of the National Standards for Culturally and Linguistically Appropriate Services (CLAS).

Response: The ACA instructs the Department to apply to Section 1557 the enforcement mechanisms available under Title VI, which include mechanisms for enforcing language access cases. This final rule relies on longstanding Federal practice in enforcing Title VI; it is far from clear that the Department would have statutory authority to enforce the CLAS standards or State LEP requirements instead. Moreover, recipients that provide language assistance in accordance with CLAS standards and State LEP requirements may still be utilizing other methods of administration that violate the final rule.

Comment: Some commenters suggested that administrative burden would be relieved by adopting uniform language access policies with other components in the Department like CMS, arguing that it would improve patient experiences and reduce errors.

Response: Because CMS program regulations are often implemented under different statutes than are civil rights regulations, and because LEP standards under Title VI have been subject to longstanding standards under DOJ and HHS guidance, the Department does not believe it is necessary at this time to adopt uniform language access standards across these different regulations. This final rule addresses regulations under Section 1557 and the civil rights statutes it incorporates.

Comment: Some commenters argued the proposed rule weakens the qualifications for language service providers by eliminating the words ''qualified'' and ''above average familiarity with'' from the proposed description of language interpreters and translators.

Response: This final rule does not weaken any qualifications for language service providers. It continues to use the term ''qualified'' six times in its regulatory text to describe ''interpreters,'' ''translators,'' or ''staff'' as relevant. As stated in the 2019 NPRM, this final rule eliminates the term ''qualified'' from the 2016 Rule only where it was redundant and clearly implied by the context—namely, a list of the translator's/interpreter's mandatory qualifications, a list that remains unchanged from the 2016 Rule.[285] And the 2016 Rule expressly declined to include any reference to ''above average familiarity.''[286]

Comment: A commenter asserted that the proposed rule will adversely affect the patient-provider dialogue in addiction treatment programs, and underscored the importance of transparency in discussions about substance use history.

Response: The Department is not aware of any evidence to demonstrate this assertion, and believes that relying on the Department's underlying regulations and guidance will not result in such adverse effects.

Comment: Commenters expressed concern over the Department's proposal to remove requirements on video

[285] 84 FR 27860, 27866.

[286] 81 FR 31390–91.

interpreting quality standards as it relates to using video remote interpreting (VRI) services for LEP individuals or spoken language interpreting. Many commenters noted that most VRI services are done on the same equipment and through the same network and bandwidth for both spoken language and sign language, and that if these standards are removed for spoken language interpreters, there will be an unintended consequence of lower-quality VRI services for deaf and hard of hearing individuals. Other commenters noted that while they appreciated the incorporation of the ADA's definition of VRI, they opposed the removal of the technical and training requirements for the use of VRI for spoken language interpretation.

Some commenters recommended that all covered healthcare entities prioritize the use of on-site sign language interpreters, limit usage of VRI to specific situations, and maintain either a directory of local interpreters available for on-site work or a contract with an interpreter service provider to secure on-site interpreters when needed. Commenters offered detailed suggestions for regulations to limit VRI usage.

Response: In place of blanket requirements for VRI standards, this final rule adopts the four-factor analysis regarding access for LEP individuals, which will help covered entities balance competing considerations related to VRI quality standards. Where high-quality VRI is necessary to provide meaningful access to LEP persons, high-quality VRI will be required just as it was under the 2016 Rule. Furthermore, as is made clear in the next subsection (on proposed § 92.102), this final rule continues to hold covered entities to the ADA Title II standards for video interpretive services where these are needed for effective communication for deaf or hard of hearing individuals.

The Department requested comment on whether HHS's Title VI regulations at 45 CFR part 80 should be amended to address the *Lau* v. *Nichols*[287] precedent.

Comment: A commenter stated that the Department's regulations implementing Title VI do not need to be amended to address *Lau* v. *Nichols* as HHS and DOJ have followed this Supreme Court precedent for decades.

Response: The Department agrees and will continue to enforce Title VI consistent with Federal law.

In reviewing § 92.101 and public comments, the Department observed that the proposed rule inadvertently omitted the word ''or'' from the end of paragraph (b)(4)(ii)(A), concerning exceptions to the prohibition on using an adult accompanying an individual with LEP to interpret or facilitate communication. The ''or'' had been included in the parallel provision of the 2016 Rule at § 92.201(e)(2)(i); in the preamble to the proposed rule, the Department explained that it would apply those exceptions ''[l]ike the current rule'' (meaning as in § 92.201(e) of the 2016 Rule). 84 FR at 27866. To correct this, the Department finalizes § 92.101 with a technical change to insert ''or'' at the end of paragraph (b)(4)(ii)(A).

(2) Effective Communication for Individuals With Disabilities (45 CFR 92.102)

The Department proposed to retain the 2016 Rule's provisions on effective communication for individuals with disabilities. 84 FR at 27866–67.

Comment: A commenter suggested that each Section 1557 covered entity should simply comply with the standards that apply to each entity under the ADA, in order to reduce burden, confusion, and complexity.

Response: As a general matter, the Department does not view a covered entity's compliance with other Federal regulations, adopted with different requirements and for different purposes, as determinative of a covered entity's compliance with Section 1557.

Comment: The Department received comments expressing concern that the proposed rule would cause major harm to people with disabilities, affecting their access to effective healthcare, especially for those individuals in underserved and rural communities. Commenters suggested that because the current rule is working as it was intended, there is not sufficient reason to reopen it. Commenters argued that the ability to effectively communicate includes the individual patient as well as the patient's family/caregivers, and that the inability to effectively communicate can have significant adverse effects on an individual's access to healthcare. Other commenters expressed support for retaining the provisions of 45 CFR 92.202 (redesignated § 92.102), regarding effective communication for individuals with disabilities. Commenters noted that effective communication is a critical component to accessing and receiving healthcare and that often covered entities rely on communication methods that are the preference of the covered entity rather than the choice of the individual with a disability. Commenters stated that giving primary consideration to the choice of aid or service requested by an individual with a disability helps to ensure effective communication and equal opportunity in the healthcare setting. Commenters commended HHS for holding all recipients of Federal financial assistance from HHS to the higher ADA Title II standards.

Response: Access to care continues to be a critical concern for the Department, and access to care clearly requires effective communication. The Department does not believe this final rule will impede individuals' access to care, but that instead it will assist individuals in understanding a covered entity's legal obligations and their own rights under Section 1557. In addition, the rule will assist the Department in complying with the mandates of Congress and further substantive compliance. Finally, because this final rule will lift unnecessary regulatory burdens on providers, the Department hopes that it will increase access to care, including in underserved and rural communities.

Comment: Commenters noted that the current regulation's language tracks the statutory text of Title I and Title III of the ADA and the regulatory language of Title II of the ADA, all of which protect against discrimination based on association or relationship with a person with a disability. They said that the proposed rule's elimination of the 2016 Rule's prohibition on associational discrimination will therefore create bewilderment concerning providers' responsibilities and individuals' rights. Commenters argued that deleting the language will create uncertainty and confusion regarding the responsibilities of providers and the rights of persons who experience discrimination, and inconsistencies with other regulatory requirements that entities are subject to, including the ADA and Section 504.

Response: As stated above, protections against discrimination on the basis of association will be available under this final rule to the extent that they are available under the incorporated civil rights statutes and their implementing regulations. The Department notes that courts have often relied on ADA statutory provisions in their handling of Section 504 claims.[288]

[287] *Lau* v. *Nichols,* 414 U.S. 563 (1974).

[288] *See* Memorandum on Coordination of Federal Agencies' Implementation of Title II of the Americans with Disabilities Act and Section 504 of the Rehabilitation Act, Acting Assistant Attorney General (April 24, 2018); *see, e.g., Theriault* v. *Flynn,* 162 F.3d 46, 48 n.3 (1st Cir. 1998); *Henrietta D.* v. *Bloomberg,* 331 F.3d 261,272 (2d Cir. 2003); *Helen L.* v. *DiDario,* 46 F.3d 325, 330 n.7 (3rd Cir. 1995); *Baird ex rel. Baird* v. *Rose,* 192 F.3d 462, 468 (4th Cir. 1999); *Delano-Pyle* v. *Victoria Cty., Tex.,*
Continued

Comment: Several commenters objected that the definition of auxiliary aids and services at proposed § 92.102(b)(1) excludes the term ''Qualified'' before ''Interpreters'' in subsection (i) and before ''Readers'' in subsection (ii), despite being part of the ADA definition at 28 CFR 35.104. Some Commenters strongly encouraged the Department to incorporate the ADA definition of ''Qualified Reader'' as follows: ''Qualified reader means a person who is able to read effectively, accurately, and impartially using any necessary specialized vocabulary.'' [289]

Response: As stated above regarding § 92.101(a), this final rule eliminates the term ''qualified'' from the 2016 Rule only where it was redundant and clearly implied by the context. In this case, subsection (b)(2) clearly lists the mandatory qualifications for interpreters required under subsection (b)(1), and it adopts that list from the ADA definition at 28 CFR 35.104 and § 36.303(f). It would therefore be redundant to describe those interpreters in subsection (b)(1) as ''qualified.'' No definition of ''Qualified Reader'' appears in the 2016 Rule, so the Department is making no change in that regard. But the Department interprets this subsection naturally as requiring qualifications for readers that are similar to the expressly stated qualifications for interpreters.

Comment: Commenters argued that although the proposed rule claims to incorporate the definition of auxiliary aids and services from the regulations implementing Title II of the ADA, the rule as proposed changes the definition of auxiliary aids and services, omitting ''acquisition or modification of equipment and devices; and other similar services and actions'' from the list of examples of aids and services. Commenters noted that this proposed change will confuse providers and people with disabilities and will lead both groups to assume the list in the proposed rule is exhaustive. Commenters opposed these deletions and requested that the Department retain the definition of auxiliary aids and services from the 2016 Rule.

Response: The Department's definition of auxiliary aids and services is consistent with, even if not identical to, that of the ADA. The Department does not deem it necessary to incorporate all of the ADA's examples, as neither the ADA's list nor this final rule's list claims to be exhaustive.

Comment: Some commenters expressed concern regarding the narrowing of the ''free of charge'' and ''timely manner'' provision at proposed § 92.102(b)(2). Commenters noted that the 2016 Rule's language is consistent with existing ADA Title II regulations, which provide that covered entities may not place a surcharge on a particular individual or group of individuals with a disability to cover the costs of the provision of auxiliary aids or program accessibility. Commenters asserted that the proposed § 92.102(b)(2) significantly narrows this provision by stating that ''interpreting service'' shall be provided to individuals free of charge and in a timely manner. These commenters strongly opposed this change and encourage the Department to replace the words ''interpreting service'' with ''auxiliary aids and services'' to be consistent with the ADA and to prevent unnecessary confusion over the requirement.

Response: Like § 92.202 of the 2016 Rule, which it replaces, § 92.102 of this final rule continues to incorporate the ADA Title II regulations at 28 CFR 35.160–164. The new section also includes new language on the qualifications for interpreters, which is where the term ''free of charge'' now appears; the term did not appear in § 92.202 of the 2016 Rule. To the extent that auxiliary aids must be provided free of charge under the 2016 Rule, they must still be provided free of charge under this final rule.

Comment: One commenter asked that the phrase ''in a timely manner'' as used in Section 92.102(b)(2) of the proposed rule be clarified with clear guidance as to what can and cannot be considered ''in a timely manner.''

Response: Application of the term ''in a timely manner'' requires a nuanced analysis that is fact-dependent. Its meaning can be understood from the long history of enforcement of Section 504 and the ADA in the courts and administratively.

Comment: Some commenters supported an exemption from the auxiliary aids and services requirement for covered entities with fewer than 15 employees, stating that it would help alleviate financial and administrative burden for smaller physician group practices that may already have limited resources. Others said that in some areas of the country, especially in small and rural communities, such an exemption could effectively bar access to many providers. Commenters said that any such exemption would be inconsistent with the standard present in Title II [290] and Title III [291] of the ADA, which require the same businesses to provide auxiliary aids and services to individuals with disabilities where necessary to ensure effective communication, regardless of the number of employees. They said that the existence of two competing regulatory standards will confuse small covered entities as to which standard they should follow. Several commenters noted that although a small economic burden may be placed on small businesses that have to comply with this requirement, there are programs that provide tax benefits and funding for the provision of reasonable accommodations, significantly reducing the burden placed on these entities.[292] Some commenters noted that because Titles II and III of the ADA already provide for sufficient mechanisms for providers to request exemptions based on a fundamental alteration in the nature of goods and services provided and undue burden, no additional exemption is needed through Section 1557.

Response: The Department believes that in the interest of uniformity and consistent administration of the law, all employers that receive Federal financial assistance from HHS, regardless of their size, should be held to the auxiliary aids and services requirement. The Department recognizes the importance of individuals being able to effectively communicate with their healthcare providers and is aware that the inability to effectively communicate can have significant adverse effects on individuals' access to effective healthcare. The Department's decision to require all entities, regardless of size, to provide auxiliary aids and services is consistent with OCR's policy for almost two decades,[293] so covered entities will

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302 F.3d 567, 574 (5th Cir. 2002); *McPherson* v. *Michigan High School Athletic Ass 'n, Inc.,* 119 F.3d 453, 459–60 (6th Cir. 1997); *Gorman* v. *Bartch,* 152 F.3d 907, 912 (8th Cir. 1998); *Zukle* v. *Regents of Univ. of Cal.,* 166 F.3d 1041, 1045 n.11 (9th Cir. 1999); *Cohan ex rel. Bass* v. *N.M. Dept. of Health,* 646 F.3d 717, 725–26 (10th Cir. 2011); *Bircoll* v. *Miami-Dade Cty.,* 480 F.3d 1072, 1088 n.21 (11th Cir. 2007).

[289] 28 CFR 35.104.

[290] 28 CFR 35.104.

[291] *See* 42 U.S.C. 12182(b)(A)(iii) (under Title III, privately operated public accommodations regardless of their size are obligated to provide appropriate auxiliary aids and services, when necessary to ensure effective communication with individuals with disabilities, unless the entity can demonstrate that taking such steps would fundamentally alter the nature of their programs, services or activities, or would result in undue financial and administrative burdens).

[292] Commenters cited U.S. Department of Justice American with Disabilities Act Update: A Primer for Small Business. (2010). Retrieved from *https://www.ada.gov/regs2010/smallbusiness/smallbusprimer2010.htm;* Internal Revenue Service. (n.d.); Form 8826, Disabled Access Credit. Retrieved from *https://www.irs.gov/forms-pubs/about-form-8826*.

[293] *See* Notice of Exercise of Authority Under 45 CFR 84.52(d)(2) Regarding Recipients With Fewer Than Fifteen Employees, 65 FR 79368 (Dec. 19, 2000).

be familiar with the obligations being imposed. Title II and Title III of the ADA already require public and private healthcare entities to provide auxiliary aids and services regardless of the number of employees. Both Titles state that an entity is not required to take any action that it can demonstrate would result in a fundamental alteration in the nature of a service, program, or activity or in undue financial and administrative burdens, and § 92.102 incorporates both of those limitations through its incorporation of the ADA Title II regulations at 28 CFR 35.160–164. Therefore, the Department finds it appropriate not to adopt an exemption from the auxiliary aids and services requirement for covered entities with fewer than 15 employees.

Comment: Commenters said that the ''primary consideration'' standard has evolved such that patients will demand that a particular translator or interpreter be used, regardless of the expense. These commenters argued that when patients demand use of a certain company or specific commercial service, this creates additional unnecessary costs for the covered entity. One commenter stated that Title III of the ADA should be the standard that applies to private businesses covered by Section 1557 regarding effective communication for individuals with disabilities. The commenter asserted that the Title II primary consideration standard is not appropriate for use in a clinical setting and that treating clinicians or the entities themselves are in the best position to determine the types of services necessary to address the communication needs of their patients. The commenter argued that applying Title II standards to private entities has created significant confusion for medical group practices accustomed to following longstanding Title III rules.

Response: Since the 2015 NPRM, the Department has held that it is appropriate, as a condition of receipt of Federal financial assistance from HHS, to hold all recipients to the higher 2010 ADA Title II standards regarding effective communication with individuals with disabilities.[294] The Department does not consider the commenters' concerns to be a sufficient reason to change this policy. Section 92.102 of this final rule seeks to avoid confusion by providing covered entities with clear, specific guidance to help them understand their rights and responsibilities regarding effective communication with individuals with disabilities. As mentioned above, it also incorporates the ''undue burden'' and ''fundamental alteration'' limitations of ADA Title II, in order to avoid excessively burdening covered entities.

(3) Accessibility Standards for Buildings and Facilities (45 CFR 92.103)

The Department proposed at § 92.103(a) to retain the 2016 Rule's requirement that new construction or alteration of buildings or facilities subject to Section 1557 must comply with the 2010 ADA Standards for Accessible Design by January 18, 2018, and to retain the 2016 Rule's allowance of departures from the 2010 ADA standards where other methods are permitted that provide substantially equivalent or greater access to and usability of the building. 84 FR at 27867. The Department proposed at § 92.103(b) to create a safe harbor for new construction or alteration of buildings or facilities subject to Section 1557, allowing existing facilities which were only required to be compliant with the Uniform Federal Accessibility Standards (''UFAS''), the 1991 ADA Standards, or the 2010 ADA Standards as of July 18, 2016, to be deemed compliant, unless there is new construction or alteration after January 18, 2018. Finally, the Department proposed at 92.103(c) to identify the three applicable building and facility detailed technical accessibility standards by cross-reference to their underlying regulations, instead of listing them in a separate definitions section.

Upon further consideration of this language and the public comments, the Department observed a potential ambiguity in § 92.203 of the 2016 Rule. The rule distinguished between construction or alteration commenced ''on or after July 18, 2016'' in the first sentence of § 92.203(a), those commenced ''on or before July 18, 2016'' in the first sentence of § 92.203(b), and those commenced ''before July 18, 2016'' in the last sentence of § 92.203(b). This potentially left it unclear how the rule would apply to construction or alteration commenced on July 18, 2016. To avoid confusion, the Department is finalizing § 92.103 with a technical change, by deleting the phrase ''on or'' from the first sentence of § 92.103(a), and adding ''on or'' before the word ''before'' in the last sentence of § 92.103(b). This resolves the ambiguity while providing leeway to activities commenced on July 18, 2016 where it was not clear how the 2016 Rule applied.

Comment: Commenters supported the proposal to continue to apply the 2010 ADA Standards' definition of ''public building or facility'' to all entities covered under Section 1557, by retaining the provisions of 45 CFR 92.203 (redesignated § 92.103) regarding accessibility standards for buildings and facilities. Commenters opposed any type of additional exemption from the requirements concerning multistory building elevators[295] and Text Telephone (TTY) requirements.[296] Some commenters strongly opposed the proposed rule's incorporation of the private entity TTY standard from the 2010 ADA Standards, and requested the retention of the existing TTY ratios, and the adoption of stringent Real-Time Text (RTT) ratios. Others noted that lack of accessible medical equipment presents barriers to effective healthcare for people with impaired mobility or strength and other disabilities, and they requested that the Department require healthcare facilities to follow the 2017 Architectural and Transportation Barriers Compliance Board (U.S. Access Board) Standards for Accessible Medical Diagnostic Equipment.[297]

Response: The Department believes that, because the great majority of entities covered by the 2016 Rule have already been subject to the 2010 ADA Standards, an approach that emphasizes uniform application of the 2010 Standards will promote conformity with pre-existing civil rights statutes while enabling greater consistency among implementing agencies. Any significant reevaluation of those standards or adoption of new standards is beyond the scope of this regulation. In the case of adopting new standards, the Department also declines to make such a significant regulatory change without the benefit of notice and public comment.

(4) Accessibility of Information and Communication Technology (45 CFR 92.104)

The Department proposed to retain the 2016 Rule's provisions on accessibility of information and communication technology for individuals with disabilities. 84 FR at 27867. The Department also proposed at 92.104(c) to update the 2016 Rule's

[294] 80 FR 54186.

[295] *See* 42 U.S.C. 12101 *et seq.* Exception 1 of section 206.2.3 of the 2010 ADA standards exempts multistory buildings besides the professional office of a healthcare provider owned by private entities from the requirement to provide an elevator to facilitate an accessible route throughout the building. This exemption does not apply to public entities.

[296] The 2010 ADA Standards also specifies TTY requirements for public buildings different from private buildings. Compare ADA 2010 Standard 217.4.3.1 (public buildings) with ADA 2010 Standard 217.4.3.2 (private buildings).

[297] *See* Information and Communication Technology (ICT) Standards and Guidelines, 82 FR 5790 (Jan. 18, 2017) (final rule); 83 FR 2912 (Jan. 22, 2018) (technical edits).

outdated term ''electronic and information technology'' with the term ''information and communication technology,'' as defined in the U.S. Access Board regulations. 84 FR at 27871.

Comment: Commenters expressed concern with the Department's proposed change to the definition of ''information and communication technology'' (ICT), in proposed § 92.104(c). Commenters noted that the critical phrase ''but are not limited to'' has been removed from the definition the Department claims to have incorporated from the U.S. Access Board's definition for ICT.[298] The commenters argue that due to the difficulty in predicting what technologies will be in place moving forward, it is important to maintain flexibility and ensure that the regulation keep pace with emerging technologies.

Response: The list of auxiliary aids was not intended as an all-inclusive or exhaustive catalogue of possible or available auxiliary aids or services—nor could it possibly be, given the new devices that will become available with emerging technology. The Department omitted the phrase ''but are not limited to'' merely in order to avoid unnecessary legal jargon. The plain meaning of ''include'' already encompasses ''but are not limited to,'' as it signifies that the listed items are only parts of a larger whole.

Comment: One commenter requested that the Department require recipients of Federal financial assistance to ensure that health programs or activities provided through their websites comply with the requirements of Title III, rather than Title II, of the ADA, if the recipient is otherwise covered by Title III. The commenter argued that the burden placed on small practices by having to comply with both Title II and Title III would likely outweigh any benefit to individuals who require accessible technology.

Response: The Department believes that this comment understates the benefit of the Title II standards to individuals who require accessible technology. Effective communication is a critical component for individuals to be able to access and receive healthcare, and this includes being able to access covered entities' websites. The Department believes that in the interest of uniformity of access for individuals with disabilities, all entities that receive Federal financial assistance from HHS should be held to the higher information and communication technology standards of Title II. The ADA does not exempt small providers from this requirement, although § 92.104 does incorporate the ADA's ''undue financial and administrative burden'' and ''fundamental alteration'' exemptions in order to protect covered entities from excessive burdens.

Comment: Some commenters stated that the Department should cross-reference Section 508 in its proposed § 92.104. The commenters noted that although the proposed rule tracks the concepts of the Section 508 regulations, it does not include the appropriate cross-reference, which will cause confusion if and when the Section 508 regulations are updated.

Response: If and when Section 508 regulations are updated, the Department will evaluate whether or not to update § 92.104 accordingly. Because this final rule does not incorporate Section 508 regulations but merely tracks them, the Department believes that a cross reference could cause unnecessary confusion if and when Section 508 regulations are updated or changed.

(5) Requirement To Make Reasonable Modifications (45 CFR 92.105)

The Department proposed at § 92.105 to retain the 2016 Rule's requirement that covered entities make reasonable modifications to policies, practices, or procedures when necessary to avoid discrimination on the basis of disability, unless the covered entity can demonstrate that the modification would fundamentally alter the health program or activity. 84 FR at 27868. The Department sought comment on whether to include an exemption for ''undue hardship.'' *Id.*

Comment: Commenters strongly opposed an exemption for undue hardship in regard to the requirement that covered entities make reasonable modifications to policies, practices, or procedures when necessary, to avoid discrimination on the basis of disability, except if the modification would fundamentally alter the nature of the health program or activity. Commenters pointed out that the current regulations track Title II of the ADA. Commenters stated that Title III does not absolve a covered entity from providing all forms of auxiliary aids if providing a particular auxiliary aid would result in undue burden, and that a provider has an obligation to find an alternative auxiliary aid in such cases. Commenters noted that because Title II and III of the ADA already provide mechanisms for providers to request exemptions based on an undue burden, no additional exemption is needed. Commenters stated that the substitute language proposed is from regulations related to employment and ill-fitting and inappropriate in a healthcare context. Commenters requested that if an exemption for undue hardship is provided, it should mirror the undue burden provision of the ADA, to ensure the two Federal laws are in sync and do not conflict with one another and lead to confusion.

Response: The Department agrees with commenters who ask that the regulations continue tracking Title II of the ADA, whose requirement for reasonable modifications includes a fundamental alteration exemption but no undue hardship exemption. The Department believes that this position helps promote continued consistency with pre-existing civil rights statutes. The reasonable modification analysis already applies to many entities subject to Section 1557 and is well-defined by regulation and decades of case law. Continuing to apply the ''reasonable modification'' analysis to Section 1557 promotes consistency with pre-existing civil rights law and is consistent with the U.S. Supreme Court's decision interpreting Section 504 in *Alexander* v. *Choate,* 469 U.S. 287 (1985), Title II of the ADA, and OCR's longstanding interpretation of Section 504.

Comment: Commenters objected to substituting the Title II reasonable modification language with language stating that covered entities ''shall make reasonable accommodation to the known physical or mental limitations of an otherwise qualified'' individual with a disability. Further, a commenter argued that use of the term ''known,'' outside the employment context, would suggest an overly narrow interpretation of the scope of Section 1557 and introduce an unnecessarily burdensome and intrusive process into the healthcare context. Commenters expressed concern that importing the ''known physical or mental limitation'' language would suggest to covered entities that their obligations are limited, and would create an undue focus on the measures that entities must take in response to requests for modifications.

Response: The Department shares the concern that introduction of the phrase ''known physical or mental limitations'' may cause covered entities to introduce

[298] *See* 36 CFR app. A § 1194 (2011) (defining ICT as ''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; customer premises equipment; multifunction office machines; software; applications; websites; videos; and electronic documents.'').

exceedingly burdensome and intrusive processes into the healthcare context. In contrast, the concept of reasonable modification taken from Title II has long applied to a wide range of entities covered by Section 1557, making such entities familiar with the requirements imposed, and is well-defined by regulation and decades of case law. The Department believes that continuing to apply the reasonable modification analysis to Section 1557 will help promote consistency with pre-existing civil rights statutes.

Comment: Several commenters noted that the citation for the proposed reasonable modification language the Department claims conforms to the Department of Justice's Section 504 coordinating regulations is to a non-existent portion of the Code of Federal Regulations. These commenters argue that these incorrect citations make it impossible for the public to analyze the context or case law of the proposed imported language and that such uncertainty makes it impossible for the public to reliably know what the Department is proposing.

Response: The Department thanks these commenters for bringing this citing error to its attention. For clarity, the Department notes that it intended to cite to 28 CFR 42.511, not § 92.205.[299] But for the reasons stated above, the Department has determined that it should retain the current Title II reasonable modification language.

Comment: Some commenters recommended that the rule include the addition of examples of programmatic modifications that are often needed by those with disabilities, such as the modification of wait times, office hours, and other business practices that can make accessibility to healthcare for people with disabilities difficult.

Response: The Department declines to enshrine a list of examples of ''programmatic modifications'' needed by those with disabilities. Because this final rule applies to a diverse range of covered entities, codifying examples would not provide meaningful guidance to the full spectrum of regulated covered entities. The Department believes that each covered entity ought to determine for itself which programmatic modifications with respect to its health programs and activities should be undertaken to avoid discrimination on the basis of disability, subject to enforcement by OCR in case of a complaint.

Comment: Commenters found inappropriate the Department's requesting comment on whether it has struck the appropriate balance in proposed §§ 92.102 through 92.105 with respect to Section 504 rights and obligations imposed on the regulated community, as such a balancing exercise is not called for by the statute and inserts inappropriate regulatory subtlety.

Response: In any rulemaking, addressing obstacles that impede individuals from exercising their rights should be balanced against potentially unnecessary obligations that may be imposed on the regulated community. Agencies engage in this type of balancing in order to ensure that the interests and issues of both individuals and the regulated community are fairly considered during the rulemaking process, helping to minimize the burden associated with Federal regulations.

Comment: A commenter said that in order to promote clarity and affirm that VRI quality standards apply in any remote interpreting situation that may arise for a person with a disability, § 92.101 of the proposed rule ought to cross-reference the VRI quality standards in § 92.102.

Response: Section 92.102 covers individuals with disabilities. § 92.101 covers individuals with LEP status, which is not a disability. Individuals with disabilities have different needs than LEP individuals, and the current regulatory text reflects that difference. If an LEP individual happens also to have a disability, then the VRI quality standards of § 92.102 will apply to him/her.

(6) Summary of Regulatory Changes

The Department finalizes the proposed sections § 92.101 through 92.105 without change, except that technical changes are made to add the word ''or'' at the end of § 92.101(b)(4)(ii)(A), to delete the phrase ''on or'' from the first sentence of § 92.103(a), and to add the phrase ''on or'' before the word ''before'' in the last sentence of § 92.103(b).

D. Title IX Regulations

The Department proposed to conform its Title IX regulations to current statutory provisions.

(1) Nomenclature, Rules of Appearance, Effective Date Modifications to Rules at 45 CFR 86.31 and 86.71

The Department proposed to make a nomenclature change to the Title IX regulation by replacing ''United States Commissioner of Education'' with the official's current title, ''Secretary of Education.''[300] The Department also proposed to update the Title IX regulation's statutory citations to include the full current text of Title IX as amended by the CRRA.

The Department also proposed to repeal a prohibition on discrimination on the basis of ''rules of appearance'' in 45 CFR 86.31. The Department further proposed to update the enforcement section in the Department's Title IX regulation at 45 CFR 86.71, which currently discusses only enforcement procedures for the interim period before the issuance of the consolidated Title IX regulation. This final rule applies language from the Title IX regulation, which incorporates Title VI procedures.

Comment: The Department received comments indicating that the rules of appearance prohibition is well supported by Title IX and that HHS provides no basis for removing the prohibition.

Response: This final rule's NPRM explained that currently, the Department is the only Federal agency with Title IX regulatory language prohibiting discrimination ''against any person in the application of any rules of appearance.''[301] The phrase ''rules of appearance'' does not appear in Title IX and was never defined in any agency's Title IX regulations. Consequently, the Department believes the phrase may cause confusion in the public about Title IX's coverage and compliance responsibilities, and has already led to at least one lawsuit. Because this language is not in the current regulations of any other agencies, this final rule limits the potential for conflicting and inequitable Federal agency enforcement of Title IX with respect to ''rules of appearance.''

(2) Abortion Neutrality of 20 U.S.C. 1688 in 45 CFR 86.2 and 86.18

The Department also proposed to modify its Title IX regulations, at 45 CFR 86.18, to reflect the statutory text Congress enacted in Title IX. This text includes what some commenters referred to as the Danforth Amendment, 20 U.S.C. 1688, which states that Title IX is not to be construed to force or require any individual or hospital or any other institution, program, or activity receiving Federal funds to perform or pay for an abortion; to require or prohibit any person, or public or private entity, to provide or pay for any benefit or service, including the use

[299] *See* 84 FR 27868 (citing to 28 CFR 92.205).

[300] *See* 45 CFR 86.2(n).

[301] *See, e.g.,* 47 FR 32527 (July 28, 1982) (Department of Education Title IX regulation); 65 FR 52858 (Aug. 30, 2000) (common rule adopted by twenty agencies), 66 FR 4627 (Feb. 20, 2001) (common rule adopted by Department of Energy); 82 FR 46656 (Oct. 6, 2017) (U.S. Department of Agriculture adopting common rule).

of facilities, related to an abortion; or to permit a penalty to be imposed on any person or individual because such person or individual is seeking or has received any benefit or service related to a legal abortion.[302] The Department also proposed to add a provision, similar to the provision of the Section 1557 regulation discussed above under ''relation to other laws,'' ensuring that its Title IX regulation would be construed consistently with various religious freedom and conscience statutes, including the explicit religious exemptions in the text of Title IX itself.

Comment: One commenter stated that adding Title IX's abortion neutrality language in the Department's Title IX regulations would be a violation of the plain language of the definition of sex discrimination in the regulations, which includes termination of pregnancy. Others noted that discrimination based on termination of pregnancy has been recognized by courts as sex discrimination and therefore argued that the proposed rule is contrary to civil rights laws and constitutional principles. Some noted that Title IX itself expressly does not permit penalties based on a woman's prior termination of pregnancy.

Others, however, supported the incorporation of Title IX's religious exemptions and other Federal conscience statutory protections, arguing that they are consistent with abortion neutrality. Still others stated that discrimination on the basis of sex should not include termination of pregnancy at all, under existing law and the statutory text of Section 1557 and Title IX. Some submitted legislative history from Title IX (Senate Committee Report 100–64) to show that Congress intended to allow for abortion exemptions and exclusion of health insurance coverage for abortion services, and that Congress did not intend to require all hospitals to provide abortion services to the general public.[303] But other commenters were critical of using legislative history to interpret a statute.

Response: This final rule does not remove the language from the Department's Title IX regulations that prohibits certain forms of discrimination on the basis of ''termination of pregnancy.'' [304] However, as stated above in the section on discrimination on the basis of sex (subsection on ''termination of pregnancy''), the Title IX regulations are governed by the text of the Title IX statute and cannot be ''construed to require or prohibit any person, or public or private entity, to provide or pay for any benefit or service, including the use of facilities, related to an abortion'' (20 U.S.C. 1688). This final rule adds language to the Title IX regulations in order to make this clear. Although some commenters cite legislative history, the Department interprets the statutory text as written. Regardless, the Department does not believe there is tension between the legislative history and the text.

By adding the abortion neutrality language to the Title IX regulations, and stating in the Section 1557 regulation that it will be applied consistent with Title IX (including that language), this final rule ensures compliance with the rationale in *Franciscan Alliance,* where the Court rightly held that the Department's regulations forbidding discrimination on the basis of sex must be construed in light of the underlying text of Title IX, including abortion neutrality.

Comment: Commenters stated that religious exemptions would make it harder to find healthcare in low provider areas, and that religious refusals also harm people who live in rural areas and must travel for an abortion. However, other commenters stated that this inclusion of various Federal conscience statutes and appropriations riders would ensure that healthcare providers who have conscience objections to abortion will feel welcome within the healthcare profession and will ease retention of healthcare providers already in the field.

Some specifically stated their support for the Department's inclusion of the First Amendment, and for Department guidance that the proposed rule be construed consistent with religious liberty and free speech protections, to clarify that the interpretation, application, and enforcement of the proposed rule will be consistent with religious liberty. Other commenters stated that referring to the First Amendment rightly addresses the recent Supreme Court ruling in *NIFLA* v. *Becerra.*[305] Commenters were concerned that the 2016 Rule would require a faith-based hospital to inform a patient about terminating her pregnancy in direct contravention of sincerely-held religious beliefs. This would be in conflict with *NIFLA,* where the Supreme Court held that such a mandate ''imposes an unduly burdensome disclosure requirement that will chill [] protected speech.'' [306]

Response: The Department agrees that this final rule should be construed consistent with the First Amendment, conscience statutes, and all relevant statutes and appropriations riders relating to abortion, to the extent they remain in effect or applicable. Agency regulations are subject to the requirements of the First Amendment in any case, and the Department considers it appropriate to say so explicitly here. All the other laws referenced establish Congressionally required parameters that may apply to the Department's interpretation, implementation, and enforcement of Title IX and of this final rule.[307] Commenters' policy objections to these statutory constraints are not a sufficient reason for the Department not to finalize this provision of the rule, which will ensure compliance with statutory requirements.

(3) Summary of Regulatory Changes

For the reasons described herein and having considered the comments received, the Department finalizes changes to 45 CFR 86.2, 86.18, 86.31, and 86.71 without change.

E. Conforming Amendments to CMS Regulations

The Department proposed to make conforming amendments to ten regulations of CMS that prohibited discrimination on the basis of gender identity and/or sexual orientation in the establishment and operation of ACA exchanges; in the marketing and design practices of health insurance issuers under the ACA; in the administration, marketing, and enrollment practices of QHPs under the ACA; in beneficiary enrollment and the promotion and delivery of services under Medicaid; and in the delivery of services under the PACE program. These conforming changes were proposed, among other

[302] *See* Public Law 100–259, 102 Stat. 28, sec. 8 (Mar. 22, 1988) (codified at 20 U.S.C. 1688).

[303] *See* Senate Committee Report 100–64 (''This bill does not expand abortion rights. Religiously-controlled organizations will continue to be able to apply for, and receive, an exemption from Title IX requirements where compliance with those requirements would violate their religious tenets. For example, a religiously controlled university that wished to exclude insurance coverage of abortions from an otherwise comprehensive student health insurance policy, could seek a religious exemption. . . . Title IX covers only students and employees, and does not reach the public at large. Therefore, claims that the bill would require hospitals to provide abortion services to the general public are false.'').

[304] *See* 45 CFR § 86.21(c)(3), 86.40(b)(1), 86.40(b)(4), 86.40(b)(5), 86.51(b)(2), 86.51(b)(6), 86.57(b), 86.57(c), 86.57(d).

[305] *Natl. Inst. of Fam. and Life Advocates* v. *Becerra,* 138 S. Ct. 2361 (2018).

[306] *Id.* at 2378.

[307] To the extent the relevant provisions are found in an appropriations rider, they apply to the Department's interpretation, implementation, and enforcement of Title IX every year that they are enacted.

reasons, to ensure uniformity across the Department with respect to regulations that cover many of the same entities.

(1) Generally

Comment: Several commenters contended that the proposed rule exceeds the authority of the Director of OCR by attempting to remove references to gender identity and sexual orientation from all HHS healthcare regulations, including those issued by other HHS agencies unrelated to Section 1557, although the rule purported to be promulgated by authority from Section 1557 and other sections within the ACA. Commenters stated that the nondiscrimination protections proposed to be eliminated from CMS regulations are unrelated to Section 1557 and its regulation, and that this elimination was proposed without sufficient legal, policy, or cost-benefit analyses as well as without knowledge of their potential impacts on various CMS programs and on LGBT patients, who (commenters said) may be discriminated against if these amendments are finalized. Also, commenters contend the conforming amendments, if implemented, would affect a wide range of healthcare programs, including private insurance and education programs. Some said they were unaware of any instances in which inclusion of sexual orientation as a basis for nondiscrimination in these CMS rules had been challenged or opposed. Others said that it was arbitrary to single out sexual orientation and gender identity for elimination, since some of the CMS regulations being amended also protect other characteristics not expressly enumerated by statute.

Response: Both the proposed rule and this final rule are promulgated by the Secretary of Health and Human Services, who has jurisdiction over all Department regulations, including those falling under the jurisdiction of CMS. Moreover, each of the programs, activities, or entities in the proposed conforming amendments falls within the scope of Section 1557 as entities established under Title I of the ACA (for example, Exchanges [308]), entities administered under Title I of the ACA (for example, QHPs [309]) or health programs or activities receiving Federal financial assistance from the Department, including contracts of insurance.[310] The ACA and certain Federal statutes identifying other protected categories provide the bases for the nondiscrimination clauses in health programs and activities funded or administered by HHS.[311]

The Department has reviewed the legal authorities underlying and cited in the nondiscrimination provisions of these CMS regulations and the explanations set forth in those rules. Some of them relied on or referenced Section 1557, some relied on different statutory provisions, and some are cross-referenced in the 2016 Rule. None of the statutory authorities underlying the CMS rules amended here explicitly references sexual orientation or gender identity. To the extent some of those regulations were promulgated based on broad authority to issue regulations,[312] inclusion of nondiscrimination criteria that are not explicitly set forth in other applicable civil rights statutes may not necessarily exceed the Department's statutory authority. Nevertheless, the Department deems it appropriate to pursue a more uniform practice concerning nondiscrimination categories across programs and activities to which Section 1557 applies, and to do so consistent with the government's position concerning discrimination on the basis of sex.

In addition, for several of the CMS final rules, their corresponding proposed rules had not mentioned adding sexual orientation and gender identity as nondiscrimination categories.[313] Although some of those proposed rules also did not mention adding other common nondiscrimination categories, the Department now views the addition of sexual orientation and gender identity as nondiscrimination categories as having presented different legal and policy concerns from other categories. Notably, these nondiscrimination categories are not required by applicable law, appear in only a handful of federal antidiscrimination statutes, and have been the subject of extensive litigation, controversy, and confusion generally. Thus, the Department believes the addition of sexual orientation and gender identity as nondiscrimination categories in its regulations should have been submitted for public comment and, notwithstanding the lack of legal challenge to these CMS regulations on this basis, proposes conforming amendments for purposes of clarity, consistency, and uniformity.

Therefore, the Department deems it appropriate to finalize the proposed conforming amendments to these CMS regulations without change (with the exception of a technical correction described below), in order to create a more uniform practice concerning nondiscrimination on the basis of sex among HHS programs to which Section 1557 applies, and to avoid the possibility that there was insufficient statutory authority to impose gender identity or sexual orientation nondiscrimination prohibitions through those regulations.

The Department is unaware of any data that would make cost-benefit analyses for these specific changes possible, and notes that the insertion of sexual orientation and gender identity language (repealed by these amendments) had already been implemented without any cost-benefit analyses. These provisions are eliminated for reasons parallel to those put forth here and in the proposed rule with respect to proper statutory construction, legal authority, and the Department's policy goals.

Comment: Some commenters supported proposals to remove the provisions prohibiting discrimination on the basis of sexual orientation specifically from regulations encompassed by the conforming amendments, in order to reflect current law and current regulatory policy. They reiterated the 2016 Rule's statement that there is no settled statutory law or court-settled law that discrimination on the basis of sexual orientation is legally included within the reach of Title IX.

Response: For the reasons explained above, the Department agrees with the 2016 Rule's decision not to include an explicit prohibition on sexual orientation discrimination. Similarly, the Department concludes it is appropriate to remove such language through these conforming amendments.

(2) Delivery of Medicaid Services (42 CFR 438.3(d)(4), 438.206(c)(2), 440.262)

The Department proposed conforming amendments to multiple provisions in Title 42 of the Code of Federal Regulations that apply to delivery of

[308] *See* Public Law 111–148, tit. I, subtit. D, Part II (Consumer Choices and Insurance Competition Through Health Benefit Exchanges).

[309] *See* Public Law 111–148, tit. I, subtit. D, Part I (Establishment of Qualified Health Plans).

[310] These include Medicare Advantage (Medicare Part C) plans, Medicare Part D plans, Medicaid Managed Care Organizations (MCOs), Medicaid Prepaid Inpatient Health Plans, (PIHPs), Medicaid Prepaid Ambulatory Health Plans (PAHPs), Medicaid Primary Care Case Managers (PCCMs), Primary Care Case Management Entities (PCCM-Es) and Programs for All-inclusive Care for the Elderly serving Medicare and Medicaid beneficiaries (PACE).

[311] *See* 42 CFR 438.3(d)(4), 438.206(c)(2), 440.262, 460.98(a)(3), 460.112(a).

[312] *See, e.g.,* ACA Section 1321 (42 U.S.C. 18041(a)) (authorizing the Secretary to ''issue regulations setting standards . . . with respect to . . . the establishment and operation of Exchanges . . . the offering of qualified health plans through such Exchanges . . . and . . . such other requirements as the Secretary determines appropriate'').

[313] *See, e.g.,* 78 FR 13406 (Feb. 27, 2013) (final rule) and 77 FR 70584, 70585 (Nov. 26, 2012) (NPRM).

Medicaid services found in § 438.3(d)(4) as applied to MCOs, PIHPs, PAHPs, PCCMs or PCCM entities, § 438.206(c)(2) by MCOs, PIHPs, and PAHPs participating in State efforts, and § 440.262 by the States themselves.

Three of the provisions applied to Medicaid managed care. The Department proposed on June 1, 2015, and then finalized on May 6, 2016, a regulation with several nondiscrimination provisions applicable to fee-for-service medical assistance under Medicaid. 80 FR 31098 (June 1, 2015) (Medicaid NPRM); 81 FR 27895 (May 6, 2016) (Medicaid final rule). The Department prohibited discrimination on the basis of ''sexual orientation and ''gender identity'' by MCOs, PIHPs, PAHPs, PCCMs, and PCCM-Es. 42 CFR 438.3(d)(4). And it required that certain of these entities promote access and/or delivery of services ''in a culturally competent manner to all enrollees . . . regardless of gender, sexual orientation or gender identity.'' 42 CFR§ 438.206(c)(2).

In promulgating these regulations, the Department relied on a statute granting general rulemaking authority to the Secretary of HHS to make and publish rules and regulations as may be necessary to efficiently administer Medicare and Medicaid. Section 1102 of the Social Security Act, 42 U.S.C. 1302(a). It also cited provisions of the Social Security Act that require Medicaid State plans for medical assistance to ''provide . . . such methods of administration . . . as are found by the Secretary to be necessary for the proper and efficient operation of the plan.'' Section 1902(a)(4) of the Social Security Act (42 U.S.C. 1396a(a)). And it cited Section 1902(a)(19) of the Social Security Act to justify additional methods of administration and new protected categories necessary for the proper operation of a State plan, for best interest of the beneficiaries, and for cultural competency. 81 FR 27895 (Medicaid final rule). None of these authorities prohibits discrimination on the basis of gender identity or sexual orientation.

In reviewing § 440.262, the Department became aware that in proposing a conforming amendment to the first sentence, the proposed rule is worded to delete the second sentence of that section, which reads ''These methods must ensure that beneficiaries have access to covered services that are delivered in a manner that meets their unique needs.'' The Department's intent was to make a conforming amendment to the first sentence of that section, but not to delete the second sentence. Therefore, the Department finalizes the conforming amendment to the first sentence of § 440.262 without change, but makes a technical correction by finalizing the section to retain the second sentence of that section. In other words, the Department is finalizing the change to the first sentence of § 440.262, but is not finalizing the deletion of the second sentence. In addition, the Department corrects the grammar of the second sentence, by changing the word ''meet'' to ''meets.'' Medicare's PACE Program Employees and Organizations (42 CFR 460.98(b)(3), 460.112(a)).

The Department proposed conforming amendments to two provisions that apply to PACE, a health program receiving HHS Federal financial assistance that is therefore subject to Section 1557.

In 2006, the Department promulgated a regulation administering PACE that prohibited discrimination on the basis of sexual orientation. 71 FR 71244 (Dec. 8, 2006) (PACE final rule). Sexual orientation had not been identified as a protected category in the statute authorizing PACE. *See* Public Law 98–21, as amended (codified at 42 U.S.C. 1396u–4 *et seq.*).

In the PACE final rule, in response to a request from two commenters to ''broaden the list of categories under which the PACE Organization cannot discriminate to include sexual orientation,'' the Department agreed to amend 42 CFR 460.98(b)(3) to prohibit discrimination on the basis of sexual orientation for Medicare and Medicaid participants. The PACE proposed rule also prohibited discrimination on the basis of sexual orientation by employees and contractors of Medicare-participating PACE programs. 42 CFR 460.112(a) (providing that ''[e]ach participant has the right not to be discriminated against in the delivery of required PACE services based on race, ethnicity, national origin, religion, sex, age, sexual orientation, mental or physical disability, or source of payment'').

Medicare Part A programs, including PACE, are subject to Title VI, Title IX, Section 504, and the Age Act. OCR has the authority to review recipient policies and procedures and certify that recipients of Federal financial assistance under Medicaid Part A comply with Title VI, Title IX, Section 504, and the Age Act, and their implementing regulations. CMS now directs applicants to an online attestation portal on the OCR website to assure compliance with those four civil rights statutes as well as with Section 1557.

In reviewing § 460.112(a), the Department became aware that in proposing a conforming amendment to the first two sentences, the proposed rule is worded to delete the remainder of the subsection. The Department's intent was to make a conforming amendment to the first two sentences of subsection (a), but not to delete its remainder. Therefore, the Department finalizes the conforming amendment to the first two sentences of § 460.112(a) without change, but as a matter of technical correction does not finalize the deletion of the remaining sentences, and instead finalizes subsection (a) to retain the remainder of that subsection.

Comment: Commenters expressed concern that PACE organizations would be allowed to discriminate against LGBTQ people under the proposed rule.

Response: The Department believes that everyone should be treated with dignity and respect and given every protection afforded by the Constitution and the laws passed by Congress. None of the statutes authorizing the PACE regulations prohibits discrimination on the basis of gender identity or sexual orientation.

(3) General Standards for Exchanges, QHPs for Exchanges, and Health Plan Issuers (45 CFR 155.120(c)(ii)), 156.200(e))

In 2012, the Department added ''sexual orientation'' and ''gender identity'' into certain regulations for the administration of the ACA by States, the Exchanges, and QHP issuers. 77 FR 18469 (Mar. 27, 2012) (''Administration of Exchanges final rule''). The Department cited Section 1321 of the ACA as its authority to add new nondiscrimination requirements. 76 FR at 41873, 41897 (July 15, 2011) (''Administration of Exchanges proposed rule'').

Section 1321 is a general regulatory provision allowing HHS to regulate establishment, operation, and standards in Exchanges and for QHPs. It does not contain the words ''sexual orientation'' or ''gender identity,'' or specify that the authority to set standards includes the authority to specify classes protected from discriminatory conduct that are not otherwise specified in nondiscrimination statutes.[314] Sections 155.120(c)(ii) and 156.200(e) were both later referenced in the preamble to the 2016 Rule as nondiscrimination provisions that the 2016 Rule

[314] Section 1321(a) of the ACA provides that the Secretary of the Department of Health and Human Services ''shall, as soon as practicable after the date of enactment of this Act, issue regulations setting standards for meeting the requirements under this title, and the amendments made by this title, with respect to—(A) the establishment and operation of Exchanges (including SHOP Exchanges); (B) the offering of qualified health plans through such Exchanges . . .'' 42 U.S.C. 18041(a)(1)(A)–(B).

''complements.'' *See* 81 FR 31376, 31428 (May 18, 2016). The 2016 Rule also provided that the States, Exchanges, and issuers are ''obligated to comply with both sets of requirements.'' *Id.*

(4) Guaranteed Coverage (45 CFR 147.104(e))

In the February 27, 2013 edition of the **Federal Register**, the Department finalized a new regulation expanding the nondiscrimination provisions applicable to QHP issuers, including prohibitions on discrimination on the basis of gender identity and sexual orientation, citing Section 1321(a) of the ACA as the applicable statutory authority. 78 FR 13406 (Guaranteed Coverage final rule, codified at 45 CFR 147.104(e)). Nevertheless, the language in the final rule prohibiting discrimination on the basis of gender identity and sexual orientation was not in the proposed rule. *See* 77 FR 70584, 70613 (Nov. 26, 2012). It appears that the Department added this language in response to a commenter asking that HHS ''broaden[ ] [§ 147.104(e)] to apply to all forms of discrimination prohibited by the March 27, 2012 Exchange final rule and section 1557 of the Affordable Care Act, such as discrimination based on age, disability, race, ethnicity, gender, and sexual orientation, not just discrimination against individuals with significant or high cost healthcare needs.'' 78 FR at 13417.

As legal authority, the Department also relied on Section 2702 of the Public Health Service Act, as amended by the Affordable Care Act, Public Law 111–148 (Mar. 23, 2010), which only required that any ''individual or group market in a State must accept every employer and individual in the State that applies for such coverage.'' There was no explicit reference to categories of individuals protected by nondiscrimination laws.

The rule administered the ACA's guarantee of coverage in the group and individual health insurance markets. *See* 42 U.S.C. 300gg–1. The Department attached the sexual orientation and gender identity nondiscrimination provision as part of the requirement for issuers to accept every employer and individual in the State who applies for coverage, subject to a few exceptions. Section 300gg–1 does not specify nondiscrimination criteria, including sexual orientation or gender identity.

The rule applied not only to the health plan issuer but also to its ''officials, employees, agents and representatives.'' 45 CFR 147.104(e). It prohibited these covered entities from discriminating based on a variety of bases, including an individual's sex, sexual orientation, or gender identity. *Id.* In the Guaranteed Coverage final rule, the Department justified the 45 CFR 147.104(e) nondiscrimination provision on the ground that it ''ensures consistency with . . . the non-discrimination standards applicable to QHPs under § 156.200(e),'' to which sexual orientation and gender identity provisions had previously been added (as described above). 78 FR at 13426. The Guaranteed Coverage final rule was also referenced in the preamble to the 2016 Rule, which described it as both ''independent of''' and ''complement[ary]'' to Section 1557. 81 FR at 31428.[315]

The Department notes that this amendment to the Guaranteed Coverage final rule does not negate the rule's requirement that health insurance issuers offering group or individual coverage ''must offer to any individual or employer in the State all products that are approved for sale in the applicable market, and must accept any individual or employer that applies for any of those products.'' 45 CFR 147.104(a). That requirement applies independent of the explicit nondiscrimination categories set forth in § 147.104(a).

(5) Enrollment in QHPs Through Exchanges by Agents or Brokers (45 CFR 155.220(j)(2)(i))

In the December 2, 2015 edition of the **Federal Register**, the Department proposed a rule that would prohibit agents or brokers from discriminating on the basis of sexual orientation and gender identity when assisting individuals and employers in applying for or enrolling in QHPs sold through a Federally-facilitated Exchange. 80 FR 75488. This proposed rule was adopted without change in March of the following year. 81 FR 12204 (Mar. 8, 2016) (codified at 45 CFR 155.220(j)(2)(i)). The final rule also stated that covered entities must comply with ''certain other Federal civil rights laws [that] impose non-discrimination requirements,'' such as Section 1557 of the ACA.[316] The final rule further directed issuers who seek certification of one or more QHPs to the OCR website for information about the Section 1557 NPRM.[317]

(6) Enrollment in QHPs and Exchanges by QHP Issuers (45 CFR 156.1230(b)(2))

In the September 6, 2016 edition of the **Federal Register**, the Department proposed a gender identity and sexual orientation nondiscrimination provision to rules governing marketing or conduct by issuers of individual market QHPs sold through the Federally-facilitated Exchanges in the direct enrollment of individuals in a manner that is considered to be through the Exchange. 81 FR 61456. The rule proposed that QHP issuers would be required to ''refrain from marketing or conduct that is misleading . . . coercive, or discriminates based on race, color, national origin, disability, age, sex, gender identity, or sexual orientation.'' *Id.* The proposed language was finalized that December. 81 FR 94058 (Dec. 22, 2016) (codified at 45 CFR 156.1230(b)(3), since redesignated as 45 CFR 156.1230(b)(2) (see 84 FR 17454, 17568 (Apr. 25, 2019, effective June 24, 2019))). The Department cited Section 1321 of the ACA as its authority to promulgate the nondiscrimination provision. The authority section of the regulation also encompasses Section 1311 of the ACA, which prohibits QHPs from ''employ[ing] marketing practices or benefit designs that have the effect of discouraging the enrollment in such plan by individuals with significant health needs.''[318]

(7) Summary of Regulatory Changes

The Department finalizes without change the proposed conforming amendments at 42 CFR 438.3(d), 438.206(c)(2), and 460.98(b)(3), and 45 CFR§ 147.104(e), 155.120(c)(ii), 155.220(j)(2)(i), and 156.200(e). It finalizes the proposed conforming amendment of the first sentence of § 440.262 without change, but retains the second sentence of that section without deleting it, and makes one grammatical correction to the second sentence. It finalizes the proposed conforming amendment of the first two sentences of § 460.112(a) without change, but retains the remainder of that subsection without deleting it.

With respect to 45 CFR 156.1230(b)(2), the proposed rule indicated it would amend § 156.1230(b)(3), but effective June 24, 2019, § 156.1230(b)(3) was redesignated as § 156.1230(b)(2). *See* 84 FR at 17568.

[315] *See* 81 FR 31376, 31428 (May 18, 2016) (''We noted that this section [92.207] is independent of, but complements, the nondiscrimination provisions that apply to . . . issuers of qualified health plans under other Departmental regulations, and that entities covered under those provisions and Section 1557 are obligated to comply with both sets of requirements.'').

[316] 81 FR 12312 (''Issuers that receive Federal financial assistance, including in connection with offering a QHP on an Exchange, are subject to Title VI of the Civil Rights Act of 1964, the Age Discrimination Act of 1975, section 504 of the Rehabilitation Act of 1973, and section 1557 of the Affordable Care Act'').

[317] *Id.*

[318] 42 U.S.C. 18031.

Therefore, this rule finalizes the change at the redesignated location of the text at § 156.1230(b)(2).

IV. Regulatory Impact Analysis

The Department has examined the impacts of this final rule as required by Executive Order 12866 on Regulatory Planning and Review, 58 FR 51735 (Oct. 4, 1993); Executive Order 13563 on Improving Regulation and Regulatory Review, 76 FR 3821 (Jan. 21, 2011); Executive Order 13132 on Federalism, 64 FR 43255 (Aug. 4, 1999); Executive Order 13175 on Tribal Consultation, 65 FR 67249 (Nov. 6, 2000); Executive Order 13771 on Reducing Regulation and Controlling Costs, 82 FR 9339 (Jan. 30, 2017); the Congressional Review Act (Pub. L. 104–121, sec. 251, 110 Stat. 847 (Mar. 29, 1996)); the Unfunded Mandates Reform Act of 1995, Public Law 104–4, 109 Stat. 48 (Mar. 22, 1995); the Regulatory Flexibility Act (Pub. L. 96–354, 94 Stat. 1164 (Sept. 19, 1980); Executive Order 13272 on Proper Consideration of Small Entities in Agency Rulemaking, 67 FR 53461 (Aug. 16, 2002); Executive Order 12250, Leadership and Coordination of Nondiscrimination Laws, 45 FR 72995 (Nov. 2, 1980), and the Paperwork Reduction Act of 1995, 44 U.S.C. 3501, *et seq.*

A. Executive Orders 12866 and Related Executive Orders on Regulatory Review

Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects; distributive impacts; and equity). Executive Order 13563 is supplemental to Executive Order 12866 and reaffirms the principles, structures, and definitions governing regulatory review established there.

As discussed below, the Department has estimated that this final rule will have a beneficial effect on the economy greater than $100 million in at least one year. Thus, it has been concluded that this final rule is economically significant. It has, therefore, been determined that this final rule is a ''significant regulatory action'' under Executive Order 12866 and, accordingly, the Office of Management and Budget (OMB) has reviewed this final rule.

The executive summary at the beginning of this preamble contains a summary of this final rule in its summary of major provisions, and describes the reasons it is needed in describing the purpose of this final rule.

(1) Consideration of Regulatory Alternatives

The Department carefully considered several alternatives, including the option of not pursuing any regulatory changes, but rejected that approach for several reasons.

First, not pursuing any regulatory changes would be inconsistent with the Administration's policies of appropriately reducing regulatory burden, in general, with respect to individuals, businesses and others, and from the ACA specifically.

Second, not pursuing any regulatory change would be inconsistent with various court rulings that have rejected or undermined the legal positions taken by the Department in the 2016 Rule. It would not, for example, ensure that the text of the Code of Federal Regulations accurately reflects the *vacatur* of the provisions including gender identity and termination of pregnancy as prohibited grounds of discrimination on the basis of sex. It also would not account for the decision of the Northern District of Illinois that the ''plain and unambiguous'' statutory text of Section 1557 indicated that a plaintiff could only use the enforcement mechanism of the underlying civil rights statute that corresponds to its claim. *Briscoe* v. *Health Care Serv. Corp.,* 281 F. Supp. 3d 725, 737–38 (N.D. Ill. 2017) (dismissing a Section 1557 claim for sex discrimination using a disparate impact standard, because plaintiffs cannot bring disparate impact claims under Title IX); *accord Galuten on Behalf of Estate of Galuten* v. *Williamson Med. Ctr.,* 2019 WL 1546940, at * (M.D. Tenn. Apr. 9, 2019); *E.S. by and through R.S.* v. *Regence BlueShield,* 2019 WL 4566053, at *4 (W.D. Wash. Sept. 24, 2018); *but see Rumble* v. *Fairview Health Servs.,* No. 14–cv–2037 (SRN/FLN) (D. Minn. Mar. 16, 2017) (declining to determine the specific standard on a motion to dismiss and rejecting the implication that Congress meant to create a ''new anti-discrimination framework completely 'unbound by the jurisdiction of the four referenced statutes,' '' but concluding Congress ''likely'' intended a single standard to avoid ''patently absurd consequences''). In addition, it would fail to account for the decisions of Federal courts in California, New York, and Iowa that did not recognize disparate impact claims for sex discrimination under Section 1557, because such claims are not cognizable under Title IX. *See Condry* v. *UnitedHealth Group,* No. 3:17–cf–00183–VC (N.D. Calif. June 27, 2018) (Slip. Op. at 7); *Weinreb* v. *Xerox Business Services,* 323 F. Supp. 3d 501, 521 (S.D.N.Y. 2018); *York* v. *Wellmark, Inc.,* No. 4:16–cv–00627–RGE–CFB, Slip. Op. at *30 (S.D. Iowa Sep. 6, 2017). A court in Pennsylvania similarly indicated that there is no disparate impact claim for discrimination on the basis of race under Section 1557, because such claims are unavailable under Title VI. *See Southeastern Pennsylvania* v. *Gilead,* 102 F. Supp. 3d 688 (E.D. Pa. 2015); *but see Callum* v. *CVS Corp.,* 137 F. Supp. 3d 817 (D.S.C. 2015).

Third, the Department believes that the status quo would not address, much less remedy, public confusion regarding complainants' rights and covered entities' legal obligations. The Department believes that revisiting the rule will address inconsistences between the Department's underlying regulations and the regulations and actions taken by other components of the Government. As applied to sex discrimination claims, the 2016 Rule set forth a definition of discrimination on the basis of sex under Section 1557 implementing Title IX that varied from the practice of other Departments. If the Department uses interpretations of Title IX that differ from other Departments and from the legal interpretation of the U.S. Government as set forth by the Department of Justice, it could lead to inconsistent outcomes across complainants and covered entities, with the problem especially acute in cases involving a single covered entity being investigated with respect to the same allegations by multiple Departments that come to different conclusions on effectively the same question.

The Department also considered adding ''gender identity'' and ''sexual orientation'' to a definition of ''sex'' or ''on the basis of sex'' under Title IX. The Department concluded it is inappropriate to do so in light of the ordinary public meaning of discrimination on the basis of sex under Title IX. This final rule will also significantly restore the ability of States to establish policies in this area, based on their weighing of the competing interests at stake. As a policy matter, the Department believes State and local entities are better equipped to address with sensitivity issues of gender dysphoria, sexual orientation, and any competing privacy interests, especially when young children or intimate settings are involved. The Department's position will not bar covered entities from choosing to grant protections on the basis of sexual orientation and gender identity that do not conflict with any other Federal law. The Department has also determined that economic incentives, performance objectives, or

other related forms of regulation are neither appropriate nor feasible solutions to the problems to be solved.

The Department also considered simply repealing the 2016 Rule *in toto* and not issuing a replacement regulation. Such an approach would be consistent with the Administration's goals of reducing the regulatory burden on covered entities, and is allowed under Section 1557, as that provision does not require the Department to issue implementing regulations. However, the Department is committed to vigorous enforcement of civil rights and nondiscrimination laws as directed by Congress, and considers it worthwhile to set forth that commitment in a Section 1557 regulation which takes the position that the Department will use the enforcement mechanisms available under the statutes cited in Section 1557 and their underlying regulations. Additionally, the Department believes that certain provisions—such as those addressing the assurance of compliance with Section 1557, effective communication and accessibility for individuals with disabilities, and certain language access services—address applications of civil rights laws without the statutory or legal conflicts, or excessive regulatory burdens, entailed by other provisions of the current Rule.

The Department also considered retaining the provision on visual standards for video remote interpreting services for LEP individuals. However, the burden of requiring covered entities to provide video technology training and utilize expensive software does not appear to be justified based on minimal benefit to language speakers who can effectively communicate when there is clear audio transmission through the remote interpreting service.

Accordingly, the Department believes it is appropriate to clarify how OCR will enforce the ACA's nondiscrimination protections by replacing the 2016 Rule with regulatory provisions (1) applying the enforcement mechanisms provided under the civil rights statutes and related implementing regulations cited in Section 1557 to the contexts identified in Section 1557, (2) vesting enforcement authority under Section 1557 with the Director of the Office for Civil Rights, and (3) specifying how Section 1557 enforcement shall interact with existing laws—while retaining certain language and disability access provisions and the assurances provision.

With respect to the requirement that covered entities provide nondiscrimination notices and taglines, the Department considered keeping the requirement but limiting the frequency of required mailings to one per year to each person served by the covered entity. To estimate the cost of this option, the Department adopted the base assumptions described in this Regulatory Impact Analysis regarding the number of covered entities and the average unit cost associated with the low-end and high-end costs of a notice and taglines mailing (materials, postage, and labor).[319] The Department adjusted the volume of mailings based on the average number of individuals served by each covered entity.[320] The Department assumed the same covered entity compliance rate for the insurance industry as under this Regulatory Impact Analysis but assumed an increased compliance rate for non-insurers (assuming 30% instead of 10%) to reflect that more entities would likely comply with the requirements if the burden were to be significantly reduced to one mailing per customer/patient per year. Based on this method, the estimated total cost of this alternative is approximately $63 million per year. Although this option poses a significantly reduced burden, the Department believes the costs under this alternative still outweigh the benefits because such mass multi-language taglines mailings would still be received overwhelmingly by English speakers and because the requirement to issue nondiscrimination notices would be largely duplicative of nondiscrimination notice requirements that already exist under Section 1557's underlying civil rights regulations.[321]

(2) Considerations for Cost-Effective Design

In this final rule, the Department replaces much of the 2016 Rule, to significantly reduce regulatory burdens and to return to the longstanding understanding of the underlying nondiscrimination obligations imposed by the civil rights laws referenced in Section 1557.

In the preamble to the 2016 Rule, the Department observed that there were pre-existing requirements under Federal civil rights laws that, ''except in the area of sex discrimination,'' applied to a large percentage of entities covered by the 2016 Rule. 81 FR at 31446. Thus, in the 2016 Rule the Department concluded it did not expect covered entities to undertake additional costs with respect to that rule's prohibitions on discrimination on the basis of race, color, national origin, age, or disability, ''except with respect to the voluntary development of a language access plan.'' *Id.*

By finalizing this rule without the 2016 Rule's definition of sex discrimination and eliminating the requirements regarding notices, taglines, and visual standards in video remote interpreting services for LEP individuals, language access plans, and duplicative grievance procedures, the final rule also allows covered entities the freedom to order their operations more efficiently, more flexibly, and in a more cost-effective manner.

Accordingly, returning to the familiar longstanding requirements is a cost-effective way of (1) removing the unjustified burdens imposed by the 2016 Rule; (2) reducing confusion among the public and covered entities; (3) promoting consistent, predictable, and cost-effective enforcement; and (4) creating space for innovation in the provision of compliant services by covered entities (including flexible and innovative language access practices and technology), while faithfully and vigorously enforcing Section 1557's civil rights protections.

(3) Methodology for Cost-Benefit Analysis

For purposes of this Regulatory Impact Analysis (RIA), the final rule adopts the list of covered entities and other cost assumptions identified in the 2016 Rule's RIA and that of the 2019 proposed rule. The use of assumptions from the 2016 Rule in the present RIA, however, does not mean that the Department adopts those assumptions in any respect beyond the purpose of estimating (1) the number of covered entities that would be relieved of burden, and (2) cost relief. For example, the 2016 Rule based several cost estimates on an expansive definition of Federal financial assistance, which significantly impacted the number of covered entities currently burdened by the 2016 Rule; thus, it is appropriate to use that definition for estimating cost relief. Such use, however, should not be interpreted as an endorsement or

[319] The average of the low ($0.035) and high ($0.32) unit costs is $0.18 per notice and tagline mailing.

[320] The estimated volume is expected to vary based on covered entity type. For instance, each of the 180 health insurance issuers serve 685,138 individuals on average, based on the number of insured individuals (123 million), which equates to 685,138 mailings per issuer. Each of the 185,649 physicians' offices serve 1,703 individuals, based on the average number of individuals (316 million) associated with 990 million physicians visits. On average, each covered entity serves about 3,000 persons per entity, which equates to 3,000 mailings per entity, based on 820 million persons served by 275,002 covered entities.

[321] *See* 45 CFR 80.6(d) (Title VI), 84.8 (Section 504), 86.9 (Title IX), 91.32 (Age Act).

acceptance of the definition for any other purpose.

The Department also does not ''carry over'' every assumption from the 2016 Rule for this final rule's RIA calculation. Most notably, the Department no longer considers its prior estimates of costs imposed due to the 2016 Rule's taglines requirement to be accurate or valid, and provides a more thorough and accurate estimate for purposes of this final rule.

Cost savings result 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. In addition, the Department quantitatively analyzes and monetizes the impact that this final rule may have 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. The Department analyzes the remaining benefits and burdens qualitatively because of the uncertainty inherent in predicting other concrete actions that such a diverse scope of covered entities might take in response to this final rule.

The Department also considered the public comments submitted in response to the proposed rule. The Department appreciates the information and various perspectives provided in those comments, which are summarized below and for which responses are provided.[322]

(4) Cost-Benefit Analysis

a. Overview

In the 2016 Rule, the Department estimated $942 million [323] in costs (over five years) due to impacts on personnel training and familiarization, enforcement, posting of nondiscrimination notices and taglines, and revisions in covered entity policies and procedures. 81 FR 31446, and 31458–59 (at Table 5). As stated earlier, the Department estimated in the 2016 Rule that these costs would arise *primarily* from requirements imposed by the 2016 Rule with which covered entities were not already complying.[324] The Department specifically identified the 2016 Rule's interpretation of sex discrimination to cover gender identity and sex stereotyping,[325] and the 2016 Rule's consideration of language access plans for compliance purposes, as provisions triggering the imposition of new costs.[326] *See* 81 FR 31459—Table 5.

In 2016, the Department estimated that the 2016 Rule's nondiscrimination notice requirement would impose approximately $3.6 million in one-time additional costs on covered entities. 81 FR 31469. Regarding these requirements, the Department stated: ''We are uncertain of the exact volume of taglines that will be printed or posted, but we estimate that covered entities will print and post the same number of taglines as notices and therefore the costs would be comparable to the costs for printing and disseminating the notice, or $3.6 million.'' 81 FR 31469. Thus, the total notice and taglines cost was estimated at $7.2 million in the first year and was predicted to go down to zero after year one, despite the regulatory requirement for covered entities to provide notices and taglines to beneficiaries, enrollees, and applicants by appending notices and taglines to all ''significant publications and significant communications'' larger than postcards or small brochures. *Compare* 81 FR 31458 (Table 5), *with* 45 CFR 92.8.

For reasons explained more fully below, the 2016 estimate of $7.2 million in one-time costs stemming from the notice and taglines requirement was a gross underestimation, and thus this final rule's elimination of those requirements would generate a large economic benefit of approximately $2.9 billion over five years on the repeal of the notice and taglines provision.

Table 1 shows the expected cost savings from the repeal of the notice and taglines provision and the quantified costs to firms for training and revising procedures and policies.

TABLE 1—ACCOUNTING TABLE OF ECONOMIC BENEFITS AND COSTS OF ALL FINALIZED CHANGES

[In millions]

	Year 1	Year 2	Year 3	Year 4	Year 5	Total
Savings:						
Total (undiscounted)	$643	$614	$585	$556	$528	$2,926
Total (3%)	624	579	536	494	455	2,688
Total (7%)	601	536	478	425	376	2,416
Costs—Quantified Costs:						
Total (undiscounted)	276	0	0	0	0	276
Total (3%)	269	0	0	0	0	269
Total (7%)	259	0	0	0	0	259
Net Total (undiscounted | 3% | 7%)	....	....	....	....	....	2,650 $2,319 (3%) $2,157 (7%)

Non-quantified benefits and costs are described below.

[322] The population, labor, and similar statistical data used in this RIA are also not changed from those used in the RIA in the proposed rule, because updating that data from the time of the proposed rule in June 2019 to the time of the publication of this final rule would not lead to substantive changes in the analysis.

[323] Throughout the regulatory impact analysis in the 2016 Rule, the 2016 estimates used 2014 dollars unless otherwise noted.

[324] 81 FR 31446 (''to the extent that certain actions are required under the final rule where the same actions are already required by prior existing civil rights regulations, we assume that the actions are already taking place and thus that they are not a burden imposed by the rule'').

[325] 81 FR 31455 (''Although a large number of providers may already be subject to state laws or institutional policies that prohibit discrimination on the basis of sex in the provision of health services, the clarification of the prohibition of sex discrimination in this regulation, particularly as it relates to discrimination on the basis of sex stereotyping and gender identity, may be new.'').

[326] Although the 2016 Rule did not require covered entities to develop a language access plan, the Rule stated that the development and implementation of a language access plan is a factor the Director ''shall'' take into account when evaluating whether an entity is in compliance with Section 1557. 45 CFR 92.201(b)(2). Therefore, the Department anticipated that 50% of covered entities would be induced to develop and implement a language access plan following issuance of the 2016 Rule. 81 FR 31454.

b. Generally Applicable Benefits and Burdens

i. Simplification and Flexibility

This final rule would result in other tangible benefits for covered entities. First, because this final rule is simpler and more easily administrable, it would be less likely that covered entities will need to pay for legal advice or otherwise expend organizational resources to understand their obligations under Section 1557, either in general or with respect to any particular situation that arises. Second, this final rule reduces the need for covered entities to expend labor and money on an ongoing basis to maintain internal procedures for mitigating the legal risk that persists due to unresolved controversy over the meaning of Section 1557. The Department solicited comment regarding the nature and magnitude of such ongoing costs incurred by covered entities, and below the Department summarizes and responds to significant comments regarding the regulatory impact of changes to the notice and taglines requirements.

This final rule will also carry intangible benefits, including that covered entities would enjoy increased freedom to adapt their Section 1557 compliance programs to most efficiently address their particular needs, benefiting both covered entities and individuals. The value of knowledge of civil rights is difficult to quantify. Covered entities will be free under the final rule to implement policies and procedures that comply with Federal civil rights laws in creative, effective, and efficient ways that are tailored to the covered entities and the communities that they serve.

ii. Policies and Procedures Concerning Gender Identity

In the proposed rule, the Department anticipated that the 2016 Rule likely induced many covered entities to conform their policies and operations to reflect gender identity as a protected category under Title IX. The Department requested and received public comments on the possible benefits and burdens related to changes in the proposed rule.

Comment: Many commenters contended that the proposed rule would lead covered entities to remove protections from transgender individuals in their policies and procedures. Commenters contended that these changes would lead to a wide range of burdensome results, including discrimination on the basis of gender identity and resulting negative health consequences, increased costs for treatment of such conditions, cost-shifting to transgender individuals, and increased burdens on the public health system due to the changes. Commenters also contended that similar results would occur from the Department's decision not to include sexual orientation nondiscrimination provisions in the proposed rule.

Response: The Department does not believe that this final rule will lead to significant burdens on entities due to changes to the gender identity language from the 2016 Rule, nor that the commenters have identified sufficient data to show that these negative consequences will occur or the extent to which they will occur. In December 2016, the *Franciscan Alliance* court preliminarily enjoined the gender identity provisions of the 2016 Rule on a nationwide basis, and more recently the court vacated those provisions. Consequently, this final rule's revisions to the provisions addressing gender identity do not change covered entities' obligations. Therefore, even though some entities may have changed their policies and procedures at the outset of the 2016 Rule, the Department concludes that because the gender identity provisions of the 2016 Rule have been vacated prior to this rule being finalized, it is even less likely than at the time of the proposed rule that this final rule will lead to changes in policies and procedures concerning gender identity. In addition, as explained above, the 2016 Rule did not include language prohibiting discrimination on the basis of sexual orientation status standing alone as a form of sex discrimination. The Department therefore does not anticipate any material change to covered entities' policies concerning sexual orientation as a result of this final rule.

In addition, it is worth noting that many covered entities are located in jurisdictions that prohibit sexual orientation and gender identity discrimination under State or local laws. Therefore, such entities are unlikely to change their policies, training, or grievance procedures concerning gender identity as a result of this final rule. Moreover, nothing in this final rule, or in the court decisions, prohibits entities from maintaining gender identity nondiscrimination policies and procedures voluntarily, and the Department believes some covered entities will continue to do so.

If some entities change their policies and procedures based on this final rule, such a reversion may entail amending organizational nondiscrimination policies and training materials, and communicating those changes to employees. The process of voluntarily reverting to previous practices would likely result in net cost savings to covered entities. Otherwise these entities likely would not take such action. In addition, the Department believes that, if this final rule led to covered entities changing policies and procedures, some covered entities may no longer incur costs associated with processing grievances related to gender identity discrimination under Title IX, because such claims will not be cognizable under this final rule.

The Department, however, is uncertain as to the total number of covered entities that will change their policies and grievance processes to reflect the changes in this final rule. The reasons for this uncertainty include, as stated above, the fact that such changes would only be indirectly attributable to this rule, not caused by this rule, because previous court rulings have negated the gender identity provisions from the 2016 Rule for over three years, and this rule has no effect on State and local gender identity protections. The Department is not aware of data about how many entities might change their policies for these indirect reasons.

Similarly, the Department also lacks the data necessary to estimate the number of individuals who currently benefit from covered entities' policies governing discrimination on the basis of gender identity who would no longer receive those benefits after publication of this rule—nor data to estimate how many of those individuals may experience the workplace and health-related negative consequences that many commenters contend will result from this final rule. The Department similarly lacks data to estimate what greater public health costs, cost-shifting, and expenses may result from entities changing their nondiscrimination policies and procedures after promulgation of this rule. The Department reiterates that it believes these effects will be minimal, again due to the fact that gender identity provisions were vacated from the 2016 Rule by the *Franciscan Alliance* court before this rulemaking was finalized.

c. Baseline Assumptions

The following discussion identifies the economic baselines from which the Department measures the expected costs and benefits of this final rule. Its baselines includes the cost estimates in the 2016 Rule, in addition to data it has gathered since the 2016 Rule was implemented, as described in more detail below. The Department also considered public comments, and

responds to significant comments in this discussion.

Key assumptions track those set forth in the proposed rule and include the following: (1) The 2016 Rule triggered significant activity on the part of covered entities, generating both costs and benefits; (2) under the December 2016 nationwide preliminary injunction in *Franciscan Alliance,* and the October 2019 final judgment in that case, the gender identity and termination of pregnancy provisions of the 2016 Rule have been unenforceable and are now absent from the 2016 Rule, without regard to whether this rule is finalized; (3) covered entities were already generally complying with civil rights laws and related regulations that were in effect before the 2016 Rule, and so this final rule generally does not impose any new burden beyond those imposed prior to the issuance of the 2016 Rule;[327] (4) the projected costs from the 2016 Rule for years 1 and 2 have been incurred, and the projected costs from years 3, 4, and 5 have not been incurred; (5) repeal of the 2016 Rule's notice and taglines requirements does not affect notice or taglines requirements required by CMS guidance or regulations that do not reference, rely on, or depend upon the taglines requirements of the 2016 Rule; (6) a relatively small percentage of physicians and hospitals currently append notices and taglines to billing statements sent to patients, while all insurance companies append notices and taglines to their explanations of benefits statements; and (7) covered employers are more likely to train employees who interact with the public than those who do not.

d. Covered Entities

i. Entities Covered by Section 1557

The 2016 Rule and this final rule apply to any entity that has a health program or activity, any part of which receives Federal financial assistance from the Department, any program or activity administered by the Department under Title I of the ACA, or any program or activity administered by an entity established under such Title. Covered entities under the 2016 Rule's definition[328] include the following:

(A) Entities With a Health Program or Activity, Any Part of Which Receives Federal Financial Assistance From the Department

The RIA for the 2016 Rule stated that the Department, through agencies such as the Health Resources and Services Administration (HRSA), the Substance Abuse and Mental Health Services Administration (SAMHSA), the Centers for Disease Control and Prevention (CDC), and the Centers for Medicare & Medicaid Services (CMS), provides Federal financial assistance through various mechanisms to health programs or activities of local governments, State governments, and the private sector. An entity may receive Federal financial assistance from more than one component in the Department. For instance, Federally qualified health centers receive Federal financial assistance from CMS by participating in Medicaid programs and may also receive Federal financial assistance from HRSA through grant awards. Because more than one funding stream may provide Federal financial assistance to an entity, the examples we provide may not uniquely capture entities that receive Federal financial assistance from only one component of the Department. Under the 2016 Rule, the covered entities consisted of the following:

(i) Entities receiving Federal financial assistance through their participation in Medicare (excluding Medicare Part B) or Medicaid (about 133,343 facilities).[329] Examples of these entities cited in the 2016 Rule's RIA include:

- Hospitals (includes short-term, rehabilitation, psychiatric, and long-term)
- Skilled nursing facilities/nursing facilities (facility-based and freestanding)
- Home health agencies
- Physical therapy/speech pathology programs
- End-stage renal disease dialysis centers
- Intermediate care facilities for individuals with intellectual disabilities
- Rural health clinics
- Physical therapy—independent practice
- Comprehensive outpatient rehabilitation facilities
- Ambulatory surgical centers
- Hospices
- Organ procurement organizations
- Community mental health centers
- Federally qualified health centers.

(ii) Laboratories that are hospital-based, office-based, or freestanding that receive Federal financial assistance through Medicaid payments for covered laboratory tests (about 445,657 laboratories with Clinical Laboratory Improvement Act certification).

(iii) Community health centers receiving Federal financial assistance through grant awards from HRSA (1,300 community health centers).[330]

(iv) Health-related schools in the United States and other health education entities receiving Federal financial assistance through grant awards to support 40 health professional training programs that include oral health, behavioral health, medicine, geriatric, and physician's assistant programs.[331]

(v) State Medicaid agencies receiving Federal financial assistance from CMS to operate CHIP (includes every State, the District of Columbia, Puerto Rico, Guam, the Northern Marianas, U.S. Virgin Islands, and American Samoa).

(vi) State public health agencies receiving Federal financial assistance from CDC, SAMHSA, and other HHS components (includes each State, the District of Columbia, Puerto Rico, Guam, the Northern Marianas, U.S. Virgin Islands, and American Samoa).

(vii) QHP issuers receiving Federal financial assistance through advance payments of premium tax credits and cost-sharing reductions (which include at least the 169 health insurance issuers in the Federally-facilitated Exchanges receiving Federal financial assistance

[327] OMB Circular A–4 discusses the practice whereby an RIA for a rule codifying a policy may include the impacts of that policy, even if the effects follow directly from an action by another branch of the federal government. The Circular notes that: ''In some cases, substantial portions of a rule may simply restate statutory requirements that would be self-implementing, even in the absence of the regulatory action. In these cases, you should use a pre-statute baseline. If you are able to separate out those areas where the agency has discretion, you may also use a post-statute baseline to evaluate the discretionary elements of the action.'' Although a baseline established prior to the *Franciscan Alliance* court's December 2016 and October 2019 orders would be considered analogous to the pre-statute baseline discussed in Circular A–4, given the existence of the RIA for the 2016 Rule, an assessment relative to a pre-*Franciscan Alliance* baseline would add little to the body of relevant analysis, and the longstanding duration of the court orders contributes to a lack of new data pertaining to certain alleged effects of language falling under those orders. For these reasons, the baseline established after December 2016, which isolates the effects most directly attributable to certain elements of this rule's finalization, is emphasized throughout the relevant parts of this RIA.

[328] As noted above, we use the list and number of covered entities and other figures from the 2016 Rule's RIA in this RIA for the sake of consistency and convenience, but such use does not mean that we adopt or accept any of the underlying analysis, definitions, or assumptions from the 2016 Rule's RIA for any other purpose related to this final rule.

[329] CMS, Provider of Service file (June 2014), *https://www.cms.gov/Research-Statistics-Data-and-Systems/Downloadable-Public-Use-Files/Provider-of-Services/POS2014.html.*

[330] HRSA, Justification of Estimates for Appropriation Committee For Fiscal Year 2016, 53, *http://www.hrsa.gov/about/budget/budgetjustification2016.pdf.*

[331] HRSA, Justification of Estimates for Appropriation Committee For Fiscal Year 2016, 53, *http://www.hrsa.gov/about/budget/budgetjustification2016.pdf.*

through advance payments of premium tax credits and cost-sharing reductions, and at least 11 health insurance issuers operating in the State Exchanges).[332]

(viii) Physicians receiving Federal financial assistance through Medicaid payments, ''meaningful use'' payments, and other sources, but not Medicare Part B payments (Medicare Part B payments to physicians are not Federal financial assistance). The Medicare Access and CHIP Reauthorization Act amended Section 1848 of the Act to sunset ''meaningful use'' payment adjustments for Medicare physicians after the 2018 payment adjustment.

In the 2016 Rule, the Department estimated that that rule likely covered almost all licensed physicians because they accept Federal financial assistance from sources other than Medicare Part B. Many physicians participate in more than one Federal, State, or local health program that receives Federal financial assistance, and many practice in several different settings, which increases the possibility that they may receive payments constituting Federal financial assistance.

For the sake of consistency and convenience, the Department uses the 2016 Rule's RIA estimate of the number of physicians receiving Federal financial assistance. As the 2016 Rule RIA noted, based on 2010 Medicaid Statistical Information System data (the latest available), about 614,000 physicians accept Medicaid payments and are covered under Section 1557 as a result.[333] This figure represents about 69% of licensed physicians in the United States, based on the 890,000 licensed physicians reported in the Area Health Resource File.[334] In addition, physicians receiving Federal payments from non-Part B Medicare sources will also come under Section 1557. The 2016 RIA noted that, as of January 2014, 296,500 Medicare-eligible professionals had applied for funds to support their ''meaningful use'' technology efforts.[335] Adding the approximately 614,000 physicians who receive Medicaid payments to the 296,500 physicians who receive meaningful use payments would yield over 900,000 physicians potentially reached by Section 1557 because they participate in Federal programs other than Part B of Medicare. Because physicians can receive both Medicaid and meaningful use payments, and these figures are not adjusted for duplication, the 900,000 result is best interpreted as an upper bound.

When the Department compared the upper-bound estimated number of physicians participating in Federal programs other than Medicare Part B (over 900,000) to the number of licensed physicians counted in HRSA's Area Health Resource File (approximately 890,000), and allowing for duplication in both the Medicare/Medicaid and HRSA numbers,[336] the Department concluded in the 2016 Rule RIA that almost all practicing physicians in the United States are reached by Section 1557 because they accept some form of Federal remuneration or reimbursement apart from Medicare Part B.

(B) Programs or Activities Administered by the Department Under Title I of the ACA

This final rule applies to programs or activities administered by the Department under Title I of the ACA. Such programs or activities include temporary high-risk pools (section 1101), temporary reinsurance for early retirees (section 1102), Department mechanisms for identifying affordable health insurance coverage options (section 1103), the wellness program demonstration project (section 1201, adding Public Health Service (PHS) Act 2705(*l*)), the provision of community health insurance options (section 1323), and the establishment of risk corridors for certain plans (section 1342).

(C) Entities Established Under Title I of ACA

This final rule applies to the health insurance exchanges established under Title I of the ACA. Such exchanges currently include the 12 State Exchanges (and D.C. Exchange), six State Exchanges on the Federal platform and 32 Federally-facilitated Exchanges.[337] Title I additionally establishes State advisory councils concerning community health insurance (section 1323) and certain reinsurance entities under the transitional reinsurance program (section 1341).

ii. Entities Covered by Title IX

Title IX applies to recipients of Federal financial assistance for education programs or activities. 20 U.S.C. 1681. The population of applicable covered entities is defined by the term ''recipient'' in the Department's Title IX regulations. The population includes any State or political subdivision thereof, or any instrumentality of a State or political subdivision thereof, any public or private agency, institution, or organization, or other entity, or any person, to whom Federal financial assistance is extended directly or through another recipient and that operates an education program or activity that receives such assistance, including any subunit, successor, assignee, or transferee thereof. *See, e.g.,* 45 CFR 86.2. Under the definition of program or activity, recipients of Federal financial assistance within the scope of Title IX may include colleges, universities, local educational agencies, vocational education systems, or other entities or organizations principally engaged in the business of providing education. *See, e.g.,* 45 CFR part 86, App. A (cross-referencing Appendix B to 45 CFR part 80).

e. Cost Savings From Eliminating Notice and Taglines Requirement

The Department's baseline for calculating the savings from repealing the notice and taglines requirement includes approximately $585 million in additional average annual costs (over the next five years) that were not considered in the 2016 Rule. It is important to note that, while industry estimates prompted the Department to reassess the burdens imposed by the 2016 Rule, the Department conducted and relied upon its own cost analysis in developing the RIA for this final rule.

The 2016 Rule estimated $7.1 million for covered entities and $70,400 for the Federal government in combined annual costs for printing and distributing nondiscrimination notices and taglines, with the costs being apportioned roughly equally between notices and taglines. 81 FR at 31453. As explained in detail below, the Department estimates the combined notice and taglines requirement has actually cost

[332] Qualified Health Plans Landscape Individual Market Medical (2015), *https://data.healthcare.gov/dataset/2015-QHP-Landscape-Individual-Market-Medical/mp8z-jtg7.*

[333] John Holahan and Irene Headen, Kaiser Commission on Medicaid and the Uninsured, Medicaid Coverage and Spending in Health Reform: National and State-by-State Results for Adults at or Below 133% FPL (2010), *https://kaiserfamilyfoundation.files.wordpress.com/2013/01/medicaid-coverage-and-spending-in-health-reform-national-and-state-by-state-results-for-adults-at-or-below-133-fpl.pdf.* Estimates are based on data from FY 2010 MSIS.

[334] HRSA, Area Health Resource Files (2015), *http://ahrf.hrsa.gov.*

[335] Mynti Hossain and Marsha Gold, Mathematical Policy Research Inc.: Prepared for The Office of the National Coordinator for Health Information Technology, HHS, Monitoring National Implementation of HITECH: Status and Key Activity Quarterly Summary (Jan. to Mar. 2014), *http://www.healthit.gov/sites/default/files/globalevaluationquarterlyreport_januarymarch2014.pdf.*

[336] The Area Health Resource File itself double counts physicians who are licensed in more than one State.

[337] CMS, State-Based Exchanges for Plan Year 2018 (Nov. 1, 2019), *https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/state-marketplaces.html.*

covered entities hundreds of millions of dollars per year.

The 2016 Rule requires covered entities to include a notice and taglines for any ''significant'' document or publication, but did not define the term ''significant.'' 45 CFR 92.8(f)(1)(i).[338] Thus, covered entities have interpreted this provision to require a notice and taglines to accompany many communications from covered entities, including annual benefits notices, medical bills from hospitals and doctors, explanations of benefits from health insurance companies or health plans, and communications from pharmacy benefit managers.

This led to an extraordinary amount of mailed or electronically delivered communications by entities such as plan administrators and pharmacy benefit managers, including with every auto-ship refill reminder, formulary notice, and specialty benefit letter. Further, some other entities that operate in multiple States have interpreted the 2016 Rule as requiring them to include taglines for as many as 60 languages, or have included that many taglines in mailed or electronically-delivered communications due to the cost or technical barriers to customizing mailing inserts on a State-by-State basis, and thus have incurred costs to send up to an additional two double-sided pages of notices with each communication.[339]

To estimate the volume of notices and taglines that accompany an annual benefits notice, we began with the approximately 300 million persons in the United States who have health insurance,[340] or approximately 91% of the U.S. population. The Department then assumed that the annual notice of benefits (that includes a notice and taglines) is sent to each policyholder, not to each individual member of a covered household, such as covered children. Of the total U.S. population, 306 million individuals belong to 117.7 million households. For the data set relied on, a ''household'' includes ''all the people who occupy a housing unit . . . . The occupants may be a single family, one person living alone, two or more families living together, or any other group of related or unrelated people[341] who share living arrangements.''[342] By implication, 17.3 million individuals do not belong to a household,[343] and live in group quarters.[344] The Department assumed that the percentage of the U.S. population that is uninsured, 9%, is the same percentage of U.S. individuals belonging to U.S. households that are uninsured. To calculate the number of annual benefits notices, the Department added the total number of individuals that do not belong to a household (17.3 million) to the total number of households (117.7 million), and discounted the sum (135 million) by 9% to exclude those individuals who are not insured. The total number of annual notices of benefits that include a nondiscrimination notice and taglines is therefore approximately 123 million (approximately 91% of 135 million).

To estimate the volume of notices and taglines that accompany communications from the health insurance Exchanges, the Department assumes the Exchanges send communications to the 11.8 million individuals enrolled in the individual market.[345] It assumes that the Exchanges send out approximately 1.5 notices per person per year. This accounts for the annual re-enrollment communication plus additional communications Exchanges will send for special enrollment periods. Thus, the total estimated volume of notices and taglines attributable to the Exchanges is 17.7 million.

To estimate the volume of notices and taglines that accompany hospital bills and explanations of benefits sent by insurance companies (or health plans) for hospital admissions, the Department first estimated the total number of hospital bills and explanation of benefits that would be sent to patients annually. There are 35 million hospital admissions per year.[346] For the purpose of this estimate, the Department assumes that each admission generates three bills from one hospital visit—each of which would include a notice and taglines document, for a total of 105 million bills, assuming three bills per admission.[347] The Department assumes that 10% of the 105 million bills will have a notice and taglines document attached, for a total of 10.5 million notice and taglines documents.

For patients who were insured upon admission to the hospital, in addition to the three hospital bills they would receive (on average), they would receive three associated explanations of benefits from their insurer or health plan, each of which would also include notice and taglines documents. If more than three service providers bill a patient for a hospital visit, then the savings associated with this patient encounter will be greater than estimated due to the additional notice and taglines documents that the insurer would send with each additional explanation of benefits beyond the initial three assumed. If fewer than three service providers bill for a hospital visit, then the savings will be less due to the decreased volume of notice and taglines documents that the insurer would send because the insurer would send fewer than three explanation of benefits. Given that approximately 91% of the U.S. population is insured, the

[338] After publishing the 2016 Rule, OCR issued guidance explaining that any significant publication printed on an 8.5 x 11 sheet of paper is not considered small sized and, thus, must include a minimum of 15 taglines. *See* OCR, Question 23, General Questions about Section 1557 (May 18, 2017), *https://www.hhs.gov/civil-rights/for-individuals/section-1557/1557faqs/index.html.*

[339] Although OCR has issued guidance stating that a covered entity may identify the top 15 languages spoken across all the States that the entity serves, *See https://www.hhs.gov/civil-rights/for-individuals/section-1557/1557faqs/aggregation_tagline/index.html,* evidence of notices that some covered entities shared with OCR suggests covered entities with beneficiaries in multiple States may issue more comprehensive tagline notices with more than 15 languages, likely because of reasonable interpretations of the relevant provisions of the 2016 Rule, and the higher cost of attempting to tailor notices and taglines to individuals based on their specific State.

[340] Calculated by subtracting total uninsured population (28.1 million as of 2016), *See https://www.census.gov/library/publications/2017/demo/p60-260.html,* from the total U.S. Population (327 million as of March 14, 2018), *See https://www.census.gov/popclock.*

[341] The calculations do not take into account households where two or more unrelated persons have individual coverage, and thus receive separate annual notices at the same household. The Department believes, however, that this exclusion has only a minor impact on the overall figures.

[342] U.S. Census Bureau, American Community Survey and Puerto Rico Community Survey 2016 Subject Definitions 76, *https://www2.census.gov/programs-surveys/acs/tech_docs/subject_definitions/2016_ACSSubjectDefinitions.pdf* (defining ''household'' under ''Household Type and Relationship'').

[343] The Department subtracted 306 million individuals belonging to a household from the total U.S. population of 323.4 million individuals. *See* U.S. Census Bureau, *https://factfinder.census.gov/faces/tableservices/jsf/pages/productview.xhtml?src=bkmk* (relied on 2016 population nationally).

[344] U.S. Census Bureau, American Community Survey and Puerto Rico Community Survey 2016 Subject Definitions 76, *https://www2.census.gov/programs-surveys/acs/tech_docs/subject_definitions/2016_ACSSubjectDefinitions.pdf* (''People not living in households are classified as living in group quarters.''). ''Group quarters include . . . college residence halls, . . . skilled nursing facilities, . . . correctional facilities, and workers' dormitories.'' U.S. Census Bureau, 2016 American Community Survey/Puerto Rico Community Survey Group Quarters Definitions, 1 *https://www2.census.gov/programs-surveys/acs/tech_docs/group_definitions/2016GQ_Definitions.pdf.*

[345] *See* CMS, *Health Insurance Exchanges 2018 Open Enrollment Period Final Report* (Apr. 3, 2018), *https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2018-Fact-sheets-items/2018-04-03.html.*

[346] CDC, Chartbook on Long-Term Trends in Health (2016), *http://www.cdc.gov/nchs/data/hus/hus16.pdf#317.*

[347] The Department presumes one hospital visit likely will generate a bill from the physician and two bills from any combination of services, such as anesthesia, ambulance service, imaging/radiology, or laboratory or blood work.

Department estimates that approximately 32 million of the 35 million hospital admissions are associated with insured patients (91% of 35 million hospital admissions).[348] This assumption does not account for variation in healthcare consumption between the insured and uninsured populations. It is possible that more hospital admissions are attributable to the uninsured than the insured population. If such is the case, the Department's estimate for the number of notices and taglines attributable to explanations of benefits would be lower. Further, this estimate does not account for outpatient hospital visits, which would increase the volume of notices and taglines. Moreover, if the elderly, nearly all of whom are insured by Medicare, make up a disproportionate share of hospital admissions, the Department's estimate for the number of notices and taglines attributable to explanations of benefits would be higher.

As discussed further below, the Department assumes 100% of insurance companies are compliant with the notice and taglines requirement. Thus, approximately 96 million notice and taglines documents are attributable to the explanations of benefits sent by insurers (32 million admissions times three explanation of benefits). Using rounded values, approximately 107 million additional notices and taglines (96 million plus 11 million) are related to hospital admissions.

To estimate the volume of notices and taglines that accompany doctor's bills and explanations of benefits from a physician's visit, the Department relied on data showing that individuals visit physicians' offices approximately 990 million times each year.[349] Given that approximately 9% [350] of Americans are uninsured, the Department assumes (and subtracting an estimated 5% for uninsured patients who do not visit the doctor, except in an emergency) that 95% of individuals who see doctors every year are insured in some form. The Department assumes that each visit to a compliant doctor's office will generate at least one bill from the doctor and at least one explanation of benefits from the health insurance company. As explained below, it also assumes that 10% of doctors and 100% of insurance companies comply with the notice and taglines requirement. Thus, approximately 99 million notices and taglines are attributable to doctors billing the patients directly, and approximately 941 million are attributable to explanations of benefits sent by insurers, which results in a total of 1.04 billion additional notices and taglines related to physician visits.

Because experience and substantial feedback from healthcare insurers suggests a very high degree of compliance with the notice and taglines requirements when it comes to documents such as explanations of benefits, the Department presumes 100% compliance for purposes of this RIA. Anecdotal evidence, however, suggests that hospital and physician compliance with the notice and taglines requirements in the documents discussed above is not standard industry practice. The Department estimates that, at most, 10% of such covered entities include notices and taglines in their significant mailed communications with patients. Although, according to the 2016 Rule's RIA, most hospitals and physicians are covered entities under Section 1557, the Department believes their failure to adopt notices and taglines as a standard billing and communication practice may be due to the fact the notice and taglines requirement in the 2016 Rule mentions a duty to notify ''beneficiaries, enrollees, applicants, and members of the public'' and does not explicitly mention ''patients.'' 45 CFR 92.8(a). Additionally, the preamble to the 2016 Rule explained that the notice and taglines requirement covered communications ''pertaining to rights or benefits,'' which insurance companies have universally interpreted as applying to significant numbers of communications they send to beneficiaries. 81 FR at 31402. For these reasons, the Department's calculations presume a 10% compliance rate for hospitals and physicians and a 100% compliance rate by health insurance companies concerning the notice and taglines requirement as it relates to bills and explanations of benefits, respectively.

To estimate the volume of notices and taglines that accompany pharmacy-related communications, the Department relied on estimates from the Pharmaceutical Care Management Association, which, due to the nature of its organization, obtained an estimated number of impacted beneficiaries from its member organizations. Approximately 173 million beneficiaries are being impacted annually by the notice and taglines requirement, and these beneficiaries receive between 6 and 28 communications per year with an accompanying notice and taglines. The Department relied on the average of this estimate (17 communications per year per beneficiary) to determine that 2.9 billion prescription-related communications (*e.g.,* communications from pharmacy benefit managers) are sent each year.[351]

To calculate the costs of the notice and taglines requirement, the Department assumes that the underlying communication to which a nondiscrimination notice and taglines document is attached is a communication that is on average three sheets of paper or less. Combined with the nondiscrimination notice and taglines (which constitute another 1–4 sides of a page, that is, 1 sheet single-sided [352] to 2 sheets of paper double-sided), the total number of sheets of paper that would be transmitted is equivalent to 4–5 sheets of paper or less. The associated costs of the notice and taglines requirement are (1) materials, (2) postage, and (3) labor. Because of the uncertainty around some of the estimates, we report ranges for some values in this analysis.

For materials, the Department assumes that materials (paper and ink) per notice and taglines mailing insert will cost between $0.025 and $0.10. The Department assumes that low materials cost would be $0.025 to print a 1-page notice and taglines on a single sheet of paper single-sided, and the high materials cost of $0.10 to print a 4-page notice and taglines on 2 sheets of paper double sided.

For postage, the Department estimates that the additional weight of the notice

[348] Calculated by subtracting total uninsured population (28.1 million as of 2016), *See https://www.census.gov/library/publications/2017/demo/p60-260.html,* from the total U.S. Population in 2016 (323,405,935), *See https://www.census.gov/popclock. http://news.gallup.com/poll/225383/uninsured-rate-steady-fourth-quarter-2017.aspx?g_source=Well-Being&g_medium=newsfeed&g_campaign=tiles.*

[349] CDC, Ambulatory Care Use and Physician Office Visits (2016), *https://www.cdc.gov/nchs/fastats/physician-visits.htm.* As noted above, the Department relies on the 2016 RIA assumption that virtually all doctors receive Federal financial assistance and, thus, are subject to the 2016 Rule.

[350] Calculated by subtracting total uninsured population (28.1 million as of 2016), *See https://www.census.gov/library/publications/2017/demo/p60-260.html,* from the total U.S. Population in 2016 (323,405,935), *See https://www.census.gov/popclock.*

[351] Source: Pharmaceutical Care Management Association (May 2, 2017), available at *https://www.regulations.gov/document?D=HHS-OCR-2019-0007-0006.*

[352] Although this cost-benefit analysis assumes a lower-bound estimate that a notice of nondiscrimination and 15 taglines may be printed on one side of one sheet of paper, the Department believes that a notice of that length is likely noncompliant with the 2016 Rule requirement to be posted ''in conspicuously-visible font size.'' *See also* OCR, Sample Notice Informing Individuals About Nondiscrimination and Accessibility Requirements and Sample Nondiscrimination Statement: Discrimination is Against the Law (printed on two sides of one sheet of paper), *https://www.hhs.gov/sites/default/files/sample-ce-notice-english.pdf.*

and taglines inserts result in a range of no incremental postage costs (low-end) to $0.21 per mailing (high-end). For instance, if an underlying communication is three sheets of paper or less, a covered entity's inclusion of one double-sided page (or shorter) of notice and taglines insert would likely weigh one ounce or less (approximately four letter-sized pages weigh one ounce).[353] Consequently, in this scenario, the notice and taglines insert would not increase the total weight of the mailing beyond the one ounce of postage that a covered entity would already expect to incur. If, however, a covered entity included 2 sheets of paper double-sided containing the nondiscrimination notice and taglines, added to a communication of three sheets of paper or more, the total weight of the mailing would likely be at least five sheets of paper, and therefore over one ounce. The marginal cost of postage for each ounce is $0.20.[354]

For labor, the Department estimates the burden to download, print, and include these notices and taglines with all significant communications for an office clerk (Occupation Code No. 43–9061) with a mean hourly wage of $16.92/hour[355] plus an additional $16.92/hour in fringe benefits, or $33.84/hour for labor costs.[356] Based on experience, entities can manually fold and insert notices and taglines into envelopes at a rate of approximately 360 per hour. Entities that use commercial machines can fold and insert notices and taglines as fast as 5,400 envelopes per hour.[357] The Department uses the average of 2,880 notices and taglines that can be folded and placed into an envelope in an hour. Under these assumptions, the unit labor cost per notice and taglines mailing is $0.01.

Considering materials, postage, and labor, the per-unit cost for the notice and taglines insert ranges from $0.035 at the low end (for one single-sided sheet of paper of notice and taglines) to $0.32 at the high end (for two double-sided sheets of paper of notice and taglines), if the Department assumes that the average underlying mailer is 3 sheets of paper.

In addition, the Department estimates that some of these costs would be mitigated absent this final rule, due to transitions to electronic delivery for some communications affected by the 2016 Rule. The Department estimated, in the RIA for the Proposed Rule, that electronic delivery would reduce costs of affected communications by approximately 10–20% absent this final rule, shifting linearly from 10% in the first year to 20% in the fifth year following implementation (in other words, increasing by 2.5 percentage points each year). Survey results from Cognizant[358] indicate that 70 percent of respondents consider it important to be able to view medical care-related statements (*e.g.,* explanation of benefits documents) electronically, and that 42 percent are able to do so currently. But the same survey found that ''[a]doption rates are low for the digital services currently offered by health insurers, even for those that respondents rated as very important,'' with ''just about half of the members who were aware of'' a given digital service having actually ''used it.'' According to another survey by InstaMed,[359] 23% of providers offer some electronic billing, but even out of those providers who do, 58% still provide fewer than half of their bills electronically.[360] Moreover, it is likely that younger generations are the ones currently enrolling in e-statements; given that a disproportionate amount of health care services and products, especially pharmaceuticals, are consumed by the elderly, the communications containing the notices and taglines affected by this rule may be relatively unlikely to use e-statements. Therefore, as one end of a range of electronic delivery estimates, the Department maintains the earlier assumption of 10 percent in the first year, growing linearly to 20 percent in the fifth year after finalization, and departs from the preliminary RIA's assumption only in that the linear growth is extended past the fifth year.

At the opposite end of the range of estimates, the electronic delivery rate is assumed to be 21 percent upfront (reflecting the higher of the two survey results cited above, with adjustment to account for the fact that in those surveys, 50% or less of patients offered electronic delivery have been accepting it) and 42 percent in Year 5 (reflecting the same survey, without such adjustment), with subsequent increases continuing at 5.25 percentage points per year.

In combining the two input ranges for Table 2 below—the cost per printed and mailed communication and the electronic delivery rates—the low ends are used together and the high ends are used together, to reflect that entities facing relatively high costs for printed communications would have greater incentive to shift to electronic delivery where feasible. The primary estimates relied on for Table 1, however, use simply the midpoint of each of the two input ranges.

Electronic delivery would eliminate postage costs, but may to a certain extent merely shift the costs of paper and printing from the entity providing the communication to the consumer/beneficiary/patient, given that some consumer/beneficiary/patient recipients of electronic communications will print them out and incur costs for the paper and ink associated with doing so. The Department has not included such consumer/beneficiary/patient costs in its estimates.

The Department averages the low and high-end estimates to determine a primary estimate of annual cost savings, which results in average savings of approximately $0.58 billion per year, over the first five years, after adjusting for electronic delivery.

As discussed above, the proposed rule noted that, with repeal of the 2016 Rule requirements, the Department assumed that two other regulatory requirements for taglines would also be fully repealed because they depend on, or refer to, the 2016 Rule for authority for the taglines requirement. The first is the requirement placed on Health Insurance Exchanges (*see* 45 CFR 155.205(c)(2)(iii)(A)), which the Department estimates issue 17.7 million communications per year, primarily through eligibility and enrollment communications. The second is the requirement placed on QHP issuers (*see* HHS Notice of Benefit and Payment Parameters for 2016; 2016 Rule, 80 FR 10750, 10788 (Feb. 27, 2015)), whose costs are incorporated into the volume calculations for annual notices of benefits, and explanations of benefits discussed in more detail above. Those

[353] *See* ''How Many Sheets of Paper Fit in a 1 Ounce Envelope for Mailing Purposes,'' *https://www.reference.com/business-finance/many-sheets-paper-fit-1-ounce-envelope-mailing-purposes-84ba93a60789c2e1.*

[354] *See* U.S. Postal Service Postage Rates, *https://www.stamps.com/usps/current-postage-rates/.*

[355] BLS, Occupational Employment and Wages (May 2018), *https://www.bls.gov/oes/2018/may/oes_nat.htm.*

[356] CMS estimates that the labor costs would be a one-time cost of $16,244 for Medicaid managed care and a one-time cost of $9,669 for CHIP managed care. The Department assumes for its calculations that the labor costs for the notice and tagline provisions are not one-time but are ongoing costs associated with the value of office clerks' time printing and including the notices and taglines with significant publications and significant communications.

[357] *See, e.g.,* Pitney Bowes, ''Folders and Inserters,'' *https://www.pitneybowes.com/nz/folders-inserters.html.*

[358] *See https://www.cognizant.com/InsightsWhitepapers/The-Digital-Mandate-for-Health-Plans-codex1760.pdf.*

[359] *See https://www.instamed.com/white-papers/trends-in-healthcare-payments-annual-report/.*

[360] *See https://www.cognizant.com/InsightsWhitepapers/The-Digital-Mandate-for-Health-Plans-codex1760.pdf* and *https://www.instamed.com/white-papers/trends-healthcare-payments-report-2018/.*

two other regulations have not yet been amended in this respect, but the Department clarified above that because those requirements inform entities they will be deemed in compliance if they are in compliance with the Section 1557 rule's notice and taglines requirement, and because the latter has now been repealed by this final rule, covered entities do not need to independently comply with those two other regulatory requirements cross referencing the Section 1557 rule. As a result, these estimates continue to assume this final rule will result in cost savings with respect to those requirements.

The Department also assumes that health insurance entities would not voluntarily append notices and taglines to routine monthly premium statements absent the 2016 Rule, but are doing so because of it (or because of a requirement in another regulation that bases its requirement on the 2016 Rule's requirement).

TABLE 2—ANNUAL SAVINGS FROM REPEAL OF REQUIREMENT TO PUBLISH AND MAIL NOTICES AND TAGLINES, BY VOLUME OF TRANSACTIONS PER TYPE PER YEAR AFTER ACCOUNTING FOR ELECTRONIC DELIVERY

[in millions]

	Count	Estimated low Savings ($0.035/unit)	Estimated high savings ($0.32/unit)
Exchange eligibility and enrollment communications	17.7	Year 1: $1 Year 5: $0	Year 1: $4. Year 5: $3.
Annual notice of benefits	123	Year 1: $4 Year 5: $3	Year 1: $31. Year 5: $23.
Explanations of Benefits—hospital admissions	96	Year 1: $3 Year 5: $3	Year 1: $24. Year 5: $18.
Explanations of Benefits—physician's visits	941	Year 1: $30 Year 5: $26	Year 1: $238. Year 5: $175.
Medical bills—hospital admissions	11	Year 1: $0 Year 5: $0	Year 1: $3. Year 5: $2.
Medical bills—physician visits	99	Year 1: $3 Year 5: $3	Year 1: $25. Year 5: $18.
Pharmacy-related notices	2,900	Year 1: $91 Year 5: $81	Year 1: $733. Year 5: $538.
Total, accounting for electronic communications	4,188	Year 1: $132 Year 5: $117	Year 1: $1,059. Year 5: $777.

The primary estimate of annual savings is approximately $0.63 billion in Year 1 and $0.51 billion in Year 5 after accounting for electronic delivery. The Department assumes that the nine other CMS regulations or guidelines requiring taglines will continue to be in effect, and the cost of complying with these CMS requirements would need to be subtracted from the total savings that the 2016 Rule's rescission generates for the healthcare sector as set forth in Table 2. These requirements include (1) Group Health Plans and Health Insurance Issuers requirements;[361] (2) Navigator requirements;[362] (3) Non-Navigator Assistance Personnel requirements;[363] Medicaid requirements;[364] Medicaid Managed Care requirements;[365] CHIP requirements;[366] CHIP Managed Care requirements;[367] Hospitals Qualifying for Tax-Exempt Status requirements;[368] and Medicare Advantage (Part C) and Prescription Drug Plans (Part D) requirements.[369]

Comment: Some commenters indicated that the notice and taglines requirements that the Department proposed for removal led to substantial costs that the Department understated. For example, they contended costs may be higher than the Department estimated in the proposed rule because plans had to revise internal documents, incur significant IT costs, and work with outside vendors to implement the 2016 Rule. Commenters also contended the 2016 Rule resulted in significant annual printing costs.

One commenter calculated that the costs of the mailings related to pharmacy services yielded additional costs of $1 billion a year. The commenter supported the Proposed Rule's RIA aggregate estimate that the requirement would save plans $101 to $928 million a year and provided a specific example in which an affected entity reported incurring $3.9 million in printing costs and $4 million in operations costs to send 55.5 million communications.

Another company reported almost $1 million in annual increased expenses on toner, developer, paper, and postage related to notice and taglines requirements. Another commenter stated the costs associated with complying with the 2016 Rule's requirement accounts for 4.5% of one company's budgeted operating income. Some commenters also stated the proposed rule would significantly reduce the administrative burden placed on providers, saying that what constitutes a ''significant'' communication has been insufficiently clear and has resulted in broad interpretations and providers using the taglines in almost every document.

Some commenters estimated that the dental profession has spent over $240 million to date on compliance with the 2016 Rule. The commenter noted that the time and cost for dental offices to interpret the regulations, print documents, alter existing publications, and modify websites has been significant. Several dental offices believe repealing the notice and taglines requirements will lead to cost savings and will allow staff to spend time on appropriate patient care and communication instead.

One commenter explained that in its Pennsylvania line of business, it serves

[361] 45 CFR 147.136(e)(2)(iii) and (e)(3), and § 147.200(a)(5).

[362] 45 CFR 155.215(c)(4).

[363] 45 CFR 155.215(c)(4).

[364] 42 CFR 435.905(b)(3).

[365] 42 CFR 438.10(d)(2) through (3), (d)(5)(i) and (iii), and (j).

[366] 42 CFR 457.340(a).

[367] 42 CFR 457.1207.

[368] 26 CFR 1.501(r) through 1(b)(24)(vi).

[369] Medicare Marketing Guidelines § 30.5.1, *https://www.cms.gov/Medicare/Health-Plans/ManagedCareMarketing/FinalPartCMarketingGuidelines.html.*

800,000 persons and sends them 2-page double-sided notices and taglines 6,205,000 times a year under the 2016 Rule, resulting in $245,175 in annual mailing costs. The commenter noted it has similar experiences in all of its Medicaid lines of business.

Other commenters suggested the Department overestimated the costs of the 2016 Rule's notice and taglines requirements. One association stated that the Department's estimate in the proposed rule overestimated by failing to account for notices generated by a machine, included in bulk mailings, or facilitated through the use of computers. The commenter also believed that, while electronic delivery would eliminate postage costs, it would not shift the cost of paper and printing to the consumer/beneficiary/patient, stating it is unlikely that a significant percentage of individuals would download and print documents sent to them electronically. Similarly, the commenter contended the Department failed to account for the significant degree to which communications can be provided electronically and the degree to which some entities, such as insurance plans, have already been doing so for years.

Another commenter, however, agreed with OCR's calculation that the notice and taglines requirement has resulted in the inclusion of one to two sheets of paper. Similarly, one commenter stated it implemented multiple versions of the two-page notice and taglines on thousands of documents in its businesses, which consumed significant resources. The commenter noted that the requirements also impacted covered entity partners as well, particularly print vendors.

Some commenters asked the Department to separate out costs for providing notices as distinct from providing taglines, and for posting notices as distinct from mailing them.

Response: The Department appreciates the comments regarding the costs of the 2016 Rule's notice and taglines requirements. The Department agrees with commenters who contend that the requirements imposed significant and costly burdens far beyond the estimates set forth in the 2016 Rule. The Department finalizes this rule in significant part to relieve those burdens.

Some commenters contended the Department's estimates in the proposed rule were understated, and others contended the Department's estimates were overstated. The comments generally provided data from specific entities or circumstances.

The Department's estimate of the average cost of mailings is based on data received from covered entities across the affected industry, and generally takes into account processes and methods used in mailings such as machines, computers, and bulk handling. Although the Department suggested that some patients and beneficiaries might print notices electronically mailed to them, the Department did not factor those potential costs in its estimate. To the extent that commenters contended the Department failed to consider the extent to which notices and taglines are delivered electronically, this is incorrect, as the Department's preliminary estimates included downward adjustments to its estimates based on electronic delivery, and its revised estimates reflect a broader range of potential electronic delivery rates. Moreover, other commenters contend that they continue to experience significant costs based on non-electronic delivery—contending in some cases that the Department's estimates of those costs were understated.

Commenters were correct to identify that some costs, such as revising internal documents, IT costs, and setting up relationships with outside vendors, resulted from the 2016 Rule. The Department does not estimate that this final rule will lead to cost savings with regard to those types of expenses, however, because they are generally sunk costs that covered entities incurred at the time of the 2016 Rule and will not be able to recover as a result of this final rule. This final rule does not prohibit entities from continuing to provide the type and number of notices and taglines required by the 2016 Rule, but gives covered entities the flexibility to not provide them.

The Department declines to accept the suggestion of some commenters that the Department separate out the costs of notices from the costs of taglines. Information from covered entities indicates that notices and taglines are usually provided together, often on overlapping pages. Because this final rule removes both requirements, the Department's estimates are intended to cover the costs of both notices and taglines.

Comment: One commenter stated that the Department improperly relied on healthcare corporations for its fact-finding and analysis in the proposed rule. In particular, conclusions that the repetitive nature of notices and taglines dilute messages, that beneficiaries do not want to receive them, and that there is no evidence that more beneficiaries have sought language assistance because of the notices, were largely gathered from the covered entities themselves.

Response: The Department relies on its own data, publicly available data, and data submitted by members of the public—including covered entities—to attempt to estimate the impact of its regulations. The Department takes into consideration the sources of the data it considers, and attempts to weigh all such data appropriately based on the information the Department has available to it.

f. Costs Arising From Removal of Notice and Taglines Requirement

Repealing the notice and taglines requirement may impose costs, such as decreasing access to, and utilization of, healthcare for non-English speakers by reducing their awareness of available translation services.

Comment: Some commenters generally supported the Department's assessment that the benefits from the notice and taglines requirements were hard to quantify and likely not significant. A health insurance plan commenter stated that since the implementation of the 2016 Rule, it has not experienced significant changes in its member demographics or languages spoken, and has not seen any notable increases in requests for translation services. One commenter also stated that its pharmacy benefit manager found that since 2017, the volume of valid complaints about discrimination are less than 1% overall and could be better handled by personnel already in place. The commenter stated further that since 2017, it has filled approximately 3.5 billion prescriptions and mailed nearly half a billion beneficiary communications. In this time period, approximately 0.002% (26 of 14,000) of calls made to the discrimination hotline were closely related to a complaint. Several commenters stated they did not see a significant increase in requests after the 2016 Rule required notices and taglines, but instead experienced relatively flat demand.

Some commenters also expressed concerns regarding wastefulness of the notice and taglines. A commenter calculated that it has spent nearly $16 million since 2017 to accommodate the current requirements and will save at least $3.5 million annually under the proposed rule. One commenter suggested that an analysis of the impact of the notice and taglines should take into account the content and frequency of the notices, overall consumer health literacy, costs and administrative burdens, and whether notices are truly meaningful to consumers.

Other commenters suggested that the 2016 Rule's notice and taglines requirements likely yielded benefits to intended individuals. A hospital commented that it observed a 10% increase in the volume of interpreter service encounters each year over the last three years. Another commenter stated that it saw a 28% reduction on its per-member per-month claims cost with its Spanish-speaking population. Several commenters from a variety of organizations request an analysis of the impact on those who most use the services affected by the proposed provision (LEP individuals) and on those who provide services to the impacted population. Several organizations, including a State government, also contended that LEP individuals are a significant portion of the population and tend towards poorer health outcomes. They also suggested that removing the notice and taglines requirements may cause such individuals to delay care or not receive care until their medical issues are more severe and costlier to treat, and they urged the Department to estimate such costs.

Another commenter stated that even though HHS justified the proposed rule in part by citing data that over three-quarters of the U.S population over the age of 18 speak only English at home and are not well served by taglines or notices, the commenter believes that if a quarter of the population does not speak English at home that is an argument against repealing the notice and taglines.

Several commenters suggested repeal of the taglines provisions may negatively impact LEP individuals. One commenter cited a study claiming that health inequities cost the U.S. economy $309.3 billion a year.

Response: The Department appreciates the comments concerning the effectiveness and benefits of the notice and taglines requirements from the 2016 Rule. As noted in the proposed rule, previously received reports from covered entities are consistent with some public comments suggesting that the 2016 Rule's requirements did not appreciably increase the use of translation services. One such report indicated that utilization of translation services did not appreciably rise after the 2016 Rule's imposition of notice and taglines requirements.[370] Although some commenters contended that they experienced an increase in translation services after the 2016 Rule, others reported a different experience. The Department generally agrees with the latter, and the difference in reports from different commenters and other sources reinforces the Department's view of the difficulty of attempting to calculate the 2016 Rule's benefits to individuals needing translation services. The Department does not believe it has data enabling it to fulfill the request of commenters who urged the Department to calculate the value of such benefits lost as the result of this final rule, as distinct from data that more generally estimate costs resulting from inequality or delay in care.

As noted in the proposed rule, there are other reasons to believe the 2016 Rule's notice and taglines requirements imposed burdens disproportionate to potential benefits for intended beneficiaries. The vast majority of recipients of taglines do not require translation services. For example, according to Census statistics, as of 2015, over three-quarters (79%) of the U.S. population over age five speak only English at home, followed by Spanish (13%).[371] Although a commenter contends this statistic provides an argument in favor of maintaining multi-language taglines, the Department disagrees regarding a requirement to send such taglines where almost 80% of the recipients likely speak only English at home, and a majority of the remainder spoke English ''very well.'' [372] Additionally, of persons selecting a written language preference when registering for coverage on the HealthCare.gov platform for 2017, 90.29% selected English, followed by 8.23% who selected Spanish.[373] These data indicate that, for the large majority of people who receive them, the required language taglines mailings provide little to no benefit because they are already proficient English speakers with little need for translation services.

Furthermore, the 2016 Rule's requirements added 47 languages to existing language access requirements, but that only increased access to 0.4% of the entire U.S. population. This was after broadly defining ''limited English proficiency'' to include those who speak English ''well'' but not ''very well.'' [374] The Department's Office for Civil Rights also produced a list of the top 15 languages in each State; however, 26 of the languages on OCR's list are spoken by less than 0.004 percent of the population. As a result, in some States, especially those with sparser populations, the 2016 Rule required health insurance issuers to provide taglines services in languages spoken by very few people in the State. For instance, in Wyoming, issuers needed to provide translation notices in Gujarati and Navajo in every significant communication sent to beneficiaries to account for approximately 40 Gujarati speakers and 39 Navajo speakers; in Montana issuers were required to provide notices to account for approximately 80 speakers of Pennsylvania Dutch; and in Puerto Rico, issuers had to provide taglines notices to account for approximately 22 Korean speakers and 22 French Creole speakers.[375]

The Department also continues to believe that the notice and taglines required by the 2016 Rule imposed burdens on many recipients and may interfere in their receipt and understanding of important healthcare information. Prior to the proposed rule, the Department received many communications from beneficiaries and advocacy groups complaining about the excessive amount of paperwork they receive. These individuals and groups

[370] *See* Aetna (May 1, 2017), available at *https://www.regulations.gov/document?D=HHS-OCR-2019-0007-0005.*

[371] U.S. Census Bureau, *B16007: Age by Language Spoken at Home for the Population 5 Years and Over,* 2011–2015 American Community Survey (American FactFinder) (2017), *https://factfinder.census.gov/bkmk/table/1.0/en/ACS/16_5YR/S1601/0100000US. See also* Kimberly Proctor, Shondelle M. Wilson-Frederick, et *al., The Limited English Proficient Population: Describing Medicare, Medicaid, and Dual Beneficiaries,* 2.1 Health Equity 87 (May 1, 2018), *http://online.liebertpub.com/doi/10.1089/heq.2017.0036* (identifying Spanish as the language of the largest majority of limited English proficient speakers in Medicaid and Medicare, according to the 2014 American Community Survey).

[372] U.S. Census Bureau, *B16007: Age by Language Spoken at Home for the Population 5 Years and Over,* 2011–2015 American Community Survey (American FactFinder) (2017), *https://factfinder.census.gov/bkmk/table/1.0/en/ACS/16_5YR/S1601/0100000US.*

[373] CMS, *Race, Ethnicity, and Language Preference in the Health Insurance Marketplaces 2017 Open Enrollment Period* (April 2017), *https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/Data-Highlight-Race-Ethnicity-and-Language-Preference-Marketplace.pdf.* States that that do not use the *HealthCare.gov* platform, such as California and New York, were not included in this report.

[374] *See* HHS OCR, Frequently Asked Questions to Accompany the Estimates of at Least the Top 15 Languages Spoken by Individuals with Limited English Proficiency under Section 1557 of the Affordable Care Act, Question 2 (Sept. 1, 2016), *https://www.hhs.gov/civil-rights/for-individuals/section-1557/1557faqs/top15-languages/index.html* (using 2013 year estimates). *See* U.S. Census Bureau, Language Spoken at Home by Ability to Speak English for the Population 5 Years and Over, *https://factfinder.census.gov/faces/tableservices/jsf/pages/productview.xhtml?pid=ACS_14_5YR_B16001&prodType=table* (2016 year estimates).

[375] OCR, Resource for Entities Covered by Section 1557 of the Affordable Care Act, Estimates of at Least the Top 15 Languages Spoken by Individuals with Limited English Proficiency for the 50 States, the District of Columbia, and the U.S. Territories (Aug. 2016), *https://www.hhs.gov/sites/default/files/resources-for-covered-entities-top-15-languages-list.pdf.*

explained that few people read the notice and taglines and most ignore the last pages of lengthy health documents. Additionally, documents that contain a significant number of pages that recipients do not value can often induce annoyance or frustration due to perceived wasting of time, ignorance of the customers' actual needs or language abilities, waste of economic resources, or insensitivity to environmental concerns.

These communications coincide with the views of some commenters and generally support the Department's conclusion that the 2016 Rule has resulted in ''cognitive overload,'' where individuals experience a diminished ability to process information when inundated with duplicative information and paperwork. These frustrations, though difficult to quantify, are reasonable to expect given the large volume of healthcare communications with notice and taglines that most Americans receive. It is also reasonable to expect that repeated mailings of taglines to people who do not want them may negatively impact their likelihood to read truly significant documents from their insurers or doctors, and may negatively impact health outcomes in some cases.

It is also noteworthy that other rules exist to benefit the persons whom the 2016 Rule's notice and taglines requirements intended to assist. Regulations under Section 504 of the Rehabilitation Act generally require the provision of auxiliary aids and services in health programs or activities that receive Federal financial assistance. 45 CFR 84.52(d). Because the notice requirement under the 2016 Rule required frequent mailed notification of the availability of auxiliary aids and services, the Department suggested in the proposed rule that repealing the notice of nondiscrimination requirement may result in additional societal costs, such as decreased utilization of auxiliary aids and services by individuals with disabilities due to their reduced awareness of such services. Some commenters agreed, but they did not suggest any way to reliably calculate such effects, and the Department is not aware of any. This impact may also be limited because the Section 504 regulations already require recipients of Federal financial assistance employing fifteen or more persons to provide notice to participants, beneficiaries, applicants, employees, and other interested persons of the availability of such aids and services. 45 CFR 85.12 and § 84.22(f).

Additionally, some commenters contended that repealing the notices and taglines may lead to persons not being made aware of their right to file complaints with OCR, and that some of those persons may suffer remediable grievances but will not complain to OCR absent notices informing them of the process. The Department continues, however, to not be aware of a way to quantify those potential effects. In addition, as noted above, the regulations implementing Section 1557's four underlying statutes already contain notice provisions, *see* 45 CFR 80.6 and Appendix to Part 80 (Title VI), § 84.8 (Section 504), § 86.9 (Title IX) and § 91.32 (Age Act), and therefore this potential cost may be minimal.

g. Cost Savings From Changes to Language Access Plan Provisions

Although the 2016 Rule did not require covered entities to develop a language access plan, the Rule stated that the development and implementation of a language access plan is a factor the Director ''shall'' take into account when evaluating whether an entity is in compliance with Section 1557. 45 CFR 92.201(b)(2). Therefore, the Department anticipated that 50% of covered entities would develop and implement a language access plan following issuance of the 2016 Rule. 81 FR at 31454.

Comment: One commenter noted that physician group practices report financial losses and significant costs when treating patients that require interpretation or translation services. The commenter stated that providing reimbursement at the Federal level would help offset extra costs incurred to provide these services free of charge and reimburse group practices for increased upfront costs and time required to care for LEP individuals. The commenter contended that face-to-face interpretation services cost between $50 and $150 per hour and may include a minimum hour requirement and transportation fee. The commenter points to one practice that reported being billed nearly $300 for a single in-person interpreter service this year due to a minimum rate and transportation fee. The practice reported paying $1,200 in interpretation fees for one month for nine individuals.

Response: The Department appreciates these comments. With respect to serving LEP patients, this final rule gives more flexibility to covered entities, while specific obligations to patients will be governed by criteria that has been set forth in longstanding guidelines. It is not within the scope of this rule to provide for Federal reimbursements.

Comment: Several commenters claim the proposed rule failed to consider the benefits to LEP individuals that will be lost by repealing certain provisions. Such commenters state there are tens of millions of LEP people who rely on protections from Section 1557. Another commenter notes that four million Medicare beneficiaries are LEP. A commenter notes that only 15 States use the Medicaid option to reimburse for interpretation. Commenters state that the language access protections in the 2016 Rule benefit Latino/a patients, Asian American and AAPI patients, LEP gender-based violence victims, low-income LEP patients, older adults, people with disabilities, and lower-income older adults.

Some commenters contend that the rule will lead to reduced awareness of language services by LEP persons and by the general public about their rights and protections. One commenter stated that if the rule is finalized, organizations like community health centers that are not funded or do not receive reimbursement for language services will face increased burdens when fewer clients will be aware of their language access rights and likely turn to them instead of to covered entities.

Commenters opposing the proposed rule claimed it would lead to inequality and a reduction in the quality of language access available; the avoidance of care, leading to worsened conditions and avoidable higher-cost hospital services; increased costs due to missed appointments, delayed care, and ''non-compliant'' self-care; increased Emergency Room use; lower preventive care access and use; malpractice costs; avoidable hospital readmissions; higher rates of uninsurance; unnecessary tests and procedures; higher rates of mortality; misunderstood diagnoses and prognoses leading to poor quality of care; and costs due to lower rates of outpatient follow-up, poor medication adherence, and lack of understanding of discharge diagnosis and instructions.

One commenter claimed that HHS's estimate that covered entities would save around $17.7 million per year by eliminating references to language access plans overlooks larger healthcare savings generated by access to interpretation services. Two commenters point to a 2017 study finding that easily accessible language interpretation services avoided an estimated 119 readmissions that were associated with savings of $161,404 per month in an academic hospital. Two commenters pointed to a 2010 report finding that at least 35 of 1,373 malpractice claims were linked to inadequate language access.

Another commenter cited a report that found that 2.5% of one malpractice carrier's closed claims involved language issues that cost the carrier over $5 million in damages, settlements, and legal fees. Costs included damages paid to patients, legal fees, time lost when defending the lawsuit, loss of reputation and patients, fear of possible monetary loss, and stress.

Response: The Department acknowledges the potential of reduced awareness of the availability of language services by LEP individuals by the changes made in this rule, or downstream effects on malpractice claims due to less awareness. As noted above, however, this final rule continues to provide protections for LEP individuals and commits the Department to enforcement of Section 1557. The Department believes, therefore, that the negative effects predicted by some commenters may be mitigated by the continued commitment to enforcement of Section 1557. The data cited by commenters either do not assess the overall impact of the 2016 Rule as compared to a regime with continued enforcement of Section 1557, or address information about broader matters without providing a method for the Department to specifically analyze how this final rule will cause the effects commenters fear may occur. In this respect, the Department believes that malpractice carriers themselves, not Federal civil rights regulators, are best equipped to determine what practices malpractice carriers should require for the sake of reducing their own financial risk.

Therefore, in consideration of the public comments and the Department's analyses, the Department adopts the estimates from the proposed rule concerning changes to language access plan provisions.

In the proposed rule, OCR estimated that the burden for developing a language access plan is approximately three hours of medical and health service manager staff time in the first year, and an average of one hour of medical and health service manager staff time per year to update the plan in subsequent years. Throughout, we assume that the total dollar value of labor, which includes wages, benefits, and overhead, is equal to 200 percent of the wage rate. The value of an hour of time for people in this occupation category, after adjusting for overhead and benefits, is therefore estimated to be $109.36 based on Bureau of Labor Statistics (BLS) data for 2018.[376] These are within the general range provided by some commenters' description of costs they have experienced.

The Department estimated that approximately 269,141 entities could potentially make changes and develop language access plans in response to the 2016 Rule, as part of the requirement to take reasonable steps to provide meaningful communication with LEP individuals (calculated by reducing the 275,002 affected entities by the 5,861 hospitals and nursing care facilities that were already subject to language access plan requirements under Medicare Part A). The Department further assumed that only 50% of the identified entities would actually make changes to implement a language access plan. If the actual compliance rate were higher, the costs would be higher. These assumptions imply that the total cost of developing language access plans will be approximately $44.1 million (269,141 entities multiplied by 50% of entities multiplied by 3 hours per entity multiplied by $109.36 per hour) in the first year and approximately $14.7 million (269,141 entities multiplied by 50% of entities multiplied by 1 hour per entity multiplied by $109.36 per hour) per year in subsequent years. 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.

By repealing the provision of the 2016 Rule regarding the Language Access Plans, the Department estimates annual savings are $14.7 million.

h. Cost Savings Attributed to Covered Entities' Handling of Certain Grievances

This final rule repeals the requirement for each covered entity with 15 or more employees to have a compliance coordinator and a written grievance procedure to handle complaints alleging violations of Section 1557. The Department estimates that, under the final rule, covered entities no longer have to incur certain labor costs associated with processing grievances related to sex discrimination complaints as they relate to gender identity as defined under the 2016 Rule because such definitions would be repealed and no longer binding. This repeal would not, however, affect the independent obligations that entities covered by Section 1557 have to comply with Federal regulations under Section 504 and Title IX to have written processes in place to handle grievances alleging certain disability and sex discrimination claims, respectively.[377]

For the sake of consistency and convenience, the Department used the methodology from the 2016 Rule as a foundation for estimating the projected savings from this proposed rule provision.

The 2016 Rule estimated that, in years three through five of the 2016 Rule's implementation, covered entities with 15 or more employees would incur $85.5 million in costs annually to handle Section 1557 grievances. 81 FR at 31458. This estimate assumed that covered entities would experience an average increase in grievances equal to OCR's projected long-term increase in caseload of about 1%. *Id.* The 2016 Rule monetized this 1% increase in caseload as a labor cost equivalent to 1% of the annual median wage for a medical and health service manager (occupation code 11–9111). *Id.* The Department continues to assume that OCR's increase in caseload attributed to the 2016 Rule reasonably informs the increase in grievance processing that covered entities will experience.

Based on OCR's tracking of Section 1557 complaints received from promulgation of the 2016 Rule (May 18, 2016) until present, OCR predicts that its long-term caseload would have increased 5% rather than 1% as originally predicted. Further, OCR believes roughly 60% of this increase (which equals 3% of the overall increase) would have been attributable to discrimination claims based on the 2016 Rule's definition of sex discrimination with respect to gender identity and sex stereotyping. The Department uses the phrase ''would have'' with regard to OCR's caseload because, as described above, the Department has been preliminarily enjoined on a nationwide basis by a Federal court from enforcing claims based on the 2016 Rule's definition of sex discrimination, and those provisions have now been vacated by the same court.

The 2016 Rule asserted that private parties have the right to challenge a violation of Section 1557 or the 2016 Rule in Federal court, independent of OCR enforcement or involvement. 45 CFR 92.302(d). In the preamble to the 2016 Rule, the Department suggested that the ability for private parties to sue

[376] BLS, Occupational Employment and Wages (May 2018), *https://www.bls.gov/oes/2018/may/oes_nat.htm.*

[377] *See, e.g.,* 45 CFR 84.7(a) (HHS regulations implementing Section 504) (requiring a written process to be in place for handling grievances alleging disability discrimination), § 86.8(a) (HHS regulations implementing Title IX) (requiring a written process to be in place for handling grievances alleging sex discrimination).

under the 2016 Rule would result in covered entities bearing increased compliance costs. 81 FR at 31395 (''the presence of a coordinator and grievance procedure enhances the covered entity's accountability and helps bring concerns to prompt resolution, oftentimes prior to an individual bringing a private right of action.''). The preliminary injunction did not apply to suits filed by private parties. Although the Supreme Court has recognized a private right of action for some civil rights statutes enforced by the Department, under this final rule the Department would no longer assert in the regulatory text or the preamble to the rule that a private right of action exists for parties to sue covered entities for any and all alleged violations. Because the issue of whether a person has a right to sue in Federal court under Section 1557 is one determined by the courts themselves and not by the Department's regulations, the Department does not estimate that this change will lead to any economic impact.

Although this final rule removes from the 2016 Rule the expansive inclusion of gender identity and sex stereotyping in the definition of sex discrimination, a court has recently vacated the gender identity provisions of the 2016 Rule. Regarding sex stereotyping, to the extent the 2016 Rule used that term to encompass gender identity, the sex stereotyping provision had no real-world effect after the court decision. To the extent sex stereotyping in the 2016 Rule did not encompass gender identity, the Supreme Court already recognized a degree of relevance of sex stereotyping in sex discrimination claims. This is discussed in more detail in the section above on sex-based discrimination. Therefore, the Department does not believe there would be a direct material economic impact regarding grievance procedures from this final rule's change in the definitions concerning sex stereotyping.

In addition, due to voluntary policies or more stringent State requirements, the Department expects that 50% of covered entities would likely continue to accept and handle grievances alleging discrimination based on gender identity and sex stereotyping as set forth under the 2016 Rule.

In the proposed rule, the Department estimated that covered entities would have experienced a 3% increase in gender identity and sex stereotyping grievance claims over the long term due to the 2016 Rule, and half of that caseload (1.5%) could have been due to the 2016 Rule's language encompassing gender identity and sex stereotyping claims in States where covered entities are not otherwise required to handle those claims. The proposed rule estimated an annual savings in labor attributed to a 1.5% decrease in grievance caseload as $123.4 million, representing 1.5% of the annual median wage of a medical and health service manager ($199,472 fully loaded) multiplied by the 41,250 covered entities with 15 or more employees.

Nevertheless, in this final rule the Department does not estimate a cost savings concerning grievance procedures. This is because, as stated repeatedly elsewhere, the court order vacating the gender identity provisions of the 2016 Rule means that this final rule's changes concerning gender identity will have no direct material economic impact. The *Franciscan Alliance* court order forms the new legal baseline in this respect, and therefore the primarily-emphasized economic baseline, for the purposes of this estimate. To the extent sex-stereotyping claims remain viable, they were already authorized by the Supreme Court's longstanding interpretation of sex stereotyping.

i. Additional Costs for Training and Familiarization

To comply with the final rule, the Department anticipates that some covered entities may incur costs to re-train employees in order to realize potential longer-term costs savings from the deregulatory aspects of this final rule's changes. The Department assumes that employers are most likely to train employees who interact with the public, and will therefore likely train between 40% and 60% of their employees, as the percentage of employees that interact with patients and the public varies by covered entity. For purposes of the analysis, the Department assumes that 50% of the covered entity's staff will receive one-time training on the requirements of the regulation. It uses the 50% estimate as a proxy, given the lack of certain information as described below. For the purposes of the analysis, the Department does not distinguish between employees whom covered entities will train and those who obtain training independently of a covered entity.

i. Number of Covered Entities That May Train Workers

The 2016 Rule estimated that 275,002 covered entities would train their employees on the rule's requirements in general (including training regarding language access provisions), and used that 275,002 figure as the basis for calculating costs to covered entities arising specifically out of the rule's prohibition on discrimination on the basis of sex. *See* 81 FR at 31450. The Department assumes, for purposes of this analysis, that the 2016 Rule's estimate was an accurate and reasonable basis for calculating costs arising from the need to provide training regarding the 2016 Rule.

TABLE 3—NUMBER OF HEALTHCARE ENTITY FIRMS COVERED BY RULE

NAIC	Entity type	Number of firms
62142	Outpatient mental health and substance abuse centers	4,987
621491	HMO medical centers	104
621492	Kidney dialysis centers	492
621493	Freestanding ambulatory surgical and emergency centers	4,121
621498	All other outpatient care centers	5,399
6215	Medical and diagnostic laboratories	7,958
6216	Home healthcare services	21,668
6219	All other ambulatory healthcare services	6,956
62321	Residential intellectual and developmental disability facilities	6,225
6221	General medical and surgical hospitals	2,904
6222	Psychiatric and substance abuse hospitals	411
6223	Specialty (except psychiatric and substance abuse) hospitals	373
6231	Nursing care facilities (skilled nursing facilities)	8,623
44611	Pharmacies and drug stores	18,852
6211	Offices of physicians	185,649
524114	Insurance Issuers	180

TABLE 3—NUMBER OF HEALTHCARE ENTITY FIRMS COVERED BY RULE—Continued

NAIC	Entity type	Number of firms
	Navigator grantees	100
Total Entities		275,002

ii. Number of Individuals Who Will Receive Training

The first category of healthcare 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 BLS occupational code for this grouping is 29–1000, and the 2018 reported count for this occupational group is approximately 5.4 million, with average loaded wages of $98.04 per hour.

The second category of healthcare staff that the Department assumes will receive training comprises degreed technical staff (Occupation code 29–2000) and accounts for 3.1 million workers with average loaded wages of $46.52 per hour. Technicians work in almost every area of healthcare: x-ray, physical, speech, psychiatric, dietetic, laboratory, nursing, and records technicians, to name but a few areas.

The third category of healthcare staff that the Department assumes will receive training comprises non-degreed medical assistants (Occupation code 31–0000), and includes psychiatric and home health aides, orderlies, dental assistants, and phlebotomists. Healthcare support staffs (technical assistants) operate in the same medical disciplines as technicians, but often lack professional degrees or certificates. The Department refers to this workforce as non-degreed, compared to medical technicians who generally have degrees or certificates. There are approximately 4.1 million individuals employed in these occupations, with average loaded wages of $31.14 per hour.

The fourth category of healthcare staff that the Department assumes will receive training is healthcare managers (approximately 0.4 million based on BLS data for occupation code 11–9111), with average loaded wages of $109.36 per hour. Because the Department assesses costs of familiarization with the regulation for one manager at each entity, it assumes that those managers will have already become familiar with the regulation and will not need additional training.

The fifth category of healthcare staff that the Department assumes will receive training is office and administrative assistants—Office and Administrative Support Occupation (Occupation code 43–0000). 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. Approximately 2.8 million individuals were employed in these occupations in health facilities in 2018, with average loaded wages of $36.50 per hour. The Department assumes that outreach workers are included in the five categories listed above, especially in the manager category.

iii. Total Costs of Training

The 2016 Rule estimated that covered entities would incur $420.8 million in undiscounted costs to train employees on the requirements of the Rule, distributed roughly evenly over the first two years after the 2016 Rule's effective date. 81 FR at 31458. This conclusion presumed covered entities were already periodically training employees on their obligations under Section 1557, but that the 2016 Rule's new sex discrimination requirements would induce covered entities to engage in additional ''comprehensive training.'' 81 FR at 31447.

For the purposes of this regulatory impact analysis, the Department assumes covered entities would face similar costs to retrain the workforce on this final rule's requirements.[378] However, because some covered entities will avoid incurring training expenses when they are not required to (as they will not be subject to the final rule), and because several States with large populations already prohibit gender identity discrimination in healthcare, the Department further assumes that only 50% of covered entities would modify their policies and procedures to reflect the changes in the final rule. Moreover, to the extent entities were motivated to provide training specifically due to the sex discrimination components of the 2016 Rule, a court has already vacated the gender identity and termination of pregnancy provisions of the 2016 Rule, and this final rule simply amends the Code of Federal Regulations to conform to the *vacatur* in that regard. The Department further assumes that 50% of covered entities, or 137,501, would train their employees to reflect the changes in this final rule. As in the 2016 Rule, the Department assumes that approximately half of the employees at these covered entities will engage in an average of an additional hour of training, and that this will occur in the first year of implementing this rule. These assumptions imply total training costs of $235.9 million. The 2016 Rule's calculations of training costs did not anticipate any ongoing training costs after year one—either in the form of annual refresher training for returning employees or training for new employees. The Department now believes that covered entities likely incur such costs, but assumes that equal costs would also be incurred under this final rule. Therefore, the Department has excluded ongoing training costs from the calculation of the baseline and from the calculation of the projected costs of the proposed rule, because such training has a net zero effect on projected costs.

j. Additional Costs for Revising Policies and Procedures

As discussed above, the Department anticipates that 50% of covered entities, or approximately 137,501 entities, would choose to revise their policies or procedures to reflect this final rule's clarification of the application of Section 1557, while other covered entities may retain their policies to ensure compliance with State or local laws. The Department assumes that it would take, on average, three to five hours for a provider to modify policies and procedures concerning this final rule. The Department selects four hours, the midpoint of this range, for the analysis. The Department further assumes that an average of three of these hours would be spent by a mid-level manager equivalent to a first-line

[378] Training costs in the 2016 Rule relied upon 2014 wages. *See, e.g.,* 81 FR at 31451 (estimating the median hourly wage for occupation code 29–1000 at $36.26, unloaded, at *https://www.bls.gov/oes/special.requests/oesm14nat.zip* .

supervisor (Occupation code 43–1011), at a cost of $57.06 per hour[379] after adjusting for overhead and benefits, while an average of one hour would be spent by executive staff equivalent to a general and operations manager (Occupation code 11–1021), at a cost of $119.12 per hour[380] after adjusting for overhead and benefits. The total cost for the estimated 137,501 covered entities to make their policies and procedures consistent with the final rule's changes is estimated to be approximately $39.9 million following implementation of this rule.

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. Due to the wide range of types and sizes of covered entities, from complex multi-divisional hospitals to small neighborhood clinics and physician offices, the above estimates of time and number of entities that would choose to revise their policies under the regulation is difficult to calculate precisely.

k. Other Benefits or Costs

The 2016 Rule's regulatory impact analysis did not include an economic cost-benefit analysis of the regulation's impact on health insurance benefit design. The Department lacks sufficient data on how much burden the 2016 Rule has placed on the development and operation of insurance benefits policies, and thus is unable to fully assess the benefit of removing this requirement.

The Department received several comments concerning the impact of the proposed rule on issues concerning discrimination on the basis of LGBTQ status, sex stereotyping, termination of pregnancy, and other provisions.

Comment: Many commenters objected that the Department did not estimate the potential for increases in the denial, delay, or substandard delivery of healthcare services from the rule's changes concerning gender identity.

One commenter suggested exploring quantitative analysis based on a survey by Harvard University and National Public Radio (NPR) in which 18% of LGBTQ people polled in 2017 reported foregoing care that they need, including preventive care, due to fears of or experiences of discrimination (including 22% of transgender people).[381] The comment estimated that this regulation will cost $1.4 billion in excess costs over the next ten years simply to treat cases of four particular cancers that would have been detected and prevented by screening, and that there will be an 18% increase in preventable mortality from these four cancers among LGBT people. The comment cited the 2016 value of a statistical life (VSL) used by the U.S. Department of Transportation to estimate these preventable deaths as being worth $39 billion to the U.S. economy over the next ten years.

Another commenter provided a list of potential sources of economic costs the proposed rule could produce concerning transgender patients, including out-of-pocket costs shifted because of transgender exclusions; increased costs from healthcare issues exacerbated by discriminatory delay or denial of care; increased costs related to sex coding; or increased costs due to substandard delivery of care. Other commenters similarly contended that literature on increased costs due to discrimination could be used to estimate economic costs. But such commenters did not provide quantitative values of such costs, or of ways to attribute the costs or portions thereof to this rulemaking.

One healthcare provider stated that they have not incurred any unreasonable costs in delivering care to its LGBTQ patients from complying with nondiscrimination protections based on sexual orientation and gender identity. The commenter added that adopting transgender-inclusive healthcare practices can reduce the costs associated with complications that arise when care is delayed or denied transgender patients due to discrimination.

One commenter stated that patients without primary care would experience an increase in emergency room visits, which would result in increased costs for the healthcare system—including from hospitals' and the government's absorbing and subsidizing the costs of uninsured patients.

Commenters raised similar comments concerning sexual orientation as did the commenters discussing gender identity or LGBTQ issues more broadly, contending the proposed rule should estimate the impact of not including protections against sexual orientation discrimination.

Response: The Department appreciates the comments concerning the regulatory impact of this final rule's changes concerning gender identity.

This rule commits the Department to vigorous enforcement of the nondiscrimination provisions of Section 1557 and Title IX as incorporated therein, according to the plain meaning of the protections set forth in those statutes. In addition, the gender identity provisions of the 2016 Rule were preliminarily enjoined on a nationwide basis by a court from December 2016 until October 2019, when they were vacated entirely. As a result, this final rule maintains the status quo with respect to gender identity under the enforcement of the Section 1557 rule.

Based on the Department's review of the public comments, the commenters did not provide, and the Department is not otherwise aware of, reliable data or methods to calculate the economic impacts concerning gender identity that they allege would be attributable to this final rule. Commenters cited various sources of data, but many were either too narrow in not providing a basis to estimate the impacts of this rule nationwide, or were too broad in discussing aspects of the healthcare system but not impacts of this specific rule. For example, citations to data about the percent of transgender persons who forgo care due to fears or experiences of discrimination, and a calculation of the costs to the healthcare system resulting from such occurrences, are not sufficient to estimate the effects of this final rule itself, due to court orders preliminarily enjoining and then vacating provisions in the 2016 Rule, State and local laws that already provide gender identity protections, and other factors that prevent the Department from showing that this final rule is causing those effects. For example, one poll cited by commenters was conducted in 2017, when the 2016 Rule was already in place, but when its gender identity provisions were preliminarily enjoined. So it is not clear from that poll that the 2016 Rule yielded the benefits the commenters say it did, and it is even less clear how this final rule will remove those benefits. Generally, the Department's review of comments is that concerns about increased costs to LGBT persons from this final rule do not offer sufficient quantitative evidence for the Department to provide an estimate along these dimensions.

Finally, as discussed above, because the 2016 Rule contained no prohibition on sexual orientation discrimination in the 2016 Rule, the Department does not deem there to be an economic impact resulting from this final rule with respect to sexual orientation discrimination.

[379] BLS, Occupational Employment and Wages, May 2018, *https://www.bls.gov/oes/2018/may/oes_nat.htm.*

[380] *Id.*

[381] NPR, ''Discrimination in America: Experiences and Views of LGBTQ Americans'' (Nov. 2017), available at *https://www.npr.org/documents/2017/nov/npr-discrimination-lgbtq-final.pdf.*

Consequently, commenters' warnings of effects of this rule's changes on these issues do not give rise to impacts that are properly attributable to this rule and that the Department believes can be estimated for the purposes of this analysis.

Comment: One commenter contended that the Department should include analysis of the consequences of removing sex stereotyping language from the rule. The commenter suggested that costs of this rescission could include increased confusion for patients and covered entities, increased discrimination based on sex stereotyping with attendant economic and non-economic costs to patients and the public health system, increased need for legal advice, and increased litigation.

Response: To the extent that sex stereotyping language from the 2016 Rule was interpreted to encompass gender identity, court orders have preliminarily enjoined and now vacated those provisions. Therefore, this final rule does not directly induce changes in this regard. To the extent that sex stereotyping is a recognized category of sex discrimination under longstanding Supreme Court precedent, this final rule commits the Department to continuing to vigorously enforce Title IX through Section 1557, and therefore the Department estimates that this final rule will not have any material effect on the scope of sex stereotyping claims as authorized by Title IX and Section 1557.

Comment: A commenter objected that the proposed rule did not estimate the economic impact of withdrawal of Federal guidance and technical support concerning the 2016 Rule.

Response: All guidance and technical support concerning the 2016 Rule was withdrawn by operation of the preamble to the proposed rule, which itself is a guidance document—not directly by this final rule. The outdated guidance documents are in the process of being removed from the Department's websites. The Department is not aware of any data that would allow it to estimate the effects of changes to its sub-regulatory guidance. To the extent that certain guidance and technical support concerned provisions of the 2016 Rule that were enjoined and vacated, this final rule is not the direct cause of the Department's non-enforcement of those provisions.

Comment: Some commenters contended that the proposed rule would lead to economic burdens concerning termination of pregnancy for women and other patients who are denied access to care. One commenter stated that there is well-documented research that shows the significant healthcare costs women experience when they face healthcare denials. Another commenter stated that women will suffer negative health effects or death if they are denied services relating to complications from an abortion or a miscarriage. Another commenter stated that there are costs to patients facing discrimination as a result of having a previous termination of pregnancy.

Several commenters contended that the proposed rule would place undue costs and burdens on survivors of sexual and domestic violence. The commenters stated that healthcare programs provide critical and costly care for survivors of domestic violence, sexual assault, and human trafficking. The commenters stated that recent data from the CDC shows that the lifetime per-victim cost of intimate partner violence was $103,767 for women victims, with 59% going to medical costs, and that more than 550,000 injuries due to intimate partner violence require medical attention each year.

Response: The Department appreciates comments in this regard. This final rule fully commits the Department to enforcement of Section 1557 and Title IX to protect women from discrimination on the basis of sex, including and especially vulnerable populations such as survivors of domestic violence, sexual assault, and human trafficking. As noted above, court orders have already enjoined and now vacated the termination of pregnancy provisions from the 2016 Rule. Therefore, this final rule does not have a direct material economic impact with regard to discrimination on the basis of termination of pregnancy. This final rule further ensures the Department will enforce Section 1557 and Title IX consistent with the statutory provisions of Title IX. The Department lacks data or methods enabling it to provide quantitative estimates of any alleged economic impacts related to termination of pregnancy provisions.

Comment: A commenter contended that the Department should conduct a cost-benefit analysis specifically on the impact of adopting Title IX's religious exemptions, or compliance with RFRA.

Response: The Department disagrees. The Title IX statute already includes certain exemptions concerning religious groups, and RFRA protects certain exercises of religion from substantial burdens. This final rule affirms that the Department will only enforce Section 1557 consistent with the statutory provisions of Title IX and RFRA, and amends the Title IX regulations to explicitly include the provisions of the Title IX statute concerning religious groups and abortion neutrality. As the Department is already bound by statute to implement Title IX and Section 1557 consistent with those statutes and with RFRA, the Department does not attribute its compliance with those statutes to be attributable to this final rule. Economic impacts due to compliance with Title IX and RFRA would be attributable, not to this final rule, but to those statutes themselves, and are not relevant for this regulatory impact analysis.

Comment: One commenter stated that the Department should estimate the economic impacts of its conforming amendments.

Response: Section 1557 encompasses all the CMS programs addressed by the conforming amendments, so the Department's estimates of impacts of changes to the Section 1557 rule already encompass the impact on entities covered by those rules.

(5) Impact on State, Local, and Tribal Entities Under Executive Orders 12866, 13132, and 13175

a. State and Local Governments

Executive Order 13132 establishes certain requirements that an agency must meet when it issues a rule that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. Executive Order 13132, 64 FR 43255 (Aug. 4, 1999). The Department does not believe that this final rule would (1) impose substantial direct requirements costs on State or local governments; (2) preempt State law; or (3) otherwise have Federalism implications. Section 1557 itself provides that it shall not be construed ''to supersede State laws that provide additional protections against discrimination on any basis described in subsection (a) [of Section 1557].'' 42 U.S.C. 18116(b).

The final rule maintains the full force of Federal civil rights laws' protections against discrimination, but does not attempt to impose a ceiling on how those protections may be observed by States. State and local jurisdictions would continue to have the flexibility to impose additional civil rights protections.

The Department believes that there would be reduced costs to State and local entities, by repealing wasteful Federal mandates and giving States more flexibility to address the needs of LEP individuals or other regional-specific issues.

The Department believes that the change to its Title IX regulations will

not have a substantial direct effect on the States, on the relationship between the national government and the States, on the distribution of power and responsibilities among the various levels of government, or on tribal self-government or sovereignty. This final rule does not subject Title IX funding recipients to new obligations, but rather implements Title IX according to its statutory text, and relieves potential burdens on the States or tribes that could have resulted from any prior interpretation of Title IX by HHS that was inconsistent with the statute. This final rule allows States and tribes to adopt or continue to provide nondiscrimination protections on the basis of sexual orientation, gender identity, or termination of pregnancy, in State, local, and tribal law. Therefore, the Department has determined that this final rule does not have sufficient Federalism implications to warrant the preparation of a Federalism summary impact statement under Executive Order 13132, and that the rule would not implicate the requirements of Executive Orders 12866 and 13175 with respect to tribes.

Comment: One commenter stated it was inconsistent for the Department to say the 2016 Rule imposed burdens on States but that the proposed rule would not impose new burdens.

Response: The 2016 Rule imposed or may have imposed burdens concerning notices and taglines, as well as gender identity and termination of pregnancy provisions beyond the text of Title IX. This final rule can relieve such burdens without imposing new burdens. To the extent that the gender identity and termination of pregnancy provisions were vacated in October 2019, the Department agrees this final rule does not relieve such burdens, but to the same extent, this final rule does not impose any corresponding burdens.

Comment: A commenter stated that HHS points to no evidence of substantial burdens on States and localities as regards the provision or coverage of medically necessary care related to gender transition.

Response: The Department's conclusion that this final rule does not impose new burdens on States and localities is independent of the Department's suggestion that the 2016 Rule, to the extent it prohibited discrimination on grounds exceeding Title IX and State and local law, also imposed burdens on such States and localities.

Comment: One commenter stated that the proposed rule could impose additional costs on States that adopted policies related to private insurance and Medicaid based on the 2016 Rule that see an increase in healthcare discrimination complaints in their State-level human rights commissions, as HHS OCR will no longer receive such complaints, and such States may reinstate or maintain exclusions and face costly litigation.

Response: The court orders preliminarily enjoining and eventually vacating the 2016 Rule's gender identity and termination of pregnancy provisions have been in effect since December 2016. States have, therefore, not been bound by those provisions, and this final rule's changes in that regard will not cause States to need to change their policies in that regard. States will also not likely see an increase in complaints at the State level as a result of this rule, because HHS OCR has not been able to enforce those provisions for almost the entire lifespan of the 2016 Rule. Finally, this rule does not require States to reinstate exclusions from coverage, so litigation that States might face as a result of doing so are not directly attributable to this final rule.

b. Tribal Governments

Executive Order 12866 directs that significant regulatory actions avoid undue interference with State, local, or tribal governments, in the exercise of their governmental functions. Executive Order 12866 at § 6(a)(3)(B).[382] Executive Order 13175 further directs that Agencies respect Indian tribal self-government and sovereignty, honor tribal treaty and other rights, and strive to meet the responsibilities that arise from the unique legal relationship between the Federal Government and Indian tribal governments. Executive Order 13175 at § 2(a). The Department does not believe that the final rule would implicate the requirements of Executive Orders 12866 and 13175 with respect to tribal sovereignty.

(6) Avoidance of Inconsistent, Incompatible, or Duplicative Regulations

Executive Order 12866 requires the Department to avoid issuing regulations that are inconsistent, incompatible, or duplicative with other regulations that it has issued or that have been issued by other Federal agencies. Executive Order 12866 at § 1(b)(10). Section 1557 itself requires avoidance of duplication by providing that the enforcement mechanisms under specifically identified civil rights laws ''shall apply for purposes of violations'' of Section 1557. 42 U.S.C. 18116(a).[383] The preamble to the 2016 Rule repeatedly stated that, with the exception of issues concerning notices, sex discrimination, and language access plans, it was merely applying civil rights protections that were already applicable and familiar to covered entities. *See* 81 FR at 31446. (''It is important to recognize that this final rule, except in the area of sex discrimination, applies pre-existing requirements in Federal civil rights laws to various entities, the great majority of which have been covered by these requirements for years.''); 81 FR at 31464 (''For the most part, because this regulation is consistent with existing standards applicable to the covered entities, the new burdens created by its issuance are minimal.'').

With regard to the current 2016 Rule's notice and taglines requirement, covered entities are already subject to dozens of regulations concerning multi-language taglines or notices concerning an individual's right to have documents translated. For example, CMS imposes taglines requirements on health insurance marketplaces, QHP issuers, group health plans and health insurance issuers, navigators, non-navigator assistance personnel, Medicaid, Medicaid managed care, Children's Health Insurance Program, Medicare Advantage, and Medicare Part D.[384]

[382] As stated in the preceding section, the final rule does not have Federalism implications.

[383] For the applicable enforcement mechanisms, *See* 45 CFR parts 80 and 81 (Title VI), 85 (Section 504), 86 (Title IX), 90 and 91 (Age Act).

[384] 45 CFR 147.136(e)(2)(iii) and (e)(3) and § 147.200(a)(5) (requiring group health plans and QHP issuers to post taglines in languages in which 10% of individuals with LEP county-wide are exclusively literate on internal claims and appeals notices, and requiring QHP issuers to post on its Summary of Benefits and Coverage), § 155.215(c)(4) (requiring Navigators and non-Navigator personnel in States with Marketplaces operated by HHS to ''[p]rovide oral and written notice to consumers with LEP, in their preferred language, informing them of their right to receive language assistance services and how to obtain them''); 42 CFR 435.905(b)(3) (Medicaid regulations requiring individuals to be ''informed of the availability of language services . . . and how to access . . . [them] through providing taglines in non–English languages indicating the availability of language services''); § 438.10(c)(5)(i) through (ii) (Medicaid managed care regulations requiring taglines until July 1, 2017); § 438.10(d)(2) through (3), (d)(5)(i), (d)(5)(iii) and (d)(5)(j) (Medicaid managed care regulations requiring taglines on ''all written materials for potential enrollees'' in the prevalent non-English languages in the State and requiring notification that ''oral interpretation is available for any language and written translation is available in prevalent languages'' during the rating period for contracts with managed care entities beginning on or after July 1, 2017), § 457.340(a) (applying certain Medicaid requirements to the Children's Health Insurance Program, including § 435.905(b)(3), which requires individuals to be ''informed of the availability of language services . . . and how to access . . . [them] through providing taglines in non-English languages indicating the availability of language services''), 457.1207 (applying certain

Furthermore, a Department of Treasury regulation imposed taglines requirements for hospital organizations to qualify for tax-exempt status.[385] Additionally, in 2003, the Department issued guidance under Title VI, setting forth a flexible four-factor framework to assess the necessity and reasonableness for providing written translation for LEP individuals.[386] Finally, the ACA itself provides that each summary of benefits and coverage provided by issuers—perhaps the single most important health insurance-related document a person receives—must be ''presented in a culturally and linguistically appropriate manner.'' 42 U.S.C. 300gg–15(b)(2).

Substantially replacing many provisions of the 2016 Rule, including removing the notice and taglines requirements, would eliminate significant redundancies identified above, while maintaining vigorous enforcement of existing Federal civil rights statutes.

B. Executive Order 13771 on Reducing and Controlling Regulatory Costs

This final rule is deemed an E.O. 13771 deregulatory action. The Department estimates that this final rule would generate $0.24 billion in net annualized savings at a 7% discount rate (discounted relative to year 2016, over a perpetual time horizon, in 2016 dollars).

Furthermore, Executive Order 13765 states that ''the Secretary of Health and Human Services (Secretary) and the heads of all other executive departments and agencies (agencies) with authorities and responsibilities under the [ACA] shall exercise all authority and discretion available to waive, defer, grant exemptions from, or delay the implementation of any provision or requirement of the [ACA] that would impose a fiscal burden on any State or a cost, fee, tax, penalty, or regulatory burden on individuals, families, healthcare providers, health insurers, patients, recipients of healthcare services, [or] purchasers of health insurance.'' Executive Order 13765, 82 FR 8351, 8351 (Jan. 24, 2017). In implementing Section 1557 of the ACA, the 2016 Rule imposed significant regulatory burdens on covered entities, including States, healthcare providers, and health insurers, without sufficient corresponding benefits for patients or beneficiaries. By proposing to substantially replace the 2016 Rule with a regulation that requires compliance with pre-existing civil rights laws, the Department is acting in accordance with Executive Order 13765 in exercising its authority and discretion to address the fiscal burdens on States, and the regulatory burdens imposed on individuals, families, healthcare providers, health insurers, patients, and recipients of healthcare service. The final rule will particularly reduce the economic burden imposed on healthcare providers and insurers required to provide taglines under the 2016 Rule. Decreasing the burden on these providers and insurers will allow them to pass along some of the cost savings to individuals, families, patients, and beneficiaries of insurance to whom they provide services or coverage. Additionally, eliminating the taglines requirement will alleviate burdens on patients and insurance beneficiaries that neither need nor want to receive repeated taglines mailings.

C. Congressional Review Act

The Congressional Review Act (CRA) defines a ''major rule'' as ''any rule that the Administrator of the Office of Information and Regulatory Affairs (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 Executive Order 12866, this rule is expected to be a major rule for purposes of the CRA because it generates cost savings of over $100 million. The Department will comply with the CRA's requirements to inform Congress.

D. Unfunded Mandates Reform Act

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, handicap, or disability. 2 U.S.C. 1503(2).

E. Regulatory Flexibility Act and Executive Order 13272 on Proper Consideration of Small Entities in Agency Rulemaking

The Regulatory Flexibility Act (RFA) requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Public Law 96–354, 94 Stat. 1164 (Sept. 19, 1980) (codified at 5 U.S.C. 601 through 612). The RFA requires an agency to describe the impact of a rulemaking on small entities by providing an initial regulatory flexibility analysis, unless the agency expects that the rule will not have a significant economic impact on a substantial number of small entities, provides a factual basis for this determination, and proposes to certify the statement. 5 U.S.C. 603(a), 605(b). If an agency must provide an initial regulatory flexibility analysis, this analysis must address the consideration of regulatory options that would minimize the economic impact of the rule on small entities. 5 U.S.C. 603(c).

For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. HHS considers a rule to have a significant impact on a substantial number of small entities if it has at least a three percent impact on revenue for at least five percent of small entities.

Based on its examination, the Department has concluded that this final rule does not have a significant economic impact on a substantial number of small entities. The preamble to the 2016 Rule discussed the character of small entities impacted by the 2016 Rule in detail. 81 FR at 31463–64. Although this final rule will affect numerous small entities, it does not create new or expanded requirements,

Medicaid managed care requirements to Children's Health Insurance Program managed care, including § 438.10(c)(5)(i)–(ii) until the State fiscal year beginning on or after July, 1, 2018), § 438.10(d)(2)–(3), (d)(5)(i), (iii), (j) (applying certain Medicaid managed care requirements to Children's Health Insurance Program managed care, in the State fiscal year beginning on or after July, 1, 2018); CMS, 2017 Medicare Marketing Guidelines, § 30.5.1, § 100.2.2, § 8, § 80–8 (Jun. 10, 2016), *https://www.cms.gov/Medicare/Health-Plans/ManagedCareMarketing/Downloads/2017MedicareMarketingGuidelines2.pdf* (providing a CMS Multi-Language Insert'' for certain Medicare Advantage Plan's and Medicare Part D Plan Sponsors' marketing materials meeting the percentage translation threshold in § 422.2264(e) and § 423.2264(e) of Title 42 of the CFR). As discussed in the RIA section, we presume 45 CFR 155.205(c)(2)(iii)(A) (requiring Marketplaces and QHP issuers to post taglines on their websites and documents ''critical for obtaining health insurance coverage or access to health care services through a QHP'') and other provisions that depend or refer to 45 CFR part 92 for their tagline requirements will no longer apply under this final rule.

[385] *See* 79 FR 78954 (Dec. 31, 2014) (finalizing rule requiring the plain language summary of the financial assistance policy for hospital organizations to qualify as tax exempt, to indicate, if applicable, whether the summary, the financial assistance policy, and the application for such assistance are available in other languages).

[386] Guidance to Federal Financial Assistance Recipients Regarding Title VI Prohibition Against National Origin Discrimination Affecting Limited English Proficient Persons, 68 FR 47315 (Aug. 8, 2003) (HHS LEP Guidance).

and, for all the reasons stated in the RIA, it will be reducing economic burdens on such entities overall. The changes concerning gender identity and termination of pregnancy, having already been vacated by court order, are not expected to result in any impact. The changes to the Department's Title IX rule would not impose any new substantive obligations on Federal funding recipients and, in fact, would provide regulatory clarity and relief for any small entities previously subject to several of the policies and requirements imposed by the Department. The changes made in conforming amendments overlap those made in the Section 1557 rule and described in the RIA.

To the extent that this final rule imposes economic costs, these are generally limited to entities' voluntary choices to revise their policies and procedures and conduct training, and the Department believes these costs are well below those required to have a significant impact on a substantial number of small entities. In addition, the majority of the costs associated with this final rule are proportional to the size of entities, meaning that even the smallest of the affected entities are unlikely to face a substantial impact.

For these reasons, the Secretary certifies that the final rule will not have a significant impact on a substantial number of small entities.

Executive Order 13272 on Proper Consideration of Small Entities in Agency Rulemaking reinforces the requirements of the RFA and requires the Department to notify the Chief Counsel for Advocacy of the Small Business Administration if the final rule may have a significant economic impact on a substantial number of small entities under the RFA. Executive Order 13272, 67 FR 53461 (Aug. 16, 2002). Because the economic impact of the proposed rule is not significant under the RFA, the Department is not subject to Executive Order 13272's notification requirement.

F. Executive Order 12250 on Leadership and Coordination of Nondiscrimination Laws

Pursuant to Executive Order 12250, the Attorney General has the responsibility to ''coordinate the implementation and enforcement by Executive agencies of . . . Title IX of the Education Amendments of 1972 (20 U.S.C. 1681 *et seq.*)'' Executive Order 12250 at § 1–2(b), 45 FR 72995 (Nov. 2, 1980). The proposed rule was reviewed and approved by the Attorney General, and this final rule was also reviewed and approved by the Attorney General in finalizing the proposed rule without change.

G. Paperwork Reduction Act

The Department has determined that this final rule does not impose additional reporting or recordkeeping requirements under the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 *et seq.* Under the rule, OCR will update and revise its burden analysis by removing the burden associated with the posting of a nondiscrimination notice and taglines, development and implementation of a language access plan, and designation of a compliance coordinator and adoption of grievance procedures for covered entities with 15 or more employees. OCR has obtained Paperwork Reduction Act approval for this reporting requirement via an update to HHS Form 690 (Consolidated Civil Rights Assurance Form)[387] separate from this rulemaking.

(D) Delegation of Authority

Notice is hereby given that I have delegated to the Director, Office for Civil Rights (OCR), with authority to re-delegate, enforcement and administration of Section 1557 of the Patient Protection and Affordable Care Act [42 U.S.C. 18116]. This delegation includes the authority to develop and direct implementation of the requirements of Section 1557 of the Patient Protection and Affordable Care Act [42 U.S.C. 18116] as applied to the Department and recipients of the Department's funds. This delegation supersedes the delegation of authority under Section 1557 to the Health Resources and Services Administration (HRSA) on April 21, 2016 in 81 FR 25680 (April 29, 2016).

List of Subjects

42 CFR Part 438

Civil rights, Discrimination, Grant programs-health, Individuals with disabilities, Medicaid, National origin, Nondiscrimination, Reporting and recordkeeping requirements, Sex discrimination.

42 CFR Part 440

Civil rights, Discrimination, Grant programs-health, Individuals with disabilities, Medicaid, National origin, Nondiscrimination, Sex discrimination.

42 CFR Part 460

Age discrimination, Aged, Civil rights, Discrimination, Health Incorporation by reference, Individuals with disabilities, Medicare, Medicaid, National origin, Nondiscrimination, Religious discrimination, Reporting and recordkeeping requirements, Sex discrimination.

45 CFR Part 86

Civil rights, Colleges and universities, Employment, Administrative practice and procedure, Buildings and facilities, Education of individuals with disabilities, Education, Educational facilities, Educational research, Educational study programs, Equal educational opportunity, Equal employment opportunity, Graduate fellowship program, Grant programs—education, Individuals with disabilities, Investigations, Reporting and recordkeeping requirements, Sex discrimination, State agreement program, Student aid, Women.

45 CFR Part 92

Administrative practice and procedure, Age discrimination, Civil rights, Discrimination, Elderly, Healthcare, Health facilities, Health insurance, Health programs or activities, Individuals with disabilities, National origin, Nondiscrimination, Reporting and recordkeeping requirements, Sex discrimination.

45 CFR Part 147

Age discrimination, Civil rights, Discrimination, Healthcare, Health insurance, Individuals with disabilities, National origin, Nondiscrimination, Reporting and recordkeeping requirements, Sex discrimination, State regulation of health insurance.

45 CFR Part 155

Actuarial value, Administration and calculation of advance payments of the premium tax credit, Administrative practice and procedure, Advance payments of premium tax credit, Age discrimination, Civil rights, Cost-sharing reductions, Discrimination, Healthcare access, Health insurance, Individuals with disabilities, National origin, Nondiscrimination, Plan variations, Reporting and recordkeeping requirements, Sex discrimination, State and local governments.

45 CFR Part 156

Administrative appeals, Administrative practice and procedure, Administration and calculation of advance payments of premium tax credit, Advertising, Advisory Committees, Age discrimination, Brokers, Civil rights, Conflict of interest, Consumer protection, Cost-sharing reductions, Discrimination, Grant programs-health, Grants administration,

[387] *See* HHS OCR, Assurance of Compliance Portal, *https://ocrportal.hhs.gov/ocr/aoc/instruction.jsf.*

Healthcare, Health insurance, Health maintenance organization (HMO), Health records, Hospitals, American Indian/Alaska Natives, Individuals with disabilities, Loan programs-health, Organization and functions (Government agencies), Medicaid, National origin, Nondiscrimination, Payment and collections reports, Public assistance programs, Reporting and recordkeeping requirements, Sex discrimination, State and local governments, Sunshine Act, Technical assistance, Women, Youth.

For the reasons set forth in the preamble, the Department of Health and Human Services amends 42 CFR parts 438, 440, and 460 and 45 CFR parts 86, 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, sex, or disability and will not use any policy or practice that has the effect of discriminating on the basis of race, color, or national origin, sex, or disability.

* * * * *

■ 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.

* * * * *

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. These methods must ensure that beneficiaries have access to covered services that are delivered in a manner that meets their unique needs.

PART 460—PROGRAMS OF ALL-INCLUSIVE CARE FOR THE ELDERLY (PACE)

■ 6. The authority citation for part 460 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395l, 1395eee(f), and 1396u–4(f)).

■ 7. Amend § 460.98 by revising paragraph (b)(3) to read as follows:

§ 460.98 Service delivery.

* * * * *

(b) * * *

(3) The PACE organization may not discriminate against any participant in the delivery of required PACE services based on race, ethnicity, national origin, religion, sex, age, mental or physical disability, or source of payment.

* * * * *

■ 8. Amend § 460.112 by revising paragraph (a) 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, age, mental or physical disability, or source of payment. Specifically, each participant has the right to the following:

(1) To receive comprehensive health care in a safe and clean environment and in an accessible manner.

(2) To be treated with dignity and respect, be afforded privacy and confidentiality in all aspects of care, and be provided humane care.

(3) Not to be required to perform services for the PACE organization.

(4) To have reasonable access to a telephone.

(5) To be free from harm, including physical or mental abuse, neglect, corporal punishment, involuntary seclusion, excessive medication, and any physical or chemical restraint imposed for purposes of discipline or convenience and not required to treat the participant's medical symptoms.

(6) To be encouraged and assisted to exercise rights as a participant, including the Medicare and Medicaid appeals processes as well as civil and other legal rights.

(7) To be encouraged and assisted to recommend changes in policies and services to PACE staff.

* * * * *

Title 45—Public Welfare

PART 86—NONDISCRIMINATION ON THE BASIS OF SEX IN EDUCATION PROGRAMS OR ACTIVITIES RECEIVING FEDERAL FINANCIAL ASSISTANCE

■ 9. The authority citation for part 86 is revised to read as follows:

Authority: 20 U.S.C. 1681 through 1688; Pub. L. 100–259, 102 Stat. 28 (Mar. 22, 1988).

■ 10. Amend § 86.2:

■ a. In paragraph (a), by adding '', 1687, 1688'' after ''1686''; and

■ b. In paragraph (n), by removing the words ''United States Commissioner of Education'' and adding in their place the words ''Secretary of Education''.

■ 11. Add § 86.18 to read as follows:

§ 86.18 Amendments to conform to statutory exemptions.

(a) Nothing in this part shall be construed to force or require any individual or hospital or any other institution, program, or activity receiving Federal funds to perform or pay for an abortion.

(b) Nothing in this part shall be construed to require or prohibit any person, or public or private entity, to provide or pay for any benefit or service, including the use of facilities, related to an abortion. Nothing in the preceding sentence shall be construed to permit a penalty to be imposed on any person or individual because such person or individual is seeking or has received any benefit or service related to a legal abortion.

(c) This part shall be construed consistently with, as applicable, the First Amendment to the Constitution, Title IX's religious exemptions (20 U.S.C. 1681(a)(3) and 1687(4)), the Religious Freedom Restoration Act (42 U.S.C. 2000b *et seq.*), and provisions related to abortion in the Church Amendments (42 U.S.C. 300a–7), the Coats-Snowe Amendment (42 U.S.C. 238n), section 1303 of the Patient Protection and Affordable Care Act (42 U.S.C. 18023), and appropriation rider provisions relating to abortion, to the extent they remain in effect or applicable, such as the Hyde

Amendment (*e.g.,* Consolidated Appropriations Act, 2019, Pub. L. 115–245, Div. B, secs. 506–07), the Helms Amendment (*e.g.,* Continuing Appropriations Act, 2019, Pub. L. 116–6, Div. F, Title III), and the Weldon Amendment (*e.g.,* Consolidated Appropriations Act, 2019, Pub. L. 115–245, Div. B, sec. 507(d)).

■ 12. Amend § 86.31 by revising paragraph (b) to read as follows:

§ 86.31 Education programs or activities.

* * * * *

(b) *Specific prohibitions.* Except as provided in this subsection, in providing any aid, benefit, or service to a student, a recipient shall not, on the basis of sex:

(1) Treat one person differently from another in determining whether such person satisfies any requirement or condition for the provision of such aid, benefit, or service;

(2) Provide different aid, benefits, or services or provide aid, benefits, or services in a different manner;

(3) Deny any person any such aid, benefit, or service;

(4) Subject any person to separate or different rules of behavior, sanctions, or other treatment;

(5) Apply any rule concerning the domicile or residence of a student or applicant, including eligibility for in-State fees and tuition;

(6) Aid or perpetuate discrimination against any person by providing significant assistance to any agency, organization, or person which discriminates on the basis of sex in providing any aid, benefit or service to students or employees;

(7) Otherwise limit any person in the enjoyment of any right, privilege, advantage, or opportunity.

* * * * *

■ 13. Revise § 86.71 to read as follows:

§ 86.71 Enforcement procedures.

For the purposes of implementing this Part, the procedural provisions applicable to Title VI of the Civil Rights Act of 1964 (42 U.S.C. 2000d) are hereby adopted and incorporated herein by reference. These procedures may be found at 45 CFR 80.6 through 80.11 and 45 CFR part 81.

■ 14. Revise part 92 to read as follows:

PART 92—NONDISCRIMINATION ON THE BASIS OF RACE, COLOR, NATIONAL ORIGIN, SEX, AGE, OR DISABILITY IN HEALTH PROGRAMS OR ACTIVITIES RECEIVING FEDERAL FINANCIAL ASSISTANCE AND PROGRAMS OR ACTIVITIES ADMINISTERED BY THE DEPARTMENT OF HEALTH AND HUMAN SERVICES UNDER TITLE I OF THE PATIENT PROTECTION AND AFFORDABLE CARE ACT OR BY ENTITIES ESTABLISHED UNDER SUCH TITLE

Subpart A—General Provisions

Sec.
92.1 Purpose.
92.2 Nondiscrimination requirements.
92.3 Scope of application.
92.4 Assurances.
92.5 Enforcement mechanisms.
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Subpart B—Specific Applications to Health Programs or Activities

92.101 Meaningful access for individuals with limited English proficiency.
92.102 Effective communication for individuals with disabilities.
92.103 Accessibility standards for buildings and facilities.
92.104 Accessibility of information and communication technology.
92.105 Requirement to make reasonable modifications.

Authority: 42 U.S.C. 18116; 5 U.S.C. 301, Pub. L. 100–259, 102 Stat. 28 (Mar. 22 1988); 42 U.S.C. 2000d *et seq.* (Title VI of the Civil Rights Act of 1964, as amended); 29 U.S.C. 794 (Section 504 of the Rehabilitation Act of 1973, as amended); 20 U.S.C. 1681 *et seq.* (Title IX of the Education Amendments of 1972, as amended); 42 U.S.C. 6101 *et seq.;* (Age Discrimination Act of 1975, as amended); *Lau* v. *Nichols,* 414 U.S. 563 (1974).

Subpart A—General Provisions

§ 92.1 Purpose.

The purpose of this part is to provide for the enforcement of section 1557 of the Patient Protection and Affordable Care Act, 42 U.S.C. 18116, prohibiting discrimination under any health program or activity receiving Federal financial assistance, or under any program or activity administered by an Executive agency, or by any entity established, under Title I of such law, on the grounds of race, color, national origin, sex, age, or disability, except as provided in Title I of such law (or any amendment thereto). Section 1557 requires the application of the enforcement mechanisms under Title VI of the Civil Rights Act of 1964 (42 U.S.C. 2000d *et seq.*), Title IX of the Education Amendments of 1972 (20 U.S.C. 1681 *et seq.*), the Age Discrimination Act of 1975 (42 U.S.C. 6101 *et seq.*), and Section 504 of the Rehabilitation Act of 1973 (29 U.S.C. 794) for purposes of violations of Section 1557 and this part.

§ 92.2 Nondiscrimination requirements.

(a) Except as provided in Title I of the Patient Protection and Affordable Care Act (or any amendment thereto), an individual shall not, on any of the grounds set forth in paragraph (b) of this section, 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) provided by the U.S. Department of Health and Human Services; or under any program or activity administered by the Department under such Title; or under any program or activity administered by any entity established under such Title.

(b) The grounds are the grounds prohibited under the following statutes:

(1) Title VI of the Civil Rights Act of 1964 (42 U.S.C. 2000d *et seq.*) (race, color, national origin);

(2) Title IX of the Education Amendments of 1972 (20 U.S.C. 1681 *et seq.*) (sex);

(3) The Age Discrimination Act of 1975 (42 U.S.C. 6101 *et seq.*) (age); or

(4) Section 504 of the Rehabilitation Act of 1973 (29 U.S.C. 794) (disability).

§ 92.3 Scope of application.

(a) Except as otherwise provided in this part, this part applies to

(1) Any health program or activity, any part of which is receiving Federal financial assistance (including credits, subsidies, or contracts of insurance) provided by the Department;

(2) Any program or activity administered by the Department under Title I of the Patient Protection and Affordable Care Act; or

(3) Any program or activity administered by any entity established under such Title.

(b) As used in this part, ''health program or activity'' encompasses all of the operations of entities principally engaged in the business of providing healthcare that receive Federal financial assistance as described in paragraph (a)(1) of this section. For any entity not principally engaged in the business of providing healthcare, the requirements applicable to a ''health program or activity'' under this part shall apply to such entity's operations only to the extent any such operation receives Federal financial assistance as described in paragraph (a)(1) of this section.

(c) For purposes of this part, an entity principally or otherwise engaged in the

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business of providing health insurance shall not, by virtue of such provision, be considered to be principally engaged in the business of providing healthcare.

(d) Any provision of this part held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, shall be construed so as to continue to give maximum effect to the provision permitted by law, unless such holding shall be one of utter invalidity or unenforceability, in which event the provision 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.

§ 92.4 Assurances.

(a) *Assurances.* An entity applying for Federal financial assistance to which this part applies shall, as a condition of any application for Federal financial assistance, submit an assurance, on a form specified by the Director of the Department's Office for Civil Rights, that the entity's health programs or activities will be operated in compliance with section 1557 and this part. 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 shall, as a condition of certification or approval, submit an assurance, on a form specified by the Director of the Department's Office for Civil Rights, that the 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 subpart is the same as the duration of the assurances required in the Department's regulations implementing section 504 at 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.

§ 92.5 Enforcement mechanisms.

(a) The enforcement mechanisms provided for, and available under, Title VI of the Civil Rights Act of 1964 (42 U.S.C. 2000d *et seq.*), Title IX of the Education Amendments of 1972 (20 U.S.C. 1681 *et seq.*), the Age Discrimination Act of 1975 (42 U.S.C. 6101 *et seq.*), or Section 504 of the Rehabilitation Act of 1973 (29 U.S.C. 794), including under the Department's regulations implementing those statutes, shall apply for purposes of violations of § 92.2 of this part.

(b) The Director of the Office for Civil Rights has been delegated the authority to enforce 42 U.S.C. 18116 and this part, which includes the authority to handle complaints, initiate and conduct compliance reviews, conduct investigations, supervise and coordinate compliance within the Department, make enforcement referrals to the Department of Justice, in coordination with the Office of the General Counsel and the relevant component or components of the Department, and take other appropriate remedial action as the Director deems necessary, in coordination with the relevant component or components of the Department, and as allowed by law to overcome the effects of violations of 42 U.S.C. 18116 or of this part.

§ 92.6 Relationship to other laws.

(a) Nothing in this part shall be construed to invalidate or limit the rights, remedies, procedures, or legal standards available to individuals aggrieved under Title VI of the Civil Rights Act of 1964 (42 U.S.C. 2000d *et seq.*), Title VII of the Civil Rights Act of 1964 (42 U.S.C. 2000e *et seq.*), Title IX of the Education Amendments of 1972 (20 U.S.C. 1681 *et seq.*), the Age Discrimination Act of 1975 (42 U.S.C. 6101 *et seq.*), or Section 504 of the Rehabilitation Act of 1973 (29 U.S.C. 794), or to supersede State laws that provide additional protections against discrimination on any basis described in § 92.2 of this part.

(b) Insofar as the application of any requirement under this part would violate, depart from, or contradict definitions, exemptions, affirmative rights, or protections provided by any of the statutes cited in paragraph (a) of this section or provided by the Architectural Barriers Act of 1968 (42 U.S.C. 4151 *et seq.*); the Americans with Disabilities Act of 1990, as amended by the Americans with Disabilities Act Amendments Act of 2008 (42 U.S.C. 12181 *et seq.*), Section 508 of the Rehabilitation Act of 1973, as amended (29 U.S.C. 794d), the Coats-Snowe Amendment (42 U.S.C. 238n), the Church Amendments (42 U.S.C. 300a–7), the Religious Freedom Restoration Act (42 U.S.C. 2000bb *et seq.*), Section 1553 of the Patient Protection and Affordable Care Act (42 U.S.C. 18113), Section 1303 of the Patient Protection and Affordable Care Act (42 U.S.C. 18023), the Weldon Amendment (Consolidated Appropriations Act, 2019, Pub. L. 115–245, Div. B sec. 209 and sec. 506(d) (Sept. 28, 2018)), or any related, successor, or similar Federal laws or regulations, such application shall not be imposed or required.

Subpart B—Specific Applications to Health Programs or Activities

§ 92.101 Meaningful access for individuals with limited English proficiency.

(a) Any entity operating or administering a health program or activity subject to this part shall take reasonable steps to ensure meaningful access to such programs or activities by limited English proficient individuals.

(b) *Specific applications*—(1) *Enforcement discretion.* In evaluating whether any entity to which paragraph (a) of this section applies has complied with paragraph (a) of this section, the Director of the Department's Office for Civil Rights may assess how such entity balances the following four factors:

(i) The number or proportion of limited English proficient individuals eligible to be served or likely to be encountered in the eligible service population;

(ii) The frequency with which LEP individuals come in contact with the entity's health program, activity, or service;

(iii) The nature and importance of the entity's health program, activity, or service; and

(iv) The resources available to the entity and costs.

(2) *Language assistance services requirements.* Where paragraph (a) of this section, in light of the entity's individualized assessment of the four factors set forth in paragraph (b)(1) of this section, requires the provision of language assistance services, such services must be provided free of charge, be accurate and timely, and protect the privacy and independence of the individual with limited English proficiency. Language assistance services may include:

(i) 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; and

(ii) Written translation, performed by a qualified translator, of written content in paper or electronic form into languages other than English.

(3) *Specific requirements for interpreter and translation services.* (i) Where paragraph (a) of this section, in light of the entity's individualized assessment of the four factors set forth in paragraph (b)(1) of this section, requires the provision of interpreter services, they must be provided by an interpreter who:

(A) Adheres to generally accepted interpreter ethics principles, including client confidentiality;

(B) Has demonstrated proficiency in speaking and understanding at least spoken English and the spoken language in need of interpretation; and

(C) Is able to interpret effectively, accurately, and impartially, both receptively and expressly, to and from such language(s) and English, using any necessary specialized vocabulary, terminology and phraseology.

(ii) Where paragraph (a) of this section, in light of the entity's individualized assessment of the four factors set forth in paragraph (b)(1) of this section, requires the provision of translation services for written content (in paper or electronic form), they must be provided by a translator who:

(A) Adheres to generally accepted translator ethics principles, including client confidentiality;

(B) Has demonstrated proficiency in writing and understanding at least written English and the written language in need of translation; and

(C) Is able to translate effectively, accurately, and impartially to and from such language(s) and English, using any necessary specialized vocabulary, terminology and phraseology.

(iii) If remote audio interpreting services are required to comply with paragraph (a) of this section, in light of the entity's individualized assessment of the four factors set forth in paragraph (b)(1) of this section, the entity to which section 1557 applies (as defined in § 92.3 of this part) shall provide:

(A) Real-time, audio over a dedicated high-speed, wide-bandwidth video connection or wireless connection that delivers high-quality audio without lags or irregular pauses in communication;

(B) A clear, audible transmission of voices; and

(C) Adequate training to users of the technology and other involved individuals so that they may quickly and efficiently set up and operate the remote interpreting services.

(4) *Restricted use of certain persons to interpret or facilitate communication.* If an entity is required by paragraph (a) of this section, in light of the entity's individualized assessment of the four factors set forth in paragraph (b)(1) of this section, to provide interpretation services, such entity shall not:

(i) Require an individual with limited English proficiency to provide his or her own interpreter;

(ii) Rely on an adult accompanying an individual with limited English proficiency to interpret or facilitate communication, except

(A) 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; or

(B) Where the individual with limited English proficiency specifically requests that the 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;

(iii) Rely on a minor child to interpret or facilitate communication, except 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; or

(iv) Rely on staff other than qualified bilingual/multilingual staff to communicate directly with individuals with limited English proficiency.

(c) *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.

§ 92.102 Effective communication for individuals with disabilities.

(a) Any entity operating or administering a program or activity under this part shall take appropriate steps to ensure that communications with individuals with disabilities are as effective as communications with others in such programs or activities, in accordance with the standards found at 28 CFR 35.160 through 35.164. Where the regulatory provisions referenced in this section use the term ''public entity,'' the term ''entity'' shall apply in its place.

(b) A recipient or State Exchange shall provide appropriate auxiliary aids and services, including interpreters and information in alternate formats, to individuals with impaired sensory, manual, or speaking skills, where necessary to afford such persons an equal opportunity to benefit from the service in question.

(1) Auxiliary aids and services include:

(i) Interpreters on-site or through video remote interpreting (VRI) services, as defined in 28 CFR 35.104 and 36.303(f); 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 telecommunication products and systems, text telephones (TTYs), videophones, and captioned telephones, or equally effective telecommunications devices; videotext displays; accessible information and communication technology; or other effective methods of making aurally delivered information available to individuals who are deaf or hard of hearing; and

(ii) Readers; taped texts; audio recordings; Braille materials and displays; screen reader software; magnification software; optical readers; secondary auditory programs; large print materials; accessible information and communication technology; or other effective methods of making visually delivered materials available to individuals who are blind or have low vision.

(2) When an entity is required to provide an interpreter under paragraph (b) of this section, the interpreting service shall be provided to individuals free of charge and in a timely manner, via a remote interpreting service or an onsite appearance, by an interpreter who

(i) Adheres to generally accepted interpreter ethics principles, including client confidentiality; and

(ii) Is able to interpret effectively, accurately, and impartially, both receptively and expressively, using any necessary specialized vocabulary, terminology and phraseology.

(3) An interpreter for an individual with a disability for purposes of this section can include, for example, sign language interpreters, oral transliterators (individuals who represent or spell in the characters of another alphabet), and cued language transliterators (individuals who represent or spell by using a small number of handshapes).

(c) 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 Americans

with Disabilities Act (ADA), as amended (42 U.S.C. 12102 *et seq.*). Where this part cross-references regulatory provisions that use the term ''handicap,'' ''handicap'' means ''disability'' as defined in this section.

§ 92.103 Accessibility standards for buildings and facilities.

(a) 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 shall comply with the 2010 Standards, if the construction or alteration was commenced 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 shall comply with the 2010 Standards if the construction was commenced after January 18, 2018. 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 shall comply with the requirements for a ''public building or facility'' as defined in section 106.5 of the 2010 Standards.

(b) 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 on or 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 was commenced on or before July 18, 2016 and such facility was not covered by the 1991 Standards or 2010 Standards.

(c) For purposes of this part:

(1) ''1991 Standards'' refers to the 1991 Americans with Disabilities Act Standards for Accessible Design at appendix D to 28 CFR part 36.

(2) ''2010 Standards'' refers to the 2010 ADA Standards for Accessible Design, as defined in 28 CFR 35.104.

(3) ''UFAS'' refers to the Uniform Federal Accessibility Standards as promulgated in 49 FR 31528 (Aug. 7, 1984).

§ 92.104 Accessibility of information and communication technology.

(a) Entities required to comply with § 92.2, unless otherwise exempted by this part, shall ensure that their health programs or 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. When undue financial and administrative burdens or a fundamental alteration exist, the covered entity shall provide information in a format other than an electronic format that would not result in such undue financial and administrative burdens or a fundamental alteration, but would ensure, to the maximum extent possible, that individuals with disabilities receive the benefits or services of the health program or activity that are provided through information and communication technology.

(b) A recipient or State Exchange shall ensure that its health programs or activities provided through websites comply with the requirements of Title II of the Americans with Disabilities Act (42 U.S.C. 12131 through 12165).

(c) For purposes of this part, ''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 computers and peripheral equipment; information kiosks and transaction machines; telecommunications equipment; customer premises equipment; multifunction office machines; software; applications; websites; videos; and, electronic documents.

§ 92.105 Requirement to make reasonable modifications.

Any entity to which section 1557 applies (as defined in § 92.3 of this part) shall make reasonable modifications to its 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. 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 regulation promulgated under Title II of the Americans with Disabilities Act, at 28 CFR 35.130(b)(7).

PART 147—HEALTH INSURANCE REFORM REQUIREMENTS FOR THE GROUP AND INDIVIDUAL HEALTH INSURANCE MARKETS

■ 15. The authority citation for part 147 continues to read as follows:

Authority: 42 U.S.C. 18021, 18031, 18041, 18044, 18054, 18061, 18063, 18071, and 18082, 26 U.S.C. 36B, 31 U.S.C. 9701.

■ 16. 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, 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

Subpart B—General Standards Related to the Establishment of an Exchange

■ 17. 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.

■ 18. 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.

* * * * *

■ 19. Amend § 155.220 by revising paragraph (j)(2)(i) to read as follows:

§ 155.220 Ability of States to permit agents and 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;

* * * * *

PART 156—HEALTH INSURANCE ISSUER STANDARDS UNDER THE AFFORDABLE CARE ACT, INCLUDING STANDARDS RELATED TO EXCHANGES

■ 20. The authority citation for part 156 continues to read as follows:

Authority: 5 U.S.C. 552; 42 U.S.C. 300jj–11 and 300jj–14.

■ 21. 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.

* * * * *

■ 22. 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.

Dated: May 20, 2020.

Alex M. Azar II,

Secretary of Health and Human Services.

[FR Doc. 2020–11758 Filed 6–12–20; 4:15 pm]

BILLING CODE 4153–01–P

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA**

WHITMAN-WALKER CLINIC, INC., *et al.*,

Plaintiffs,

v.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, *et al.*,

Defendants.

Case No. 1:20-cv-01630 (JEB)

**INDEX OF DECLARATIONS IN SUPPORT OF
PLAINTIFFS' MOTION FOR A PRELIMINARY INJUNCTION OR, IN THE ALTERNATIVE, A STAY PENDING JUDICIAL REVIEW
PURSUANT TO 5 U.S.C. § 705**

1. Naseema Shafi, CEO of Whitman-Walker Clinic, Inc. d/b/a Whitman-Walker Health.

2. Dr. Sarah Henn, Chief Health Officer of Whitman-Walker Health.

3. Dr. Randy Pumphrey, Senior Director of Behavioral Health at Whitman-Walker Health.

4. Bamby Salcedo, President and CEO of the TransLatin@ Coalition.

5. Arianna Inurritegui-Lint, Executive Director of Arianna's Center.

6. Darrel Cummings, Chief of Staff of the Los Angeles LGBT Center.

7. Dr. Robert Bolan, Chief Medical Officer and Director of Clinical Research for the Los Angeles LGBT Center.

8. Dr. Ward Carpenter, Co-Director of Health Services for the Los Angeles LGBT Center.

9. Adrian Shanker, Founder and Executive Director of the Bradbury-Sullivan LGBT Community Center.

10. Hector Vargas, Executive Director of American Association of Physicians for Human Rights d/b/a GLMA: Health Professionals Advancing LGBTQ Equality.

11. Roy Harker, Executive Director of AGLP: The Association of LGBTQ+ Psychiatrists.

12. Dr. Deborah Fabian, Member of GLMA: Health Professionals Advancing LGBTQ Equality.

13. Dr. Randi Ettner.

14. Elena Rose Vera, Executive Director of the Trans Lifeline.

15. Carrie Davis, Chief Community Officer of The Trevor Project.

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA**

WHITMAN-WALKER CLINIC, INC., *et al.*,

Plaintiffs,

v.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, *et al.*,

Defendants.

Case No. 1:20-cv-1630

DECLARATION OF NASEEMA SHAFI, CEO, WHITMAN-WALKER HEALTH

I, Naseema Shafi, declare as follows:

1. I am the Chief Executive Officer of Whitman-Walker Clinic, Inc., d/b/a Whitman-Walker Health ("Whitman-Walker"). I received a J.D. degree from the University of Maryland School of Law in 2005. I have served at Whitman-Walker for more than thirteen years, first as a Compliance Analyst and Director of Compliance; then as Chief Operating Officer, and subsequently as Deputy Executive Director. I assumed the CEO position in January 2019.

2. I am submitting this Declaration in support of Plaintiffs' motion for a preliminary injunction to prevent the revised regulation under Section 1557, published by the U.S. Department of Health and Human Services ("HHS") on June 19, 2020 (the "Revised Rule"), from taking effect.

3. The mission of Whitman-Walker is to offer affirming community-based health and wellness services to all with a special expertise in lesbian, gay, bisexual, transgender, queer and questioning (LGBTQ) and HIV care. We empower all persons to live healthy, love openly, and achieve equality and inclusion.

4. Whitman-Walker was founded in 1973, and legally incorporated in 1978 to respond

to the health care needs of the LGBTQ community. In the early 1980s, we were one of the first nonprofit health clinics in the nation to respond to the HIV/AIDS epidemic. We became a Federally Qualified Health Center Look-Alike in 2007 and received full FQHC status in 2013. Our team provides a range of services, including primary medical care; HIV and lesbian, gay and bisexual (LGB) specialty care; medical, behavioral and care coordination services specific for transgender and gender expansive people;; behavioral-health services; dental services; legal services; insurance-navigation services; community health services that include HIV and STI testing; prevention counseling; women's health services; and youth and family support. These services are provided not only to people that live in Washington, DC, but also to people from neighboring states like Maryland and Virginia, and from across the region, including people from Pennsylvania, West Virginia and Delaware. Without nondiscrimination protections in health care, such as those contained in the 2016 Final Rule, many of these patients are unable to find nondiscriminatory, welcoming and competent care in their own communities.

5. In 2019, Whitman-Walker provided health care services to more than 20,760 individuals.

6. Whitman-Walker's patient population is incredibly diverse and reflects Whitman-Walker's commitment to being a health care home for individuals and families that have experienced stigma and discrimination, or have otherwise encountered challenges in obtaining affordable, high-quality health care. We are nationally known as experts in HIV and Hepatitis C specialty care and in gender-affirming care for transgender and gender expansive persons.

7. In 2019, more than 10% of the health care patients and clients we serve identified as transgender or gender expansive. Almost 45% of health care patients—60% of those who provided information on their sexual orientation—identified as lesbian, gay, bisexual, or otherwise

non-heterosexual. More than 9% of patients we served had limited English proficiency.

8. Whitman-Walker also employs a dynamic and diverse workforce that reflects the diversity of the populations we serve. At the present, we employ over 315 medical and behavioral-health providers and support staff, medical-adherence and insurance-navigation professionals, community health-workers, lawyers and paralegals, researchers, administrators, and professionals working in finance, development, human resources, and external affairs. We have employees of many races, ethnicities, genders, sexual orientations, religious and spiritual traditions, and life experiences. What unites us all is our shared commitment to creating and sustaining a welcoming, inclusive health care home for everyone who seeks our care.

9. Over the years, Whitman-Walker health care providers, lawyers and paralegals have encountered many instances of discrimination against our patients and legal clients by health care providers and staff outside of Whitman-Walker, based on sex assigned at birth, gender identity, transgender status, sexual orientation, HIV status, or actual or perceived ethnicity or immigration status. Our health care providers, lawyers, and other staff also have many years of experience advocating for patients with health insurance plans that discriminate against gender-affirming care, same-sex couples, and patients living with HIV or Hepatitis C who need specialized care. As such, Whitman-Walker was extensively involved in the proceedings that resulted in the rule published by HHS in May 2016 ("2016 Final Rule"), the Request for Information in 2013, and the Notice of Proposed Rulemaking in 2019.

10. Whitman-Walker receives various forms of federal funding from HHS and from institutions affiliated with or funded by HHS, including but not limited to funds under the Public Health Services Act ("PHSA"), direct grants, funding under the Ryan White Comprehensive AIDS Resources Emergency Act of 1990, 42 U.S.C. § 300ff et seq. ("Ryan White funding"), funds under

the 340B Drug Discount Program, research grants from the Centers for Disease Control and Prevention and the National Institutes of Health, and Medicaid and Medicare reimbursements. Whitman-Walker also receives funds from the Health Resources and Service Administration ("HRSA") and is a Federally Qualified Heath Center. In 2019, Whitman-Walker's federally funded research contracts and grants totaled more than $7 million.

11. As an entity principally engaged in the business of providing health care that receives federal funding from HHS, Whitman-Walker is a "health program or activity" subject to the Revised Rule.

12. By eliminating the regulatory protections and clear guidance provided in the 2016 Final Rule, the Revised Rule presents a grave threat to the health and wellbeing of the patient population that we serve, most specifically LGBTQ patients and patients with LEP. The Revised Rule also frustrates our ability to provide referrals to our patients and imposes increased costs on Whitman-Walker.

Harms to Whitman-Walker's LGBTQ Patients

13. The Revised Rule eliminates the definition of "on the basis of sex" and the specific prohibition of discrimination on the basis of gender identity, transgender status, and sex stereotyping. The Revised Rule also eliminates specific provisions related to discrimination against transgender individuals, as well as the provision relating to the discrimination on the basis of association. The elimination of these provisions will result in direct harms to the LGBTQ patients that Whitman-Walker serves.

14. The LGBTQ patients and clients Whitman-Walker serves, especially Whitman-Walker's transgender and gender-expansive patients, already face particularly acute barriers to care and health disparities that will be compounded by the Revised Rule. It is quite likely that the

Revised Rule will result in a substantial increase in discrimination against LGBTQ individuals by health care providers and institutions outside of Whitman-Walker, as well as by health insurance companies.

15. Dr. Henn's and Dr. Pumphrey's declarations describe a number of incidents of discrimination that our patients have encountered in other health care facilities and offices that our patients have reported to our medical and behavioral health providers. In addition, the lawyers, legal assistants and volunteer attorneys in our Legal Services Department have learned of many similar incidents from their clients.

16. Since the mid-1980s, Whitman-Walker has had an in-house Legal Services Department. Our attorneys and legal assistants provide information, counseling, and representation to Whitman-Walker's patients, and to others in the community who are LGBTQ or living with HIV, on a wide range of civil legal matters that relate directly or indirectly to health and wellness – including access to health care and discrimination based on HIV, sexual orientation, or gender identity. They also oversee legal clinics, staffed largely by volunteer attorneys, which assist transgender and gender-nonconforming individuals to change their legal names and to correct their birth certificates, driver's licenses, passports, Social Security records, and other identity documents to reflect their new names and actual gender identities.

17. Over the years, Whitman-Walker Legal Services staff and volunteer attorneys have encountered many instances of discrimination by health care providers and their staff based on the sexual orientation or gender identity of patients. Recent examples include:

a. As recounted in Dr. Henn's Declaration, Whitman-Walker transgender patients seeking gender affirming surgery have been rejected at local hospitals, even for procedures that are often performed on non-transgender patients (such as breast

surgery), and even though the patients had health insurance or were otherwise able to pay for the procedures.

b. In one instance, a health care worker at a dialysis clinic confronted a Whitman-Walker patient with end-stage renal disease and objected to being involved in the patient's care because of hostility to his sexual orientation.

c. In another case, a transgender woman who was about to have surgery at a Washington, DC hospital for an inner ear condition (unrelated in any way to her transgender-related health care) was confronted and harassed by hospital staff objecting to her gender identity. She was repeatedly and intentionally referred to as "he" and as "a man" by staff in the radiology department when she went for a pre-surgical scan; by desk staff at the surgery center; and by the nurse preparing her for surgery. Several nurses talked about her with each other and laughed. One staff person refused to talk with the patient when she addressed them. Even the anesthesiologist who she was expected to entrust with her life in one of her most vulnerable moments before surgery, mocked her and intentionally referred to her as a man. Health care providers are supposed to provide comfort to patients when they seek health care. Instead, the staff increased her fear just before her surgery because they showed complete disrespect and lack of care for the patient's health and wellbeing.

d. Another transgender woman went to the office of an ophthalmologist at the same medical center for an eye exam. She arrived on time, filled out the initial paperwork, and then waited for about 45 minutes without being called for her appointment. The patient went to the desk to inquire, and was treated rudely by

the staff. The staff then arbitrarily called a security guard to eject her from the office. As the patient spoke to the security guard, one of the clinic staff came to her and said, loudly and offensively, "Sir, your kind needs to go away. We're not serving your kind." She complained to the Office of the Chief Medical Officer and was eventually seen by the ophthalmologist on another day, after considerable effort by her and Whitman-Walker staff.

e. A transgender woman was seen by a medical provider at Whitman-Walker, who examined her and determined she might have broken her ankle. She was sent to the Emergency Room at a Washington, DC hospital. She identified herself to the ER check-in staff as a woman and presented a driver's license that contained a female gender marker. She then waited for a number of hours (she remembers five or six) without being examined. When she inquired about the delay, she was treated rudely and misgendered by ER staff. She was finally called from the waiting area, but was taken to the men's dressing room, rather than the area for women patients, to undress and put on a gown for a scan. During the four or more hours before she received the scan, examination and treatment, she suffered very significant physical pain.

18. By eliminating the explicit protections against discrimination based on gender identity, transgender status, and failure to conform with sex stereotypes, the Revised Rule invites an increase in discriminatory experiences for LGBTQ patients seeking health care services, such as those documented above. This result in harm to the patients and community that Whitman-Walker serves.

19. The discriminatory experiences LGBTQ patients have with other health care

providers erode patients' trust in health care providers overall and thus also challenges the ability of Whitman-Walker to treat its patients effectively and provide appropriate services and referrals.

20. The Revised Rule also empowers religiously-motivated discriminatory behavior by health care providers that is corrosive to fundamental professional standards, threatens patients' welfare, and places a significant strain on our ability to fulfill our critical mission. For example, the Revised Rule undermines our ability to provide referrals and our patients' ability to access health care. A significant amount of medical care in the United States is provided by religiously affiliated hospitals. This is illustrated by the fact that more than one in every six hospital beds in the country are in religiously-affiliated hospitals.[1] To the extent that the Revised Rule leads these institutions (or even a fraction of the medical professionals and staff at these institutions) to rely on the Rule's broad religious exemptions and refuse to provide care to LGBTQ patients, many patients will be left without other treatment options and there will be fewer specialists to whom we can refer our patients and feel confident that we are not exposing our patients to religiously-motivated discriminatory behavior.

21. The discrimination invited by the Revised Rule will also encourage LGBTQ patients to remain closeted to the extent possible when seeking medical care outside Whitman-Walker. When patients remain closeted to a health care provider, however, they are exposed to significant adverse health consequences. For instance, a patient who conceals or fails to disclose a same-sex sexual history may not be screened for HIV or other relevant infections or cancers, or may not be prescribed preventative medications such as PrEP, which is extremely effective at preventing HIV transmission. Patients who fail fully to disclose their gender identity and sex

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[1] Julia Kaye, et al., Am. Civil Liberties Union, *Health Care Denied: Patients and Physicians Speak Out About Catholic Hospitals and the Threat to Women's Health and Lives* (Mar. 2016), https://www.aclu.org/sites/default/files/field_document/healthcaredenied.pdf.

assigned at birth may not undergo medically indicated tests or screenings (such as tests for cervical or breast cancer for some transgender men, or testicular or prostate cancer for some transgender women).

22. Furthermore, at a time of public health crisis such as the present COVID-19 pandemic, the delay of necessary health care for fear of discrimination will make it harder for health care providers to help stem the pandemic, thereby potentially exposing more people to COVID-19, to which LGBTQ people are already more vulnerable.

23. The Revised Rule further notes that covered entities are not discriminating on the basis of sex if they refuse to use a transgender patient's pronouns consistent with their gender identity; refuse them access to sex-specific facilities that are consistent with their gender identity and instead forces them into facilities/shared rooms based on the sex they were incorrectly assigned at birth; and identifies them by the sex they were incorrectly assigned at birth such as on patient identification bracelets and any signage outside the patient's room. These discriminatory actions, which as documented above, have been experienced by Whitman-Walker's patients at other health care facilities, are inconsistent with the 2016 Final Rule and Section 1557 of the Affordable Care Act. They are also detrimental to transgender patients' health and wellbeing, and can lead to significant distress.

24. Whitman-Walker medical and behavioral health providers, care navigators and attorneys assist hundreds of transgender patients every year to navigate private health plans, Medicaid, and Medicare to obtain the gender-affirming services that they need—including a wide range of surgical procedures and hormone therapy. Many private and public plans continue to resist coverage of medically necessary procedures—if not through blanket exclusions of "sex change" or "sex transition" procedures, then through denials of coverage of specific procedures.

25. The 2016 Final Rule, which prohibits "categorical coverage exclusion[s] or limitation[s] for all health services related to gender transition" and denials, limitations, or restrictions "for specific health services related to gender transition if such denial, limitation, or restriction results in discrimination against a transgender individual," 81 Fed. Reg. at 31,472 (formerly codified as 45 C.F.R. § 92.207(b)), has been very valuable in persuading Medicaid administrators, insurance company personnel, and employee health plan sponsors to eliminate outdated exclusions and to agree to cover procedures when supported by evidence of medical necessity.

26. These provisions and others that specify insurance practices and plan features that constitute forms of unlawful discrimination provide useful guidance, not only for consumers and others advocating on their behalf – including health care providers like Whitman-Walker who assist patients in determining coverage of health care being provided or contemplated – but also for health insurance companies and plan administrators. For example, one of our Legal Services attorneys used the 2016 Rule to persuade a client's union health plan to eliminate a discriminatory exclusion and cover his mastectomy and chest reconstruction. The attorney also relied on the 2016 Rule to successfully overturn a Blue Cross company's denial of coverage of a transgender client's breast augmentation and genital surgery.

27. Based on Whitman-Walker's experience, the Revised Rule, which eliminates the aforementioned provisions, invites health plans to discriminate through the exclusion of gender-affirming procedures, which in turn threatens transgender patients who suffer from crippling gender dysphoria, and through the reinstitution of insurance practices regarding the "tiering" of certain drugs (e.g., to determine co-pays or cost-sharing ratios) that are of great concern to patients living with HIV or other medical conditions or disabilities that require expensive treatments.

28. In addition, the Revised Rule perplexingly exempts many forms of health insurance from Section 1557, subjecting LGBTQ patients who rely on those forms of insurance to discrimination based on sex assigned at birth, gender identity, transgender status, sexual orientation, race, national origin, age, or disability. For example, under the Revised Rule, "an entity principally or otherwise engaged in the business of providing health insurance shall not, by virtue of such provision, be considered to be principally engaged in the business of providing healthcare." 85 Fed. Reg. at 37244–45 (to be codified as 45 C.F.R. § 92.3(c)). The Revised Rule also excludes HHS health-related programs and activities from Section 1557, unless the programs were established under Title I of the ACA. This limitation would affect numerous health-related programs and activities, including those of the Centers for Medicare and Medicaid Services. The narrowing of covered entities under Section 1557 will result in discrimination against LGBTQ patients, who already face disproportionate barriers to accessing appropriate care, and eliminate LGBTQ patient's remedies to address such discrimination.

29. In sum, the Revised Rule will exacerbate the acute health disparities LGBTQ people already face and send the message that discrimination on the basis of gender identity, transgender status, sexual orientation, and failure to conform with sex stereotypes is permissible under federal law, which will increase the number of Whitman-Walker's LGBTQ patients who will be denied care outside Whitman-Walker.

Harms to Whitman-Walker's LEP Patients

30. As noted above, Whitman-Walker serves hundreds of LEP patients in any given year. Language access protections for LEP patients are essential to ensuring that LEP patients receive adequate care, understand their rights, and are able to communicate fully and effectively with their health care providers. Whitman-Walker has found the clear guidance provided by the

2016 Final Rule to be helpful in improving the health and wellbeing of our LEP patients as they obtain care at Whitman-Walker and elsewhere.

31. The Revised Rule, however, eliminates the requirement that covered entities take reasonable steps to provide meaningful access to "each individual with LEP eligible to be served or likely to be encountered" and replaces it with a general reference to "LEP individuals." See, e.g., 85 Fed. Reg. at 37,245. Focusing on LEP individuals in general as opposed to each individual will result in some individuals not receiving the services they need for meaningful access, and thereby result in more acute health problems and outcomes for patients and raises concerns about patient safety.

32. The weakening of protections for LEP individuals will harm Whitman-Walker's LEP patients who get care elsewhere or are referred to providers outside our organization for specialty care, as they will no longer benefit from the notices, taglines, and additional language access provisions that are critical to ensure meaningful access to care. The Revised Rule will thus diminish or eliminate meaningful access to health care for Whitman-Walker's LEP patients, who will not be aware of their rights or the programs or services available to them when they go to other health care facilities.

33. Whitman-Walker will face increased burdens due to fewer clients being aware of their language access rights and the likelihood that more people will turn to Whitman-Walker for help in their language, rather than other covered health care providers. Whitman-Walker will also be burdened with increased costs because its patients will come to us sicker as a result of inadequate care elsewhere.

Additional Harms to Whitman-Walker

34. Escalating health care discrimination and fear of such discrimination, resulting

from the Revised Rule, is likely to result in increased demand for Whitman-Walker's health care services, which will present considerable operational and financial challenges. Many of Whitman-Walker's health care services lose money due to low third-party reimbursement rates and indirect cost reimbursement rates in contracts and grants which are substantially less than Whitman-Walker's cost of service. Increased demand for Whitman-Walker's health care services, driven by increased discrimination and fear of discrimination outside of Whitman-Walker, would exacerbate that pressure. We likely will be called upon to see more patients, and that patient care does not financially cover itself. As a result, Whitman-Walker may not be able to meet the increased demand and sustain the additional financial burdens resulting from an increased load of patients who either fear discrimination elsewhere or who were discriminated against or denied services at other institutions.

35. In addition, Whitman-Walker has large numbers of patients who require gender-affirming care, including hormone therapy and affirming, supportive mental health services. To the extent that the Revised Rule results in insurance plans and insurance companies reducing their coverage of such therapies, Whitman-Walker itself – as well as our patients – will be directly harmed by reduced reimbursements. In order to sustain the care that these patients need, we will be forced to turn to other measures, such as increasing charges to the patients themselves, and increasing our reliance on fundraising and grant revenue (which already is stretched thin).

36. The operational and financial pressures we will likely experience due to increased demand for our services as discrimination, and fear of discrimination, mount in the LGBTQ and LEP communities, will come at a time when Whitman-Walker already is struggling with the challenges posed by the COVID-19 pandemic. Since March of this year, many of our services have temporarily closed, and other health care services are being provided entirely through telemedicine

rather than in-person. Telemedicine services are being reimbursed at rates substantially lower than in-person services. The resulting very significant decline in revenues, and the very great operational challenges posed by suspending many services and re-tooling others, are posing challenges unique in Whitman-Walker's history. It will be particularly difficult to respond to increased demand at this already-difficult time.

37. At the same time, given Whitman-Walker's mission to provide health care to marginalized communities, including the LGBTQ community and people living with HIV, Whitman-Walker needs to increase its education programs and community outreach to help those affected by the Revised Rule find the health care services that they need and assist them with their trauma resulting from the Revised Rule. Whitman-Walker needs to continue informing the community about its commitment to serving all patients in a nondiscriminatory and welcoming manner and notifying its patients that the Revised Rule will not change Whitman-Walker's commitment to providing exceptional health care services to all members of the community. Whitman-Walker will continue fighting for its patients' rights, including, for example, advocating on behalf of transgender patients who seek treatment for gender dysphoria, but who are rejected because of their sex assigned at birth and gender identity. As a result of the Revised Rule, Whitman-Walker will also need to devote more resources to working with outside providers and organizations to remind them of the importance of providing health care to all patients on non-discriminatory terms.

38. The Revised Rule also adversely impacts Whitman-Walker by necessitating a diversion and reallocation of resources in order to provide referrals to patients that it does not have the resources to treat either because Whitman-Walker has reached its capacity for new patients (especially in the behavioral-health departments) or because the patient requires treatment in a

specialty that Whitman-Walker does not offer. These types of referrals are routine at Whitman-Walker where its focus is on primary care and HIV-specialty care. The Revised Rule will make it significantly more difficult and resource-intensive for us to locate, monitor, and provide appropriate referrals. With an increase in referral requests as a result of the Revised Rule, Whitman-Walker will need to allocate additional staff time to pre-screen service referrals to ensure that staff are sending patients to LGBTQ-affirming, LEP-welcoming providers and not to providers who themselves or whose staff would cause additional harm to Whitman-Walker patients.

39. The impact on Whitman-Walker and its patients of a broad, legally unsupported expansion of health care providers' refusal rights is also particularly worrisome. Religiously affiliated hospitals and health care systems occupy a large and growing percentage of health care markets, and providing a broad exemption from Section 1557's nondiscrimination provisions will affect Whitman-Walker's ability to make referrals and result in increased expenditures. It will also cause unnecessary confusion.

* * * * *

40. Health care systems should be safe places for everyone to seek care; where people's identities are affirmed, regardless of race, religion, sexual orientation, gender identity, disability, national origin, or other characteristics. It is Whitman-Walker's mission to offer affirming community-based health and wellness services to all, with a special expertise in LGBTQ and HIV care, and to empower all persons to live healthy, love openly, and achieve equality and inclusion. The Revised Rule frustrates our ability to live up to our mission by fostering discrimination against Whitman-Walker's LGBTQ patients, LEP patients, and others. The Revised Rule endangers the health, safety, and wellbeing of our patients; inhibits our ability to

provide them with the health care that they need, including the provision of referrals; increases the costs we must incur in order to provide our patients with adequate health care, as well as by the likelihood that more people will turn to Whitman-Walker to fill gaps in care and assistance caused by the Revised Rule; and imposes new compliance costs.

[*Signature on next page*.]

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Dated this 1st day of July, 2020.

Naseema Shafi

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

WHITMAN-WALKER CLINIC, INC., *et al.*,

Plaintiffs,

v.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, *et al.*,

Defendants.

Case No. 1:20-cv-1630

DECLARATION OF DR. SARAH HENN, MD, MPH
CHIEF HEALTH OFFICER, WHITMAN-WALKER HEALTH

I, Sarah Henn, declare as follows:

1. I am the Chief Health Officer of Whitman-Walker Clinic, Inc., d/b/a Whitman-Walker Health ("Whitman-Walker").

2. I received my medical degree from the University of Virginia; interned at Emory University; was a resident in Internal Medicine at the University of Virginia; and completed an Infectious Disease Fellowship at the University of Maryland. I earned a Masters of Public Health degree at The Johns Hopkins Bloomberg School of Public Health. I maintain active board certifications in Infectious Disease and Internal Medicine. A copy of my curriculum vitae is attached as **Exhibit A**.

3. I have been a physician at Whitman-Walker since 2007, and became Chief Health Officer in May 2018. I oversee all health care related services at Whitman-Walker, as well as maintain a panel of patients for whom I provide direct care. In addition, I am the primary investigator for multiple HIV and Hepatitis C treatment and prevention trials, and am the Leader

of our Clinical Research Site for the AIDS Clinical Trials Group funded by the National Institutes of Health.

4. I am submitting this Declaration in support of Plaintiffs' motion for a preliminary injunction to prevent the revised regulation under Section 1557, published by the U.S. Department of Health and Human Services ("HHS") on June 19, 2020 (the "Revised Rule"), from taking effect.

5. Whitman-Walker provides a range of services, including medical and community health care, transgender care and services, behavioral-health services, dental-health services, legal services, insurance-navigation services, and youth and family support. Whitman-Walker provides primary medical care, HIV and Hepatitis C specialty care, and gender-affirming care to transgender and gender non-binary persons within the diverse community of the greater Washington, DC metropolitan area. In calendar year 2019, our medical, dental, behavioral-health and community-health professionals provided health services to 20,760 patients—including medical care to 11,817 individuals, dental care to 2,014 patients, and walk-in sexually-transmitted-infection testing and treatment to 1,762 persons. In 2019, 3,587 of our patients were individuals living with HIV; 2,148 identified as transgender; and 9,295 identified as gay, lesbian, bisexual or otherwise non-heterosexual.

6. Whitman-Walker's patient population, including patients to whom I provide direct care and whose care I oversee, includes many persons who have experienced refusals of health care or who have been subjected to disapproval, disrespect, or hostility from medical providers and staff in hospitals, medical clinics, doctor's offices, or Emergency Medical Services personnel because of their actual or perceived sexual orientation, gender identity, transgender status, gender presentation, ethnicity or race, religious affiliation, poverty, substance use history, or for other reasons.

7. My patients and those whose care I oversee tell us that they are apprehensive or fearful of encountering stigma and discrimination in health care settings because of their past experiences. Many of our patients have delayed medical visits or postponed recommended screenings or treatment because of such fears. Frequently, persons living with HIV, diagnosed with sexually transmitted infections, struggling with substance use disorders, or whose gender identity is different from the sex that they were assigned at birth, face heightened stigma and discrimination and are particularly apprehensive in medical encounters. Our patients' concerns have been magnified by their belief that the federal government is permitting, if not encouraging, discrimination by health care personnel and health care institutions under the Revised Rule.

8. There is every reason to believe that the Revised Rule's elimination of protections from discrimination based on gender identity, sexual orientation, transgender status, failure to conform with sex stereotypes, along with its expansion of religious exemptions and weakening of safeguards for services to patients with Limited English Proficiency (LEP), will result in more discrimination against lesbian, gay, bisexual, transgender, queer and questioning (LGBTQ) patients, and inadequate services to LEP patients, at other clinics, doctors' offices, hospitals, pharmacies, and other health care facilities outside Whitman-Walker.

9. I and other Whitman-Walker health care providers, including referral coordinators, behavioral-health providers, and other staff, have learned of many instances of discrimination, from our patients and from communications with outside providers and staff. Examples include the following:

a. Whitman-Walker was recently contacted by a transgender woman suffering from tonsillitis. She wanted treatment but knew of no hospital or facility other than Whitman-Walker where she could go. The caller reported that

in her suburban area, she and other transgender individuals she knows are routinely disrespected and poorly treated when they seek medical care, and asked for advice on where transgender patients can receive good care.

b. A gay man reported that he consulted a cardiologist for a heart issue. The cardiologist reviewed his medications and saw that one was Truvada—an antiretroviral medication that is used for "Pre-Exposure Prophylaxis" or "PrEP"—taken by persons who are not HIV-infected to avoid contracting HIV during sex. The cardiologist was startled and disapproving, and began lecturing the patient about what the cardiologist considered his inappropriate sex life.

c. A transgender man, together with his girlfriend, consulted a fertility clinic about their pregnancy options. Clinic staff told them that they would not help people like them.

d. A transgender patient of Whitman-Walker attempted to fill a prescription at a non-Whitman-Walker pharmacy for a hormone prescribed to assist in their gender transition, and was refused by the pharmacist.

e. Our patients seeking to fill prescriptions for Truvada for PrEP have also been refused by some pharmacies.

f. A gay man who is a long-term HIV survivor went to a local hospital emergency room after an accident that occurred during sex. He was treated with contempt by ER staff and was lectured about his sex life.

g. A transgender individual went to a local hospital emergency room suffering from acute abdominal pain. The individual was subjected to intrusive,

hostile questioning by ER personnel, loudly and in public, about their anatomy and gender identity.

h. One of our physicians, while in residency at a hospital in a major Midwestern city, heard other residents refuse to refer to transgender patients by pronouns conforming to their gender identity, citing their religious beliefs. They continued to refuse even when informed that they were violating hospital policy.

i. A transgender woman was scheduled to receive an ultrasound for cancer. The first radiological technician she encountered refused to perform the ultrasound. When she protested, a second technician performed the procedure, but mocked her openly.

j. Transgender patients have reported to us that they have been in medical or mental-health crisis and called for an ambulance, and that the Emergency Medical Service personnel who have arrived on the scene have intentionally used pronouns inconsistent with their gender identity, even when the patients have asked them to stop and told them that their language was increasing their distress.

k. A gay man who was engaged in sex, while under the influence of drugs, experienced a physical episode and was fearful he was having a heart attack. He called an ambulance, but the Emergency Medical Service personnel who arrived belittled him and his situation and refused to take him to an emergency room.

l. Local hospitals and surgeons have refused to perform gender-transition-related surgeries on Whitman-Walker transgender patients, even when they routinely perform the procedures in question on non-transgender patients, including in situations where the patient's insurance would cover the procedure or when the patient was able to pay for the procedure. This has happened with orchiectomies, breast augmentations, and breast reductions - procedures which are all routinely performed for treatment of cancer or for other reasons not related to gender identity.

m. A number of primary care physicians in our area have refused to prescribe hormone therapy for transgender patients seeking to transition from the sex they were assigned at birth to their actual gender identity. Many of these doctors have stated that they are not "comfortable" with such hormone therapy.

n. Our providers have seen situations in which a teenager who is transgender or gender-expansive has presented at a local hospital with symptoms for which hospitalization was indicated, but their hospitalization was delayed and even denied because hospital personnel took them less seriously than they took other young people with similar presentations who were not transgender.

o. Our transgender patients frequently report instances of being treated with disrespect and hostility by staff in doctors' offices, hospitals, and clinics. Frequently, staff at these facilities will refuse to address patients by their chosen names and gender pronouns, if these are not the same as the patients'

legal names and sex assigned at birth, or if patients appear to be transgender. The persistent use of names and pronouns other than what the patients have requested appears intentional and intended to communicate strong disapproval of the patients. I and my staff who frequently consult with transgender patients hear of such experiences from as many as four out of every five transgender patients. To state the obvious, there is no medically indicated reason to refuse to call patients by their names and pronouns, consistent with their gender identities.

10. These and many other experiences reveal that many medical providers and other staff continue to harbor explicit or implicit biases against LGBTQ people. Many providers and staff who harbor such feelings or beliefs nonetheless have provided care to LGBTQ patients, and kept their personal beliefs in check, because of anti-discrimination laws and regulations, such as the 2016 Final Rule; non-discrimination policies at many hospitals, clinics, and other health care facilities; and professional norms. The Revised Rule counteracts such non-discrimination policies and norms by signaling that discrimination based on sexual orientation, gender identity, and transgender status is permissible under federal law, and by extending religious exemptions to health care settings where they are inappropriate and dangerous. The result will likely be a significant increase in discriminatory incidents, denials of care, and the attendant harms to patients' health and well-being.

11. Discriminatory incidents are not only insulting and demoralizing for patients, but can jeopardize the patient's health, when a screening or treatment is denied or postponed, or the patient is discouraged from seeking medical care out of fear of repeated discrimination. Many if not most of my and Whitman-Walker's transgender patients express strong distrust of the health care system

generally, and a demonstrative reluctance to seek care outside Whitman-Walker unless they are in a crisis or in physical or mental stress. This is because they want to avoid discrimination or belittlement. Such incentives to avoid regular check-ups and other medical care can result in disease processes that are more advanced at diagnosis, less responsive to treatment, or even no longer curable in the case of some cancers.

12. In addition, LGBTQ people are more vulnerable to COVID-19. For example, LGBTQ people are less likely compared to the general population to have health insurance to begin with and are more likely to be smokers with the resultant comorbidities such as asthma, COPD, and CVD which increase the risk for complications from COVID-19. LGBTQ people are also more likely to work in jobs in that have been highly affected by the COVID-19 pandemic, often with more exposure and/or higher economic sensitivity to the COVID-19 crisis.[1]

13. As health care has had to go virtual due to the COVID-19 pandemic, hard coding within electronic health records and other limitations in functionality have made it very challenging for people with LEP to access care. In many cases for walk-in COVID-19 testing, registration and screening is being accomplished via the telephone. Many LGBTQ people and people with LEP have a challenging time with this need for electronic resources.

14. The Revised Rule frustrates my ability and the ability of my colleagues to successfully refer patients for specialty care from outside providers because we cannot assure our patients that those providers will provide care free from discrimination.

[1] Human Rights Campaign Found., *The Lives and Livelihoods of Many in the L T Community are at isk Amidst CO D Crisis* (Mar. 2020), https://assets2.hrc.org/files/assets/resources/COVID19-IssueBrief-032020-FINAL.pdf?_ga=2.249711620.386339034.1593392090-1365884386.1591027992.

15. The Revised Rule also erodes trust between patients and their health care providers, endangers the provider-patient relationship, and is likely to harm many patients' health.

16. Good medical care is based on trust as well as frank, and full communication between the patient and their provider. In many, if not most encounters, providers need patients to fully disclose all aspects of their health history, sexual history, substance-use history, lifestyle, and gender identity in order to provide appropriate care for the patients' mental and physical health. Incomplete communication, or miscommunication, can have dangerous consequences. For instance, a patient who conceals or fails to disclose a same-sex sexual history may not be screened for HIV or other relevant infections or cancers; and a patient who fails to fully disclose their gender identity and sex assigned at birth may not undergo medically-indicated tests or screenings (such as tests for cervical or breast cancer for some transgender men, or testicular or prostate cancer for some transgender women). The Revised Rule completely overlooks the importance of this information to medical providers, and instead focuses myopically on the limited instances in which sex assigned at birth may be relevant to care. Patients need to be encouraged to fully disclose all information relevant to their health care and potential treatment, which can only be achieved when patients are assured that the information they provide will be treated confidentially and with respect, and will not be used against them to deny treatment.

17. In order for Whitman-Walker's heath care providers to provide proper medical care and services to the LGBTQ community, our health care providers rely on frank and complete communication with their patients and the individuals who seek their services, and want the same happen when our patients need care elsewhere. Without full disclosure, we are not able to treat adequately our patients.

18. Patients remaining closeted to health care providers also results in increased costs to the health care system. When a patient is closeted and medical providers do not order medically necessary tests or screenings as a result, Whitman-Walker and its patients, as well as the health care system as a whole, suffer downstream effects, such as the exacerbation of a patient's distress and more acute conditions, and increased costs. In addition, I and other Whitman-Walker health care providers will bear an increased risk of malpractice when patients do not feel comfortable revealing important information about their sexual orientation, gender identity, and health history.

19. The Revised Rule also discourages LGBTQ patients from seeking preventative screenings and necessary medical treatment for fear of being subjected to discrimination.

20. The delay of preventative screenings and necessary health care can result in more acute health problems and outcomes for patients and raises concerns about patient safety. For example, research has identified pervasive health disparities for LGBTQ people with respect to cancer, HIV, obesity, mental health, tobacco use, and more. The delay of preventative screenings and necessary health care thus endangers the health and wellbeing of Whitman-Walker's LGBTQ patients and exposes them to lasting harms.

21. The delay of preventative screenings and necessary health care at other health care facilities fostered by the Revised Rule will cause LGBTQ patients to come to Whitman-Walker with more acute conditions and/or diseases that are more advanced at diagnosis, less responsive to treatment, or no longer treatable. This will in turn strain Whitman-Walker's resources, increase costs for providers, make it harder for our health care providers to treat the patients, and increase costs to the health care system in general.

22. Discrimination by health insurance providers against transgender individuals is yet another barrier to care that my patients and the patients whose care I oversee frequently experience.

Our providers, care navigators, and Legal Services attorneys continuously advocate for patients whose insurance – including Medicaid plans, Medicare, and private insurance plans – denies coverage of surgical procedures hormone therapies that are medically indicated and vital to patient health and well-being. The 2016 Final Rule has been an important tool in advocating for our patients. By declaring that discrimination in insurance based on gender identity or transgender status is not prohibited in federal law, and by limiting the types of insurance plans that are subject to federal nondiscrimination requirements, the Revised Rule will increase barriers to life-saving, medically-necessary care for transgender patients by allowing health insurers to revert back to policies excluding coverage for gender-affirming care. If patients with such coverage exclusions are to access the care they require, they will incur debilitating out of pocket costs to pay for their medical treatment. For many if not most of our transgender patients, lack of insurance coverage of gender-affirming surgeries and other treatments will mean that they are simply unavailable.

23. Ensuring that our health services are fully accessible to persons with limited English proficiency, and that our health care providers and other staff are able to communicate fully with all of our patients, is critical to Whitman-Walker's mission. Whitman-Walker has a number of patients whose primary language is Spanish or some other language, and who lack English proficiency. In 2019, approximately 9% of our patients had limited proficiency in English and needed interpreter services. Over the past several years, we have devoted considerable time and attention to developing and implementing a language access plan and training all staff in the details of that plan.

24. I and the providers I supervise have patients who, in hospital and medical-clinic settings, were refused Spanish-language interpreters, even when such interpreters were available

in the facility, because the provider or other staff thought that the patient ought to know English, or because of bias against immigrants.

25. Patients in these situations have had difficulty understanding their diagnosis and/or treatment plan, greatly increasing risk of a negative result and harm. Notices to LEP patients explaining their rights and what programs and services are available to them are crucial to promoting positive patient health outcomes. The Revised Rule's elimination of the requirement of such notices will result in harm to Whitman-Walker LEP patients by diminishing their meaningful access to health care, outside of what Whitman-Walker can provide. In addition, the Revised Rule will cause more patients to seek out care at Whitman-Walker due to a lack of appropriate language services available elsewhere.

26. Whitman-Walker's mission and fundamental principles of medical ethics that I adhere to in overseeing and providing care to patients dictate that all patients are deserving of the best and most respectful care available to them. All health care professionals are taught that their personal beliefs about a patient's actions, identity or beliefs cannot compromise the care that they provide to that patient in any way. Whitman-Walker and I, in my role as Chief Health Officer for Whitman-Walker, communicate that message to all health care staff from the beginning of the recruitment process to the first day of employment, and reinforce the message regularly.

27. The possibility that providers outside Whitman-Walker could invoke the overly broad religious exemptions in the Revised Rule to opt out of any aspect of care would fundamentally disrupt our care model and operations, as it would make it harder to refer patients to specialists and strain Whitman-Walker's already limited resources. Such discrimination would also violate basic tenets of medical ethics. Broad-based denials of care cannot be accommodated without lasting damage to the patient morale, health center, and our reputation in the community.

28. The Revised Rule removes or substantially weakens safeguards against health care discrimination against LGBTQ individuals, and the weakening of safeguards for LEP patients will make health care for significant numbers of Latinx people less accessible and less effective. In other words, the Revised Rule will make it harder for us to care for our patients who will face discrimination or have diminished access to care elsewhere as a result of the Revised Rule.

29. Although Whitman-Walker prides itself on being a refuge for LGBTQ individuals, LEP persons, and others who have experienced discrimination or culturally inadequate care elsewhere, it would be quite difficult for us to accommodate the substantial increase in demand for our services caused by the Revised Rule. Many if not most of our services are under-compensated due to private and public insurance reimbursement rates, and grant funds that do not fully account for the actual cost of service. Moreover, the COVID-19 pandemic has posed extraordinary financial and operational challenges. Many of our health services have been temporarily suspended since March of this year, or shifted entirely to telemedicine, with substantially lower reimbursement rates. The logistical challenges remain daunting, even without a significant increase in new patients.

[*Signature on next page.*]

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Dated this 30 day of June, 2020.

Sarah Henn, MD, MPH

EXHIBIT A

Curriculum Vitae of Sarah Henn, MD, MPH

Sarah L. Henn, MD, MPH

1525 14th Street NW • Washington, DC 20005 • Phone: 202.745.6174 • E-Mail: shenn@whitman-walker.org

Education and Post-Doctoral Training

Bachelor of Arts 1988 - 1992
Hamilton College, Clinton, New York, Major International and Comparative Political Studies, Minor German

Doctor of Medicine 1993 - 1997
University of Virginia School of Medicine, Charlottesville, Virginia

Internship 1997 - 1998
Internal Medicine, Emory University Medical Center, Atlanta, Georgia

Residency 1998 - 2000
Internal Medicine, University of Virginia Medical Center, Charlottesville, Virginia

Master of Public Health 2001 - 2003
The Johns Hopkins Bloomberg School of Public Health, Baltimore, Maryland, Concentration in International Health

Fellowship 2004 - 2006
Infectious Diseases, University of Maryland Medical Center and the Institute for Human Virology, Baltimore, Maryland

Certifications, Licensures, & Appointments:

Board Certifications:

- American Board of Internal Medicine, Internal Medicine, 2000, recertified 2010
- American Board of Internal Medicine, Infectious Diseases, 2006, recertified 2016

Medical Licensure:

- District of Columbia, 2007 – present

Academic Appointments:

- George Washington University, Clinical Assistant Professor, 2008 - present

Professional Experience

Chief Health Officer May 2018 – present

Whitman-Walker Health, Washington DC

Responsibilities: Medical lead of a Federally Qualified Health Center serving over 12,000 clients with over 300 employees and an annual budget of over 100 million dollars. Key member of the executive team responsible for strategic planning and the overall management of the organization. Reports directly to the CEO/Executive Director.

Key Achievements:

- Established in conjunction with seven regional FQHC leaders the Coordinated Care Network, an incorporated independent entity, in the District of Columbia to centralize coordinated primary care, increase quality, reduce cost, and increase influence with payers and stakeholders positioning WWH effectively for value based payment transformation which negotiates directly with Medicaid MCO payers around service delivery for the care of over 100,000 individuals in the District of Columbia
- Expanded clinical services to include adolescents with a specialty focus on HIV Prevention, Sexual Health, and Gender Affirming Care
- Clinical Research Site (CRS) Leader of AIDS Clinical Trials Group (ACTG) site as part of Johns Hopkins' Clinical Trails Unit (CTU)

- Serves of the Executive Committee of the DC Center for AIDS Research (CFAR) and is a member of the DC CFAR housed at the George Washington University Milken School of Public Health

Senior Director of Health Care Operations and Medical Services January 2015 – April 2018

Whitman-Walker Health, Washington DC

Responsibilities: Leads medical operations of a Federally Qualified Health Center serving over 18,000 clients with near 300 employees and an annual budget of over 100 million dollars. Serves on the senior leadership team providing strategic direction for the health center. Oversees the integrated delivery of primary medical, specialty HIV, HIV prevention, gender affirming, dental, occupational therapy, aesthetics, laboratory, and pharmacy services. Negotiates and oversees contracts with outside vendors.

Key Achievements:

- Achieved Patient Center Medical Home highest level 3 accreditation for demonstrating strong performance and significant improvement in performance measures across the triple aim of better patient experience, better health, and lower per capita cost.
- Led the design and implementation of an improved patient scheduling system increasing same day and next day scheduled appointments to 30% of all patient visits and decreasing new patient wait times to under one week
- Improved laboratory patient experience while simultaneously negotiating improved rates with LabCorp achieving cost savings of up to 50% on frequently order tests and $10,000 per month in credit to WWH's account for labs performed for clients who are <200% federal poverty level
- Oversee pharmacy contract and performance in a pharmacy that dispenses up to 1000 prescriptions daily with a net profit of close to a million dollars monthly in close conjunction with the Deputy Executive Director
- Awarded over 1 million dollars in new research grants in 2017 from the National Institute of Drug Abuse and the Patient Centered Outcomes Research Institute
- Significantly improved health center policies, trainings, and practices related to LGBT health helping to result in WWH being recognized as a "Leader in LGBT Healthcare Equity" with a score of 100/100
- Achieved increased service integration and productivity by leading weekly interdepartmental medical operations meetings and working closely with providers to create buy-in and improve morale
- Transitioned medical operations of the Elizabeth Taylor Medical Center serving more than 10,000 patients to a new facility at 1525 14th St NW in May 2015
- Expanded medical services at the Max Robinson Center, in Southeast DC, more than tripling the number of care providers ensuring that the full suite of patient services are consistently available

Interim Sr. Director of Evidence Based Medicine 2015

Whitman-Walker Health, Washington DC

Responsibilities: Oversaw the clinical research department and the execution of large-scale research studies and collaborations. Acted as leader of clinical research site (CRS) for AIDS Clinical Trials Group (ACTG) and primary investigator for the Study to Help the AIDS Research Effort (SHARE), which is one of the four clinical sites for the Multicenter AIDS Cohort Study (MACS).

Key Accomplishments:

- Reorganized the structure of the department to allow for increased staff development opportunities and quality monitoring of research programs
- Maintained industry research funding of over 2 million annually while more than doubling ACTG study participation

Medical Director **2009 – 2014**

The Elizabeth Taylor Center, Whitman-Walker Health, Washington DC

Responsibilities: Performed overall planning, organizing, scheduling, directing, and evaluation of clinical medical providers ensuring excellent patient care experience. Worked closely with the Chief Medical Officer and the Senior Director of Quality Improvement in the delivery of the highest quality of care and the development of quality improvement projects.

Key Accomplishments:

- Implemented ongoing provider education to improve quality indicators.
- Supervised 15 providers, including other physicians, physician volunteers, physician-assistants, and nurse practitioners

Staff Physician **2007 - 2009**

Whitman-Walker Health, Washington DC

- Provided primary care at clinical sites in Northwest and Southeast Washington, DC and Northern Virginia
- Specialized in complex HIV care and Hepatitis C treatment
- Initiated Hepatitis C treatment program

Clinical Instructor, Division of Infectious Diseases **2006 - 2007**

University of Maryland Medical Center, Baltimore, Maryland

- Maintained active outpatient infectious disease clinics at both the University of Maryland and the Veterans Administration Hospital in Baltimore, MD
- Attended on the inpatient HIV hospital services overseeing Infectious Disease fellows, Medical residents, and students
- Developed a research protocol to reduce maternal to child transmission of Hepatitis B in HIV co-infected mothers

Technical Advisor for PEPFAR **2004 - 2007**

Institute for Human Virology, Baltimore, Maryland

- Launched and evaluated points of service for HIV/AIDS care in Nigeria
- Provided technical assistance and expertise to Nigerian physicians and medical staff in order to initiate HIV treatment for patients

Clinical Associate Staff Physician **2002 - 2003**

The Cleveland Clinic Foundation, Cleveland, Ohio

- Trained internal medicine residents, interns, and medical students
- Attended on the inpatient medicine wards, primary care clinic, and pre-operative clinic performing medical consultations on national and international referrals.

- Supervised patient care team

Associate Physician **2000 - 2002**

Shenandoah Internal Medicine, Augusta Medical Center, Virginia

- Practiced private practice Internal Medicine in rural Virginia
- Attended to patients in both the outpatient and inpatient setting
- Cared for patients in the Intensive Care Unit, Cardiac Step Down Unit, and performed cardiac stress testing

Publications

Peer-reviewed journal articles

1. Lathouwers E, Wong EY, Brown K, Baugh B, Ghys A, Jezorwski J, Mohsine EG, Van Landuyt E, Opsomer M, De Meyer S. Week 48 Resistance Analyses of the Once-Daily, Single-Tablet Regimen Darunavir/Cobicistat/Emtricitabine/Tenofovir Alafenamide (D/C/F/TAF) in Adults Living with HIV-1 from the Phase III Randomized AMBER and EMERALD Trials. AIDS Res Hum Retroviruses. 2019 Oct 21;. doi: 10.1089/AID.2019.0111. [Epub ahead of print]

2. Eron JJ, Orkin C, Cunningham D, Pulido F, Post FA, De Wit S, Lathouwers E, Hufkens V, Jezorwski J, Petrovic R, Brown K, Van Landuyt E, Opsomer M. Week 96 efficacy and safety results of the phase 3, randomized EMERALD trial to evaluate switching from boosted-protease inhibitors plus emtricitabine/tenofovir disoproxil fumarate regimens to the once daily, single-tablet regimen of darunavir/cobicistat/emtricitabine/tenofovir alafenamide (D/C/F/TAF) in treatment-experienced, virologically-suppressed adults living with HIV-1. Antiviral Res. 2019 Oct;170:104543.

3. Naggie S, Fierer DS, Hughes MD, Kim AY, Luetkemeyer A, Vu V, Roa J, Rwema S, Brainard DM, McHutchison JG, Peters MG, Kiser JJ, Marks KM, Chung RT. Ledipasvir/Sofosbuvir for 8 Weeks to Treat Acute Hepatitis C Virus Infections in Men With Human Immunodeficiency Virus Infections: Sofosbuvir-Containing Regimens Without Interferon for Treatment of Acute HCV in HIV-1 Infected Individuals. Clin Infect Dis. 2019 Mar 28;. doi: 10.1093/cid/ciy913. [Epub ahead of print]

4. Orkin C, Molina JM, Negredo E, Arribas JR, Gathe J, Eron JJ, Van Landuyt E, Lathouwers E, Hufkens V, Petrovic R, Vanveggel S, Opsomer M; EMERALD study group. Efficacy and safety of switching from boosted protease inhibitors plus emtricitabine and tenofovir disoproxil fumarate regimens to single-tablet darunavir, cobicistat, emtricitabine, and tenofovir alafenamide at 48 weeks in adults with virologically suppressed HIV-1 (EMERALD): a phase 3, randomised, non-inferiority trial. Lancet HIV. 2018 Jan;5(1):e23-e34.

5. Cahn P, Kaplan R, Sax PE, Squires K, Molina JM, Avihingsanon A, Ratanasuwan W, Rojas E, Rassool M, Bloch M, Vandekerckhove L, Ruane P, Yazdanpanah Y, Katlama C, Xu X, Rodgers A, East L, Wenning L, Rawlins S, Homony B, Sklar P, Nguyen BY, Leavitt R, Teppler H; ONCEMRK Study Group. Raltegravir 1200 mg once daily versus raltegravir 400 mg twice daily, with tenofovir disoproxil fumarate and emtricitabine, for previously untreated HIV-1 infection: a randomised, double-blind, parallel-group, phase 3, non-inferiority trial. Lancet HIV. 2017 Nov;4(11):e486-e494.

6. Wyles D, Ruane PJ, Sulkowski MS, Dieterich D, Luetkemeyer A, Morgan TR, Sherman KE, Dretler R, Fishbein D, Gathe JC, Henn S, Hinestrosa F, Huynh C, McDonald C, Mills A, Overton ET, Ramgopal M, Rashbaum B, Ray G, Scarsella A, Yozviak J,

McPhee F, Liu Z, Hughes E, Yin PD, Noviello S, Ackerman P for the ALLY-2 Investigators, Daclatasvir plus Sofosbuvir for HCV in Patients Coinfected with HIV-1. N Engl J Med. 2015 Aug 20;373(8):714-25.

7. Alcaide ML, Feaster DJ, Duan R, Cohen S, Diaz C, Castro JG, Golden MR, Henn S, Colfax GN, Metsch LR, The incidence of Trichomonas vaginalis infection in women attending nine sexually transmitted diseases clinics in the USA. Sex Transm Infect. 2015 Jun 12 pii: sextrans-2015-052010.

8. Metsch LR, Feaster DJ, Gooden L, Schackman BR, Matheson T, Das M, Golden MR, Huffaker S, Haynes LF, Tross S, Malotte CK, Douaihy A, Korthuis PT, Duffus WA, Henn S, Bolan R, Philip SS, Castro JG, Castellon PC, McLaughlin G, Mandler RN, Branson B, Colfax GN., Effect of risk-reduction counseling with rapid HIV testing on risk of acquiring sexually transmitted infections: the AWARE randomized clinical trial. JAMA. 2013 Oct 23;310(16):1701-10.

9. Silver D, Karnik G, Osinusi A, Silk R, Stabinski L, Doonquah L, Henn S, Teferi G, Masur H, Kottilil S, Fishbein D., Effect of HIV on liver fibrosis among HCV-infected African Americans. Clinical Infectious Disease. 2013 May;56(9):1280-3.

10. Henn SL, Forrest GN, Febrile Neutropenia Associated with Painful Lesions of the Palms and Digits. Clinical Infectious Disease. 2006;43(6):747, 791-2.

11. Henn S, Bass N, Shields G, Crow TJ, DeLisi LE, Affective illness and schizophrenia in families with multiple schizophrenic members: independent illnesses or variant gene(s)? Eur Neuropsychopharmacol. 1995;5 Suppl:31-6.

Abstracts

1. Alt Olsen H, Sarkodie E, Coleman M, Davies M, Henn, S, Fast Forward to Viral Suppression: A Nurse-driven Model for Facilitating Same Day Start of ARVs Following Reactive HIV+ Result or First-time Engagement in HIV Care. 2019, Association of Nurses in AIDS Care, Portland. Abstract #B-11.

2. Coleman M, Sarkodie E. Eggleston A, Kelley E, Henn S, Measuring Retention in Real World PrEP Programs; What is the best way to evaluate engagement with PrEP? 14th International Conference on HIV Treatment, Prevention, and Adherence, Miami. Abstract # 3381.

3. Alt Olson H, Sarkodie E, Coleman M, Davies M, Henn S, Fast Forward to Viral Suppression: Immediate Initiation of ARVs Following Reactive HIV+ Test Results or Engagement in HIV Care for the First Time at a Community Health Center in Washington, DC. 2019. 14th International Conference on HIV Treatment, Prevention, and Adherence, Miami. Abstract #5035.

4. Alt Olson H, Sarkodie E, Colemen M, Davies M, Henn S, Immediate Initiation of ARVs Following Reactive HIV+ Test Result or Engagement in HIV Care for the First Time at a FQHC in Washington. 2019. 6th Annual SYNChronicity Conference.

5. Walsh B, Coleman M, Dietrich M, Du Mond J, Jue J, Sadler M, Saperstein S, Wickham C, Henn S, Improvements in Engagement, Retention, and Viral Load Suppression in a Mobile Outreach Retention and Engagement (MORE) Project at a Community Health Center in Washington DC. 2017. 9th IAS Conference on HIV Science. Abstact #A-854-0225-05081.

6. Dieterich M, Coleman M, Du Mond J, Jue J, Sadler M, Saperstein S, Wickham C, Walsh B, Henn S, HIV+ Participants in the Mobile Outreach and Retention (MORE) Program in Washington, DC with Co-Morbid Mental Health and/or Substance

Abuse Diagnoses are Significantly Less Likely to Achieve Viral Suppression Despite Comprehensive Support. 2017 12th International Conference on HIV Treatment and Prevention Adherence, Miami. Oral Abstract #277.

7. Osinusi A, Wang C, Zhang X, Shivabesan G, Shivakumar B, Silk R, Doonquah L, Henn S, Teferi G, Masur H, Kottillil S, Fishbein D, Augmentation of Interferon signaling pathway by Nitazoxanide: A therapeutic strategy for HIV/HCV Coinfected Relapsers to Peg-interferon and Ribavirin therapy. 2012 19th Conference on Retroviruses and Opportunistic Infections, Seattle.

8. Silver D, Karnik G, Osinus A, Silk R, Stabinski L, Doonquah L,Henn S, Tefari G, Masur H, Kotillil S, Fishbein D, Liver Fibrosis in African Americans, Comparing HCV Mono-Infection with HIV-HCV Co-Infection. 2011 American Association for the Study of Liver Disease Conference, San Francisco.

9. Henn SL, Weekes E, Forrest GN, Methicillin Resistant Staphylococcus Aureus Bacteremia Treated with Linezolid: A Retrospective Review of Outcomes. 2006 46th Interscience Conference on Antimicrobial Agents and Chemotherapy (ICAAC), San Francisco. Abstract #876.

Awards:

Outstanding Employee of the Year 2016, Whitman-Walker Health, selected by employees and the Employee Advisory Group

George McCracken Infectious Disease Fellow 2006, Interscience Conference on Antimicrobial Agents and Chemotherapy, San Francisco

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA**

WHITMAN-WALKER CLINIC, INC., *et al.*,

Plaintiffs,

v.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, *et al.*,

Defendants.

Case No. 1:20-cv-1630

**DECLARATION OF RAND PUMPHRE , D.MIN., LPC, BCC
SENIOR DIRECTOR OF BEHA IORAL HEALTH, WHITMAN-WALKER HEALTH**

I, Randy Pumphrey, declare:

1. I am the Senior Director of Behavioral Health at Whitman-Walker Clinic, Inc., d/b/a Whitman-Walker Health ("Whitman-Walker").

2. After earning a B.S. in American Studies, I received Masters of Divinity and Doctor of Ministry degrees from Wesley Theological Seminary. I initially worked as a Board Certified Chaplain at St. Elizabeth's Hospital (which became the Commission on Mental Health Services for the District of Columbia and the Psychiatric Institute of Washington), and subsequently received my Professional Counselor Licensure in 1997.

3. I have worked in mental-health and substance-use-disorder treatment since 1984, initially as an intern at Washington Hospital Center, then with St. Elizabeth's Hospital. In 1998 I became the Clinical Director of the Lambda Center, a joint partnership between the Psychiatric Institute of Washington and Whitman-Walker Clinic. I joined Whitman-Walker's staff in 2007 as the Manager of Mental Health Services, and became Senior Director of Behavioral Health in 2015.

In addition to managing Whitman-Walker's behavioral-health services, I maintain a panel of patients for whom I provide direct care. A copy of my curriculum vitae is attached as **Exhibit A**.

4. I am submitting this Declaration in support of Plaintiffs' motion for a preliminary injunction to prevent the revised regulation under Section 1557, published by the U.S. Department of Health and Human Services ("HHS") on June 19, 2020 (the "Revised Rule"), from taking effect.

5. As the Senior Director of Behavioral Health, I oversee Whitman-Walker's robust portfolio of mental-health services, and substance-use-disorder-treatment services. Our mental-health services include individual and group psychotherapy, psychiatry, and peer counseling. For individuals struggling with substance misuse, we offer individual and group counseling and support, and Medically-Assisted Treatment (MAT). In 2019, we provided mental-health or substance-use-disorder-treatment services to 2,912 patients. Our psychiatrists, psychologists, licensed psychotherapists, and trained peer counselors have a special mission to the lesbian, gay, bisexual, transgender, queer and questioning (LGBTQ) community, and also to individuals living with HIV and their families and caregivers.

6. Many if not most of the individuals in our very diverse behavioral-health-patient population face considerable stigma and discrimination—as people living with HIV, as sexual or gender minority people, as people of color—and many of them struggle with internalized stigma and with acute or lower-level but persistent trauma. Many of them have experienced difficulty in finding therapists or other mental-health or substance-use-disorder professionals who are understanding and welcoming of their sexual orientation, gender identity, or struggles with HIV. We frequently receive phone calls and other inquiries from people seeking non-discriminatory, welcoming assistance with their substance use, depression, anxiety, or other challenges. Many of

these individuals have suffered from traumatizing encounters with hostile or disapproving health care professionals.

7. The Revised Rule's elimination of protections from discrimination based on gender identity, sexual orientation, transgender status, failure to conform with sex stereotypes, or LEP status, along with its expansion of religious exemptions, will result in more discrimination against LGBTQ patients, LEP patients, and patients living with HIV at other clinics, doctors' offices, hospitals, pharmacies, and other health care facilities outside Whitman-Walker. This increase in discrimination will harm the patients I serve and the patients whose care I supervise by directly harming their mental and behavioral health, discouraging access to mental and behavioral health care, and harming the patient-provider relationship, resulting in poor outcomes.

8. Experiencing discrimination in health care settings can have pronounced negative impacts on patients' mental and behavioral health. For example, a 2019 report by the Williams Institute at UCLA found that experiencing discrimination in health care settings is a unique risk factor for heightened suicidality among transgender individuals, a population already at heightened risk compared with the general population.[1] Conversely, nondiscrimination protections prohibiting discrimination in health care based on gender identity or transgender status have been associated with a decrease in suicidality among transgender and other gender minority individuals.[2] This is consistent with what I have observed over my years of experience in mental and behavioral health.

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[1] *See* Jody L. Herman et al., The Williams Institute, *Suicide Thoughts and Attempts Among Transgender Adults* (2019), https://williamsinstitute.law.ucla.edu/publications/suicidality-transgender-adults/.

[2] *See* Alex McDowell et al., *Association of Nondiscrimination Policies with Mental Health Among Gender Minority Individuals*, JAMA Psych. (May 6, 2020), https://jamanetwork.com/journals/jamapsychiatry/article-abstract/2765490.

9. The Revised Rule, by signaling that discrimination based on sexual orientation, gender identity, and transgender status is now permitted in health care settings, will on its own invoke increased fear and trauma among LGBTQ patients. Our clinic is likely to see an increased demand for mental-health services and behavioral-health services as a result. Patients will likely come to our care more distressed than they would otherwise due to the increased discrimination invited by the Revised Rule.

10. I and the providers and other behavioral-health staff that I supervise at Whitman-Walker have learned from patients about many incidents of discrimination or mistreatment based on a patient's actual or perceived sexual orientation, gender identity, or transgender status in other behavioral-health settings. For instance:

a. A transgender teenager was hospitalized after a suicide attempt. Hospital staff refused to address the teenager by the young person's preferred pronouns and gender throughout the teenager's hospital stay. This was experienced by the teenager as disapproval and contempt for the young person's gender identity. This discrimination exacerbated the teenager's acutely fragile state when the teenager was so desperately in need of health care providers' support and health care services that were free of judgment.

b. A facility that specializes in inpatient mental health and substance-use-disorder treatment, and which has explicit non-discrimination policies, nonetheless has significant trouble from nurses on weekend shifts (when the facility uses pool nurses rather than regular employees), who express strong disapproval of LGBTQ patients based on their religious beliefs or cultural upbringing. Despite the facility's non-discrimination policies, LGBTQ

patients encounter hostility, expressions of disapproval, and lack of responsiveness to their needs or requests from these nurses. For patients hospitalized for mental or substance-use disorders, these experiences can activate their disorders.

c. As I previously noted, behavioral health staff that I supervise often receive calls or other communications from LGBTQ persons expressing desperation about finding a therapist or substance use professional who will not discriminate against them because of their sexual orientation or gender identity.

d. Our behavioral-health providers who regularly interview our transgender patients to assess their stage of gender transition and readiness for gender-affirming surgical procedures, or who provide psychotherapy for these patients, report that the large majority of the patients they meet with—as many as four out of every five—report incidents of mistreatment or discrimination by health care providers and staff at hospitals, other clinics, doctor's offices, and other facilities.

e. A patient who was employed by a church consulted his health care provider. One of the nurses called his church and told them he was gay and living with HIV. As a result, he was fired and lost his pension, forcing him to live on a severely limited income.

11. These incidents reveal that many health care providers and other staff harbor explicit or implicit biases against LGBTQ people. Because of legal requirements, health care facility non-discrimination policies, and professional norms, many of them have kept their personal beliefs and feelings in check. By signaling that discrimination based on sexual

orientation, gender identity, and transgender status is permissible under federal law, the Revised Rule is very likely to result in many more incidents of discrimination and greater harm to LGBTQ individuals struggling with mental health or substance use issues, including the patients whom I treat and whose treatment I supervise.

12. Behavioral-health treatment assumes, and requires, trust between the patient and provider, and full and frank disclosure by the patient of all potentially relevant information about their life, including their sexual orientation, sexual and affectional experiences, and gender identity. I, and the providers that I supervise at Whitman-Walker, frequently work with patients who have concealed some or all aspects of their sexual and affectional orientation or history, or gender identity, from non-Whitman-Walker therapists or other behavioral health providers, often to the patients' harm. The Revised Rule will very likely discourage LGBTQ people and others needing treatment from fully disclosing relevant information to their therapists or counselors, or to those helping them with substance-use issues, which will likely increase their distress and undercut the effectiveness of their treatment.

13. For persons with traditionally stigmatized sexual orientation—such as gay, lesbian, or bisexual people—or who are transgender or gender expansive, competent mental-health services, or services for treatment of substance-use disorders, require an accepting—indeed, an affirming—attitude towards their sexual orientation or gender identity by their provider. Discriminatory behavior, statements, or attitudes expressed by a provider are a tremendous barrier to effective care. It is critical that a patient feel empowered and supported in fully disclosing their sexuality and gender identity to their counselor, therapist, psychologist, or psychiatrist. Without a trusting patient-provider relationship and full disclosure of all possibly relevant feelings and facts by the patient, effective treatment is unlikely to be possible. This is critical for good medical care

as well. The kind of discrimination permitted by the Revised Rule will erode patient-provider trust among the patients our clinic serves, making it more difficult for patients at Whitman-Walker to achieve successful outcomes in their care.

14. The COVID pandemic has greatly increased the fear and apprehension in our community. Many LGBTQ people, including many of our patients, who have lived through the HIV/AIDS era are feeling re-traumatized by a new pandemic. During the first three months of the pandemic and related shutdown, we have seen a significant numbers of our substance use clients relapse. Many people's fear of encountering discrimination in health care settings has been heightened. Our substance use patients who are struggling and are LGBTQ have expressed reluctance to use city-operated treatment facilities because they fear hostility and discrimination from other patients and staff at those facilities. The issuance of the Revised Rule, with its message that LGBTQ discrimination is permitted, and its extensive, approving discussion of anti-transgender sentiments among health care providers, could not have come at a worse time.

15. In addition, our staff have experienced major operational challenges in responding to COVID-19 – including shifting behavioral-health services to telemedicine and temporary suspension of some services. This is a particularly difficult time to respond to increased demand for our services stemming from increased fear of discrimination encouraged by the Revised Rule.

16. I and Whitman-Walker provide referral services for patients who need specialist care that we do not provide—including inpatient behavioral health care as well as specialist medical care. We also receive many outside requests for recommendations for LGBT-welcoming, non-discriminatory therapists and substance-use professionals in the community. The Revised Rule will make it significantly more difficult for us locate and monitor appropriate referrals, and patients will suffer as a result. Even more concerning, our behavioral-health patients who may

need hospitalization for a mental-health or substance-use crisis, or may need specialist medical care, will be in greater danger of encountering discrimination at inpatient behavioral health facilities or when they seek medical care outside Whitman-Walker—which may make their care at Whitman-Walker more difficult and perhaps less successful.

17. All Whitman-Walker employees, and all volunteers who serve as peer counselors or otherwise are involved in any way with our behavioral-health services, are asked to commit to our mission, which is to be welcoming to and understanding of every patient, regardless of sexual orientation, gender identity, race or ethnicity, income or educational background, or life experience. We welcome staff and volunteers from a wide range of religious, spiritual, cultural, and philosophical perspectives, but patient needs must always be paramount. The overly broad religious exemptions in the Revised Rule threaten to substantially harm patients who are already vulnerable to stigma and discrimination. The message that health care providers' religious preferences or beliefs take priority over patient needs also violates fundamental professional ethical standards that apply to all licensed therapists, psychologists, psychiatrists, and substance-use-disorder-treatment professionals, including myself.

18. The Revised Rule removes or substantially weakens protections for LGBTQ individuals vulnerable to discrimination in health care settings. The inevitable increase in discrimination against LGBTQ individuals in health care settings that will follow from the Revised Rule will make it harder for us to care for our patients at the Whitman-Walker Clinic.

[*Signature on next page.*]

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Dated this 30 day of June, 2020.

Randy Pumphrey, D.MIN., LPC, BCC

EXHIBIT A

Curriculum Vitae of Randy Pumphrey, D.Min., LPC, BCC

Randy W. Pumphrey D.Min, LPC, BCC
2016 Perry Street NE
Washington, D.C. 20018
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Whitman-Walker email: rpumphrey@whitman-walker.org
Private Practice (cell) 202-369-4252
(e-mail) rpumphreylpc@verizon.net

PROFESSIONAL EXPERIENCE

Senior Director of Behavior Health at Whitman Walker Health (January 2015 to present)

- Works with the Chief Health Officer, Executive Director of the Health Center and the Chief Program Officer to strategically develop behavioral health programs, including recruitment and operational alignment with other health care services.
- Provides vision, leadership and strategic development to the behavioral health staff ensuring integration of services across the health center.
- Acts as member of Leadership Team, demonstrating leadership principles that encourage active feedback and an engaged workforce
- Develops and oversees programs for provision of behavioral health care, providing specific goals for implementation to other Behavioral Health staff.
- Monitors behavioral care outcome information, including: census data, Peer Review data, third-party related data and other metrics provided by Quality Improvement and Informatics to ensure appropriate response and program development.
- Monitors productivity, third-party revenue, and trends in health care delivery to ensure Behavioral Health programs are responsive to current payment methodologies and ready for future changes in health care reform.
- Collaborates with Administrative staff on various tasks including: grant funding, marketing and communication materials, development and fundraising, and community relations.
- Builds successful professional relationships with local community groups, business leaders, health care facilities and other organizations, acting as liaison and spokesperson for behavioral matters.
- Oversees the operations of all behavioral programs to ensure adherence to Whitman-Walker policies and compliance with local and Federal law.
- Ensures that behavioral health programs are being delivered by appropriately licensed and credentialed providers.
- Provides direct behavioral health care to clients
- Works with the Chief Medical Officer and Senior Director of Health Care Operations to strategically develop behavioral health programs, including recruitment and operational alignment with other health care services.
- Provides vision, leadership and strategic development to the behavioral health staff ensuring integration of services across the health center.
- Acts as member of Leadership Team, demonstrating leadership principles that encourage active feedback and an engaged workforce
- Develops and oversees programs for provision of behavioral health care, providing specific goals for implementation to other Behavioral Health staff.
- Monitors behavioral care outcome information, including: census data, Peer Review data, third-party related data and other metrics provided by Quality Improvement and Informatics to ensure appropriate response and program development.
- Monitors productivity, third-party revenue, and trends in health care delivery to ensure Behavioral Health programs are responsive to current payment methodologies and ready for future changes in health care reform.
- Collaborates with Administrative staff on various tasks including: grant funding, marketing and communication materials, development and fundraising, and community relations.

- Builds successful professional relationships with local community groups, business leaders, health care facilities and other organizations, acting as liaison and spokesperson for behavioral matters.
- Oversees the operations of all behavioral programs to ensure adherence to Whitman-Walker policies and compliance with local and Federal law.
- Ensures that behavioral health programs are being delivered by appropriately licensed and credentialed providers.
- Provides direct behavioral health care to clients

Behavioral Health Manager for Mental Health at Whitman Walker Health (August 2007 to December 2014.)

- Hire and Manage all Mental Health clinicians
- Provide individual administrative and clinical supervision to eight staff therapists and Master Level clinical interns
- Conduct individual and group psychotherapy (group topics include – Sexual Compulsion in Gay Men, Long Term Survivors of HIV, Stress Management with HIV)
- Manage department budgets
- Manage grant budgets
- Conduct community workshops on a variety of Mental Health issues and topics
- Operate as Deputy Behavioral Health Director in absence of Behavioral Health Director
- Provide administrative direction and supervision to the Mental Health Department

Private Practice – Psychotherapy and Spiritual Directions (October 2007 to present)

- Individual and couple's therapy with focus on co-occurring disorders, relationship issues – including love addiction and love avoidance, sexual compulsion, anxiety, depression, loss and grief, HIV, trauma and issues related to sexual orientation acceptance.
- Spiritual Direction – work in tandem with other therapists to deal with psycho-spiritual conflicts with their clients. Deal directly with client struggling to find meaning and acceptance through a variety of spiritual practice.

Director of The Lambda Center: Behavioral Healthcare for the LGBTQ community.

A partnership between The Psychiatric Institute of Washington and Whitman-Walker Clinic (September 1998 to July 2005 and The Psychiatric Institute of Washington from July 2005 to August 2007.)

- Hire and supervise all clinical staff
- Direct an interdisciplinary treatment team working with lesbian, gay, bisexual and transgender adult clients.
- Manage the operation of an Inpatient detoxification and mental health stabilization program, a Partial Hospitalization program, and an Intensive Outpatient program.
- Supervise Master's level interns in Counseling Psychology and Community Counseling as well as Master level counseling staff for LPC licensure.
- Conduct individual, group psychotherapy, a full spectrum of co-occurring recovery groups, process oriented topic groups as well as skills groups dealing with life management skills, cognitive impairments, emotional regulation, living with HIV/AIDS, spirituality, grief and loss, relational issues, family dynamics, sexual identity integration and gender identity integration.
- Orient all new hospital staff on issues of cultural competency.
- Successfully led Lambda Center through three Joint Commission Surveys, DCRA annual surveys, CMS surveys, APRA certification surveys and Tricare surveys.
- Education and community relations through seminars, national conferences, grand rounds and workshops that teach mental health and addiction treatment professionals about therapeutic interventions with the gay, lesbian, bi-sexual and transgender communities.

Chaplain

The Psychiatric Institute of Washington, Washington, D.C., (July 1986 –March 2005).

- Served as consultant with hospital administration to create an integrated spiritual program for a free standing Psychiatric hospital.
- Conduct weekly worship as well as special holiday celebrations for the Children's unit, the Adolescent unit and the Adult units.
- Facilitate weekly spiritual resource groups, process groups, dual diagnosis step groups, and conduct individual pastoral counseling.
- Consult with treatment staff regarding the religious and spiritual issues of clients within a variety of specialized programs including — intensive care, dual diagnosis, Gay and Lesbian, the Center for Post Traumatic Syndrome and Child / Adolescence.
- Assess the spiritual needs of clients upon referral.
- Designed assessment tool used by the hospital.
- Grand Round presentations "Mind, Body, Spirit -- The Healing Formula," "The Emerging Spirit - The Integration of Spirituality in Mental Health Care," "Spirituality in the Treatment of Gay and Lesbian persons."

Administrative Chaplain for the Acute Psychiatric Hospital

Commission on Mental Health Services, Saint Elizabeths Campus, D.C., (July 1987 - August J998).

- Coordinate and manage pastoral staff providing spiritual care for the Acute Psychiatric Hospital.
- Conduct individual and group pastoral counseling and spiritual direction to clients suffering with a full range of psychiatric disorders and dual diagnosis.
- Educate and counsel persons living with HIV infection/AIDS, addiction recovery and sexual identity integration.
- Teach interns and residents therapeutic and sensitivity issues with lesbian/gay/bisexual/transgender persons.
- Facilitate and lead workshops for hospitals and churches dealing with "Spirituality and Recovery," "Living with AIDS," "Meditation," "Visitation and Referral," and "Sensitivity to the Mentally III."
- Create group therapy forum for staff who had survived recent loss to work through issues of grief and loss.
- Conceptualized and implemented new pastoral care procedures to increase our direct patient care and maximize pastoral effectiveness.
- Monitor clinical record keeping.
- Clinical experience in Acute Care, Dual Diagnosis, Geriatric, Forensic, Long Term Chronic Care and Out-patient Day Programs. Clinical Supervision of pastoral interns and residents.
- Train, delegate, and schedule pastoral staff; residents, and interns.
- Perform weekly worship, preach, and distribute the Sacraments.

Pastoral Assistant

First United Methodist Church, Bradbury Heights, Washington D.C., (Oct. 1984-May 1985).

- Designed and implemented an educational program for youth.
- Participated on all church committees.
- Created and preached a special Advent worship series and taught the Lenten Bible study.

Youth Minister

Korean United Methodist Church of Washington D.C., (Oct. 1981 -Jan. 1983).

- Designed a Christian education program for trans-generational children.
- Conducted a weekly English worship service.
- Created and counseled a United Methodist youth group.
- Trained Korean parents as Sunday school teachers.

EDUCATION

Doctorate of Ministry; Wesley Theological Seminary, September 1991 to May 1997.
Thesis: "A Spiritual Recovery Program Informed by Process Theology."

Clinical Training: Clinical Pastoral Education

- The Commission on Mental Health, Washington, D.C.
  2 Basic units, 2 Advanced units, and 9 Supervisory units, June 1985 – August 1988.
- The Washington Hospital Center, Washington, D.C.
  1 Basic unit, September 1984 - May 1985.

Masters of Divinity; Wesley Theological Seminary, Sept. 1981 to May 1985.
Focus on Pastoral Care and Counseling.
Chair of the Arts Committee and Co-creator of the Liberation Resource Committee.

Bachelor of Science; Towson University, Towson Maryland, September 1979 to May 1981.
Major: American Studies with a concentration in American literature and Human development,
Honors: Cum Laude.
Outdoors adventure club, Orientation department team leader.

Associates of Arts Degree
Anne Arundel Community College, Maryland, Sept. 1977 to May 1979.
Major: American Studies
Honors: Magna Cum Laude

Additional continued education in a variety of mental health issues including – CBT, Ethics, Post Induction Therapy, Inner Child integration and Shame and Pain Reduction, Sexual Compulsion, Love Addiction, and Trauma

CREDENTIALS and PROFESSIONAL ASSOCIATIONS

- Licensed Professional Counselor in the District of Columbia. PRC1134 Exp.12/31/1998.
- Board Certified by the Association of Professional Chaplains, May 1990 (Retired Status)
- Ordained Elder in the United Methodist Church, June 1989.
- DC Behavioral Health Association Board, Secretary second term

LANGUAGES

Proficient at intermediate level signed English

REFERENCES:

UPON REQUEST

CERTIFICATE OF SERVICE

I hereby certify that on January 19, 2021, I electronically filed the foregoing brief with the Clerk of the Court for the United States Court of Appeals for the District of Columbia Circuit by using the appellate CM/ECF system. Participants in the case are registered CM/ECF users, and service will be accomplished by the appellate CM/ECF system.

/s/ Joshua Dos Santos
JOSHUA DOS SANTOS

[ORAL ARGUMENT NOT SCHEDULED]

No. 20-5331

IN THE UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

WHITMAN-WALKER CLINIC, INC., et al.,

Plaintiff-Appellees,

v.

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, et al.,

Defendants-Appellants.

On Appeal from the United States District Court
for the District of Columbia

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**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA**

WHITMAN-WALKER CLINIC, INC., *et al.*,

Plaintiffs,

v.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, *et al.*,

Defendants.

Case No. 1:20-cv-1630

**DECLARATION OF BAMBY SALCEDO,
PRESIDENT AND CEO, THE TRANSLATIN@ COALITION**

I, Bamby Salcedo, declare as follows:

1. I am a 50-year-old transgender woman, an immigrant, and a person living with HIV.

2. I was born and raised in Guadalajara, Mexico, where I lived until age 16. Seeking refuge from the discrimination I faced as an LGBTQ person, I immigrated to the United States in 1986, initially settling in central California and later moving to Los Angeles, where I have lived for the last 30 years. English is my second language.

3. I am a founding member and the President and CEO of the TransLatin@ Coalition ("the Coalition"), a 501(c)(3) national membership organization that was founded in 2009 in Los Angeles, California, by transgender and gender nonconforming Latinx immigrant community leaders.

4. I am submitting this Declaration in support of Plaintiffs' Motion for a Preliminary Injunction to prevent the revised regulation under Section 1557 of the Affordable Care Act ("ACA"), published by the U.S. Department of Health and Human Services ("HHS") on June 19, 2020 (the "Revised Rule"), from taking effect. The Revised Rule eliminates explicit regulatory

protections for LGBT people in health care that were included in the previous rule implementing Section 1557, which was promulgated in May 2016 ("2016 Final Rule").

5. The TransLatin@ Coalition was formed to organize and advocate for solutions to the unique challenges and specific needs of transgender, gender nonconforming, and intersex Latinx immigrants residing in the United States. The Coalition seeks to address these challenges in three key ways: one, by building a national network of affiliated transgender-led organizations and groups that provide direct services to transgender and gender nonconforming Latinx people; two, by amplifying educational and other resources that promote the empowerment of transgender and gender nonconforming Latinx individuals and leaders; and three, by working in partnership with local and national organizations across the country to create change that addresses the needs of and issues faced by transgender and gender nonconforming Latinx people through community-led campaigns, policy change, and leadership development. The Coalition's specific mission is "to advocate for the specific needs of the Trans Latin@ community that resides in the U.S.A. and to plan strategies that improve our quality of life."

6. The TransLatin@ Coalition's structure has three components. First, and foremost, the TransLatin@ Coalition is composed of thousands of transgender and gender nonconforming Latinx individual members across the United States, including in states and territories without any state-level protections from discrimination on the basis of sexual orientation, gender identity, or transgender status. These members include transgender Latinx individuals like me; Arianna Lint, a transgender woman and immigrant from Peru, based in Florida; and Elia Chino, a transgender woman and immigrant from Mexico, based in Texas. Second, the Coalition is made up of a network of affiliated organizations and groups across the country including in Tucson, Arizona; South Florida; Atlanta, Georgia; Chicago, Illinois; New York City; Houston, Texas; and

Washington, D.C. Leaders of these affiliated organizations—like Ms. Chino, the Executive Director of the Fundación Latinoamericana de Acción Social (FLAS) in Houston, Texas, and Ms. Lint, the Executive Director of Arianna's Center in South Florida and Puerto Rico—form part of the Coalition's leadership. The Coalition's affiliated organizations, and the individual Coalition members who are part of those organizations, serve thousands of transgender and gender nonconforming individuals across the United States. Lastly, in addition to the work of its network of affiliated organizations, the Coalition provides direct services to transgender, gender nonconforming, and intersex Latinx people through its Center for Violence Prevention and Transgender Wellness ("Transgender Wellness Center") in Los Angeles, California.

7. Among the services the Coalition and its affiliates provide are: community drop-in spaces; daily food distribution; re-entry services to people recently released from incarceration and immigration detention including rental assistance, transportation and food vouchers; English as a Second Language ("ESL") classes; immigration-focused legal services; leadership and workforce development education and training programs; emergency and transitional housing; case management; and, most notably, referrals to health care providers and organizations that provide competent and affirming health care services to our members and patrons, including gender affirming care.

8. The TransLatin@ Coalition and its membership are also involved in legislative advocacy in various states and Puerto Rico in order to ensure that government officials hear transgender and gender nonconforming Latinx voices on issues that affect the community's health and safety.

My Personal Experiences with Discrimination in Health Care

9. As an openly transgender woman living with HIV, I have experienced persistent discrimination from both health care providers and insurers during my life.

10. When I first moved to California as an adolescent, I lived with my father and his wife. However, because they did not accept my LGBTQ identity, I was forced to move and go live with extended family members outside of Sacramento, where I worked in a tortilla factory as a minor. While there, I experienced wage exploitation and was unable to be my authentic self. As such, without familial support or much proficiency in English, I moved to Los Angeles on my own as a teenager.

11. After moving to Los Angeles, I started my gender transition at age nineteen. At that time, there was virtually no one providing LGBTQ-welcoming, let alone gender affirming, health care in the way we know it today. I had to find community and support from other transgender women who, because of pervasive discrimination in housing and employment, were homeless and doing street-based sex work to survive like me. Indeed, I received most of my health care, both gender affirming and otherwise, through informal means, namely, from these other transgender women living on the street.

12. A year after starting my gender transition, I learned I was HIV-positive. This was a very traumatic and terrifying experience for me as many of my friends were dying from AIDS. At the time, there were no known effective treatments for HIV. I recall vividly how many of my friends were dying of AIDS as a result of lack of access to care or because AZT was not working.

13. As a young 20-year-old, transgender Latina immigrant from Mexico with no familial support, I was terrified. I remember telling myself, “I don’t want to die.” And so, even though I

was undocumented at the time and feared the consequences that may stem from my seeking health care, I went to a health clinic to ask for help.

14. At the clinic, however, I was told that they "did not know how to treat HIV," and that in any event, "they didn't treat people like me." I did not know how to advocate for myself at that time, so this was a devastating blow to my self-esteem, mental health, and wellbeing.

15. Because of the pain from my HIV diagnosis and the discrimination I faced from health care providers, as well as in employment and housing, I resorted to self-medication and abused drugs, attempting to stop the pain and the feelings of hurt and rejection I had.

16. The only care that was available for poor, undocumented people then, was through the community-based HIV support groups that were prevalent at the height of the HIV/AIDS epidemic, though these rarely served transgender women like myself. Ironically, the first time that I received consistent health care from any source was when I was incarcerated in 1993 for drug possession. This was around the time that HIV retroviral drugs were developed, and for the first time, I began receiving consistent HIV treatment while incarcerated.

17. After my incarceration, I again had to obtain my health care, both gender affirming and otherwise, through informal means, such as from other transgender women living on the street. I did not know how health insurance worked or whether it might even be available to me.

18. I saw many of my transgender friends experience complications from using street-based hormones, and I worried about the risks I was facing as well. Each time I tried to pursue hormone replacement therapy or other treatments for gender dysphoria through formal channels, however, it was denied to me because I was transgender.

19. Having had these experiences so often over the course of my life has created a persistent apprehension of and mistrust towards health care providers, whom I fear might deny me needed health care because I am transgender and because of my HIV status.

20. I have heard similar stories of discrimination in health care from many members of the Coalition, who share the same fear and apprehension. For example, one Coalition member, who is an undocumented transgender Latinx woman, was turned away from the emergency room when her breast implant burst and became infected. She was in excruciating pain at the time, yet the hospital refused to help her.

21. Even before the Revised Rule, I have long feared discrimination in health care services when I travel at least twice a month to states with no state protections from discrimination based on sexual orientation, gender identity, or transgender status. When I am in Texas, Florida, Georgia, or Arizona for my work, I expend precious time and energy worrying what might happen if I have a medical emergency and whether I would be turned away because I am transgender, as I had been in the past.

22. Even in California, I carry this concern as so many hospitals across this state are religiously affiliated and have discriminated against many of The Coalition's members, with hospital staff alleging that "their faith" means they cannot serve transgender and gender nonconforming people.

23. Knowing that the 2016 Final Rule explicitly states that such discrimination is unlawful does provide me with a level of comfort, even if it does not provide complete assurance that my fears will not be realized. The Revised Rule's elimination of the clear regulatory protections in the 2016 Final Rule eliminates whatever amount of comfort I might have had, and

heightens my fears, as it communicates to health care providers that such discrimination is acceptable.

24. This fear of discrimination in health care settings is even more troubling in the context of the COVID-19 pandemic. I have heard from Coalition members that even if they are experiencing severe symptoms, they will delay seeking care because they are worried they will be turned away, or experience other discrimination because they are transgender. These fears have been heightened by the Revised Rule. And delays in seeking care can be even more deadly for Latinx people, who are more likely to be affected by and die from COVID-19 than non-Latinx people.[1]

25. At the Coalition, we have already faced tremendous loss caused by the COVID-19 pandemic and fears of discrimination in health care. In March of this year, we lost a beloved TransLatin@ Coalition member and former board member based in New York for these exact reasons: Lorena Borjas. I spoke to Lorena a few days before she passed, and recall how she told me how she did not want to go to the hospital because of her experiences of discrimination from health care providers, even though she was experiencing symptoms consistent with COVID-19. By the time Lorena finally went to the hospital, she was in such a poor state of health that little could be done. If Lorena had not feared mistreatment at the hospital and been admitted sooner, there is a strong likelihood she would still be alive today.

26. For these reasons, I am even more afraid when I travel for work to states like Arizona, Texas, Georgia, or Florida, none of which has state level antidiscrimination protections for LGBTQ people in health care. I fear that, as a result of the Revised Rule, people like me will

[1] Maria Godoi & Daniel Wood, *What Do Coronavirus Racial Disparities Look Like State By State?*, NPR (May 30, 2020), https://www.npr.org/sections/health-shots/2020/05/30/865413079/what-do-coronavirus-racial-disparities-look-like-state-by-state.

experience even more discrimination from health care providers and insurers because of our sex, gender identity, transgender status, national origin, disability, LEP status, or some combination of these characteristics.

27. Without clear federal protections like those being eliminated by the Revised Rule, we will have no recourse to address the discrimination we face. The Revised Rule deprives us of the clear nondiscrimination guidance the 2016 Final Rule provides to health care providers and insurers, and actually fosters discrimination against LGBTQ and LEP people.

The Revised Rule's Negative Effects on Transgender Latinx People

28. Not only do I worry about the personal harm I will experience because of the Revised Rule, I also worry about the significant harm to the transgender and gender nonconforming Latinx people who form part of the Coalition and whom the Coalition and its affiliated organizations serve. Many are immigrants to the United States, live in communities in which English is not the primary language spoken and who therefore speak, read, or write English less than very well, and many are living with HIV/AIDS. The Coalition's members and the individuals whom the Coalition and its affiliates serve already have experienced or fear discrimination from health care providers and insurers based on their sex, gender identity, transgender status, sexual orientation, national origin, LEP, disability or some combination of these characteristics. The Revised Rule now invites health care providers to discriminate against them because of their sex, gender identity, transgender status, sexual orientation, national origin, disability, and/or LEP status.

29. I also worry about the Coalition's ability to carry out its activities on behalf of its members and the individuals whom the Coalition and its affiliates serve, as well as the diversion of our already limited financial resources in order to respond to that harm.

30. The findings of the national "2015 U.S. Transgender Survey: Report on the Experiences of Latino/a Respondents," which the TransLatin@ Coalition co-published with the National Center for Transgender Equality, and the TransLatin@ Coalition's 2016 survey and report on health care experiences and outcomes for transgender and gender nonconforming Latinx people living in the California entitled "The State of Trans Health: Trans Latin@s and Their Healthcare Needs," help explain why the Revised Rule will cause even more harm to the Coalition's national membership and the individuals whom the Coalition and its affiliates serve throughout the United States. A copy of the "2015 U.S. Transgender Survey: Report on the Experiences of Latino/a Respondents" is attached as **Exhibit A**. A copy of the "The State of Trans Health" report is attached as **Exhibit B**.

31. According to the 2015 U.S. Transgender Survey, nearly one-third (32%) of transgender Latinx respondents who saw a health care provider in the past year reported having at least one negative experience related to being transgender. These experiences included being refused treatment, being verbally harassed, being physically or sexually assaulted, or having to teach the provider about transgender people in order to get appropriate care. As a result, more than a quarter (26%) of transgender Latinx respondents did not see a doctor when they needed to because of fear of being mistreated because of their transgender status. This is consistent with the findings of the Coalition's 2016 study "The State of Trans Health," where nearly one third of transgender and gender nonconforming Latinx people surveyed felt that their healthcare needs were not being met because they "fear mistreatment for being trans," and because of "a dislike of trans patients by clinics." The "State of Trans Health" also found that forty-two percent (42%) of those surveyed strongly agreed that a lack of "trans sensitive healthcare providers," was a barrier to meeting their healthcare needs.

32. As the findings of the 2015 U.S. Transgender Survey and "The State of Trans Health" demonstrate, the Revised Rule's invitation to health care providers and insurers to discriminate against The Coalition's membership and the individuals whom the Coalition and its affiliates serve based on sex, gender identity, transgender status, sexual orientation, national origin, disability, and/or LEP status will worsen the health and wellbeing of transgender and gender nonconforming people.

33. Transgender and gender nonconforming people will likely delay necessary health care and preventative screenings due to fear of discrimination, and will face reduced access to care as result. In addition, they will face barriers to coverage of gender affirming care because of the Revised Rule's guidance that insurers may exclude such care from coverage.

34. As the Coalition's members and the individuals whom the Coalition and its affiliates serve avoid necessary, routine, and preventative health care for fear of discrimination, they will face an increase in preventable health problems and consequences, including death, which will severely impede their ability to work, maintain housing, and afford other material necessities.

35. Under the Revised Rule, the Coalition's members and the individuals whom the Coalition and its affiliates serve will be required to pay considerable out of pocket medical expenses because insurers refuse to provide life-saving and medically necessary care, even though they do not have the financial recourse to do so.

36. Because of the desire to avoid discrimination encouraged by the Revised Rule, the Coalition's members and the individuals whom the Coalition and its affiliates serve will likely seek informal medical care from unlicensed providers they consider affirming. Not only may these unlicensed providers not be able to help, but they may also cause more harm. Further, transgender and gender nonconforming people who are harmed or unable to be helped by these informal

providers are likely to again avoid seeking licensed medical care for fear of discrimination, which will leave their underlying conditions and new health issues unaddressed. It is easy to see how this cycle could be serious and potentially life threatening.

37. Because many of the Coalition's members and the individuals whom the Coalition and its affiliates serve are immigrants and people who speak, read, or write English less than very well, they face increased harm from the Revised Rule's elimination of a single legal standard. Rather than being able to assert claims under a single legal standard, intersectional discrimination claims will be subject to different standards, enforcement mechanisms, and remedies based on which characteristics are at issue. Discrimination based on sexual orientation, gender identity, transgender status, national origin, disability and LEP status is often intertwined, as threads braided into one rope, and is difficult to separate.

38. The Revised Rule also includes two specific changes that will disproportionately harm the Coalition, its members, and the individuals whom the Coalition and its affiliate serve: the removal of discrimination protections in the Center for Medicaid and Medicare regulations and the removal of language access protections.

39. Without protection from discrimination on the basis of sexual orientation and gender identity in public health insurance programs, transgender and gender nonconforming Latinx people will suffer disproportionately. The Coalition's "State of Trans Health" study found that 49.5% of transgender respondents receive health insurance coverage through Medicare, Medicaid, or Medi-Cal, California's state Medicaid program. Nationwide, as reflected in the 2015 U.S. Trans Survey, 18% of transgender Latinx respondents obtain their insurance through Medicaid or Medicare.

40. Additionally, our members and the thousands of people whom the Coalition and its affiliates serve also will be harmed by the Revised Rule's removal of language access protections.

Coalition members have expressed that seeing notices in health care settings in their first language and receiving communications from insurers they can read and understand increases the likelihood they will continue to seek preventative and necessary medical care when needed.

41. Without these accessible notices of rights, translation services, and information about how to file complaints, many Coalition members and those whom the Coalition and its affiliates serve will avoid seeking care until they feel they are sufficiently proficient in speaking and reading English, which will worsen their underlying and untreated medical conditions.

The Revised Rule's Harms to The TransLatin@ Coalition

42. As a direct result of the Revised Rule, the Coalition and its network of affiliated organizations will see a significant increase in requests for referrals to health care providers who will continue to provide affirming and welcoming health care services. The Coalition and its affiliates will need to divert resources to vet additional health care providers, as the already-known affirming providers will not to meet the demand for their services.

43. This increase in referral requests also will create a substantial backlog in available providers and appointments, resulting in critical delays in treatment for potentially serious health conditions.

44. The delay in seeking treatment, in turn, will result in serious financial difficulties for many individuals because they will have to pay for the expensive treatment required to address worsened health conditions and because of their inability to work while ill. As a result, the TransLatin@ Coalition and its network of affiliated organizations will be forced to divert significant financial resources to emergency support services including daily food distribution, rental assistance, and transportation and grocery vouchers. Emergency community support is one of the Coalition's and its affiliates' fundamental programmatic services. With the Revised Rule,

there will be an increase in demand for these services because of the increased number of transgender people who will be out of work, unable to pay rent, or afford other material necessities as result of delayed treatment of serious or semi-serious health conditions.

45. As more clients experience this ongoing harm precipitated by the Revised Rule, the TransLatin@ Coalition and its affiliated organizations will inevitably run out of resources to provide these emergency support services, completely undermining the Coalition's ability to perform one of its most fundamental programmatic services.

46. Furthermore, the COVID-19 pandemic has already put severe strain on the long-term availability of the TransLatin@ Coalition's fundamental programmatic services like emergency community support. To accommodate the lack of employment and economic stability facing many members and individuals whom the Coalition and its affiliates serve, the Coalition and its affiliates have been forced to shift resources in a way that would make the programmatic impact of the Revised Rule even more detrimental.

47. While providing these services is an important programmatic component of the TransLatin@ Coalition's work, it is only a part of the organization's overall activities. A significant redirection of funds required by the impact of the Revised Rule will impede the Coalition's ability to perform other programmatic activities like economic and workforce development training programs, coordinated human resources and cultural competency trainings, community research and education programs, and local and state advocacy campaigns for laws protecting the Coalition's members.

48. The Revised Rule also will significantly harm the Coalition's ability to conduct its re-entry services program—an important organizational activity that provides support to some of the most vulnerable of the Coalition's members and the individuals returning to their communities.

These transgender and gender nonconforming people will need immediate connections to medical services, which will be delayed by, or in some cases prevented altogether as a proximate fallout from the Revised Rule, due to the limited number of LGBTQ-affirming health care providers who will be (and already are) overwhelmed by demand.

49. The Revised Rule will also prevent the TransLatin@ Coalition from fully performing its programmatic activities that support members and individuals with LEP through ESL classes and other translation services.

50. The removal of language access measures from health care providers' offices and in health insurance communications will make it much more difficult for the TransLatin@ Coalition's members and individuals with LEP to be aware of their rights; which language services are available, if any; how to access such services; and how to handle discrimination and other complaints.

51. As a result of the Revised Rule's reconstruction of the language barrier once again preventing access to health care and insurance benefit communications, the Coalition and its affiliates will experience an unsustainable increase in demand for their ESL classes and translation services. They also will have to narrow their designed programmatic focus of these programs to understanding and navigating health care and related services, rather than the intended holistic language instruction addressing all facets of social interaction.

52. The Coalition will be in a difficult situation, as the demands for ESL classes and translation support focused on navigating health care settings increase exponentially, in concert with the increased demand for emergency financial support. The Coalition will be forced to make an impossible choice between which core programmatic activities to attempt to maintain. For the

Coalition, the only acceptable alternative is to provide severely limited services in both activities, which means the Revised Rule causes lasting injury to these desperately needed programs.

53. In addition to shifting much of the Coalition's and its affiliates' already limited budgets to emergency services and services to support members and individuals with LEP, the impact of the Revised Rule will also require shifting an unexpected amount of limited resources to education programs and community outreach. The efforts will be necessary to support the Coalition's members, and the individuals and communities we collectively serve in finding non-discriminatory health care providers, devising individual solutions for health insurance exclusions for gender confirming care, and securing non-discriminatory mental health treatment for the trauma resulting from widespread discrimination.

54. The Coalition will also attempt to devote a dwindling amount of resources to working with health care providers, insurers and other related organizations to educate and remind them of the importance of providing health care and insurance coverage to all patients in a nondiscriminatory manner. This will be especially difficult in states where the Coalition has a presence but which have no state-level anti-discrimination protections that include sexual orientation, gender identity, or transgender status, such as Texas, Florida, Arizona, and Georgia.

55. The Revised Rule threatens to completely overwhelm the programs and activities that the Coalition, our affiliated organizations, and the Coalition's individual members have been doing for more than a decade to uplift, support, and improve the lives of transgender, gender nonconforming, and intersex Latinx people in the United States. The harm to the TransLatin@ Coalition will be long-lasting and difficult, if not near impossible, to undo.

* * * * *

56. The Revised Rule poses serious and ongoing threats to the health and overall wellbeing of transgender and gender nonconforming people like the TransLatin@ Coalition's

members and the thousands of transgender and gender nonconforming individuals the Coalition and its affiliated organizations collectively serve in communities across the United States. The Revised Rule also threatens the ability of the TransLatin@ Coalition to fulfill its mission and engage in core programmatic activities.

[*Signature on next page*.]

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Dated this 6th day of July, 2020.

Bamby Salcedo, M.A.
President/CEO
The TransLatin@ Coalition

EXHIBIT A

2015 U.S. Transgender Survey: Report on the Experiences of Latino/a Respondents

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2015 U.S. TRANSGENDER SURVEY

Report on the Experiences of Latino/a Respondents

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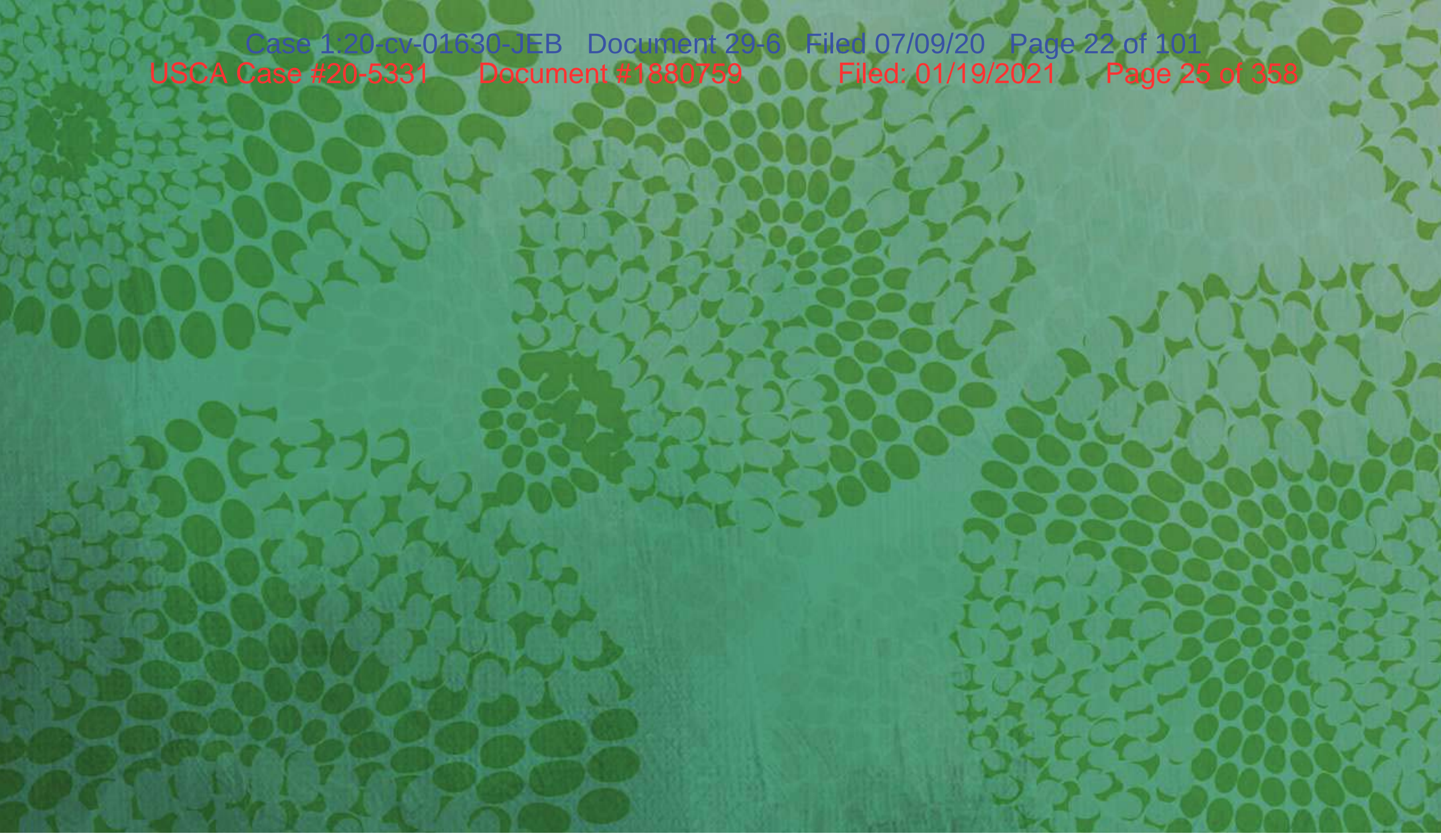

Introduction

The 2015 U.S. Transgender Survey (USTS) is the largest survey examining the experiences of transgender people in the United States, with 27,715 respondents nationwide. The USTS was conducted by the National Center for Transgender Equality in the summer of 2015 and was offered online in English and Spanish. The results provide a detailed look at the experiences of transgender people across a wide range of categories, such as education, employment, family life, health, housing, and interactions with the criminal justice system.

The Report of the 2015 U.S. Transgender Survey documented the experiences of USTS respondents, including differences based on demographic and other characteristics.[1] Among the most important findings was that many respondents were impacted by the compounding effects of multiple forms of discrimination, and transgender people of color who completed the survey experienced deeper and broader forms of discrimination than white USTS respondents and people in the U.S. population overall.

This report focuses on the unique experiences of the 1,473 USTS respondents who identified as Latino/a or Hispanic,[2] highlighting disparities between the experiences of Latino/a transgender people, other USTS respondents, and the U.S. population.[3] While the findings in this report reflect a range of Latino/a transgender people in the United States, the survey likely did not fully capture the experiences of those who were most affected by factors that may limit access to online surveys, such as factors related to language, education, economic and housing stability, and disabilities. All findings in this report are presented as weighted percentages.[4]

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Key Findings

- **21% of Latino/a respondents were unemployed**, three times the rate among Latino/a people in the U.S. population (7%).
- **43% of Latino/a respondents were living in poverty**, compared to 18% of Latino/a people in the U.S. population.
- **31% of Latino/a respondents have experienced homelessness at some point in their lives** and **14% experienced homelessness in the past year because of being transgender.**
- **48% of Latino/a respondents have been sexually assaulted at some point in their lifetimes** and **12% of Latino/a respondents were sexually assaulted in the past year**.
- **59% of Latino/a respondents said they would feel somewhat or very uncomfortable asking the police for help**, compared to 53% of white respondents in the USTS sample.
- **32% of Latino/a respondents who saw a health care provider in the past year reported having at least one negative experience related to being transgender**, such as being refused treatment, being verbally harassed, being physically or sexually assaulted, or having to teach the provider about transgender people in order to get appropriate care.
- **1.6% of Latino/a respondents were living with HIV**, more than five times higher than the rate in the U.S. population (0.3%).
- **45% of Latino/a respondents experienced serious psychological distress in the month before completing the survey** (based on the Kessler 6 Psychological Distress Scale), nine times the rate in the U.S. population (5%).

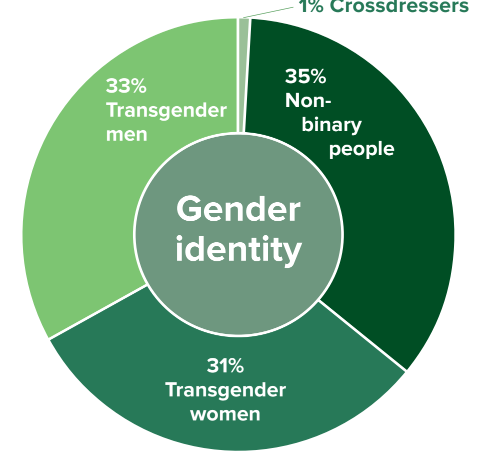
Portrait of Latino/a Respondents

This section outlines aspects of Latino/a respondents' identities and demographic characteristics, such as gender, age, geographic location, and educational attainment, to provide important context for their experiences.

Gender Identity

Thirty-five percent (35%) of Latino/a respondents were non-binary,[5] 33% were transgender men, 31% were transgender women, and 1% identified as crossdressers[6] (Figure 1).

Figure 1: Gender identity



Experiences with Transitioning

Sixty-one percent (61%) of Latino/a respondents were currently living full time in a gender that was different from the one on their original birth certificates, referred to in this report as having transitioned. This included 72% of transgender men and women and 42% of non-binary respondents. More than one in five (21%) respondents who had transitioned did so before the age of 18, nearly half (47%) transitioned between the ages of 18 and 24, 22% transitioned between ages 25 and 34, and 11% transitioned at age 35 or older.

Respondents were asked how much time had passed since they began transitioning. Nearly one-third (29%) began their transition within one year of taking the survey, 38% transitioned 2 to 5 years prior, 15% transitioned 6 to 9 years prior, and 18% transitioned 10 or more years prior.

Outness

Respondents were asked whether different groups of people in their lives knew that they were transgender to determine if they were "out" about their transgender identity to family members, friends, supervisors and coworkers, classmates, and health care providers. Specifically, they were asked whether all, most, some, or none of the people in each of those groups knew they were transgender.

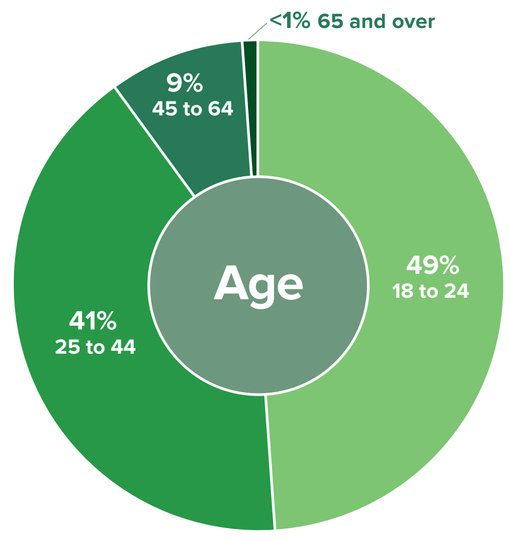
Results for outness to any particular group reflect only those respondents who had people from that group in their lives. Overall, 7% reported that they were out to all of the people in their lives, across all groups of people, 44% were out to most, 46% were out to some, and 2% were out to none of the people in their lives.

Sixty percent (60%) of respondents were out to all or most of the immediate family that they grew up with, and 36% were out to all or most of their extended family. Respondents were less likely to be out to at work or school: approximately one-half reported that none of their current supervisors (50%) or coworkers (42%) knew that they were transgender, and 51% reported that none of their classmates at their current school knew they were transgender.

Age

Most respondents were between the ages of 18 and 24 (49%) or 25 and 44 (41%) (Figure 2).

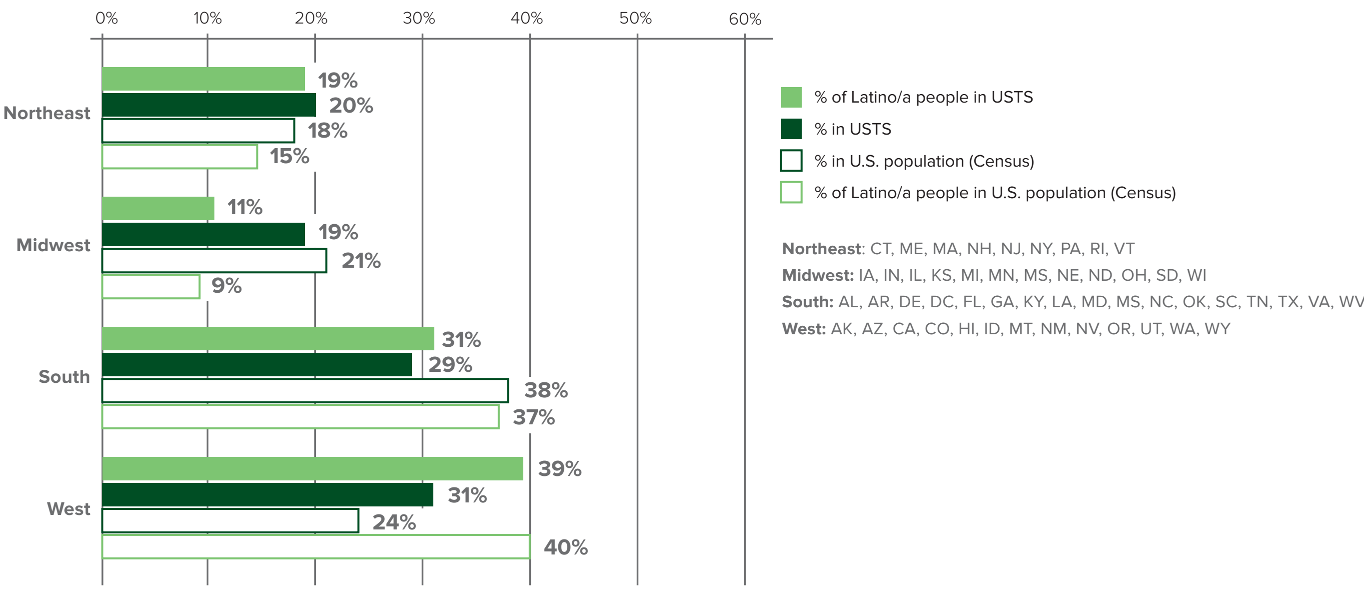
Figure 2: Age



Location

Respondents lived in 48 states, the District of Columbia, and Puerto Rico. The geographical distribution of USTS Latino/a respondents differed from the distribution in the USTS sample overall but was generally similar to the distribution of Latino/a people in the U.S. population. Latino/a respondents were more likely to live in the West (39%) than respondents in the USTS sample overall (31%), similar to the trend in the U.S. population, where Latino/a people were more likely to live in the West (40%) than the U.S. population overall (24%)[7] (Figure 3).

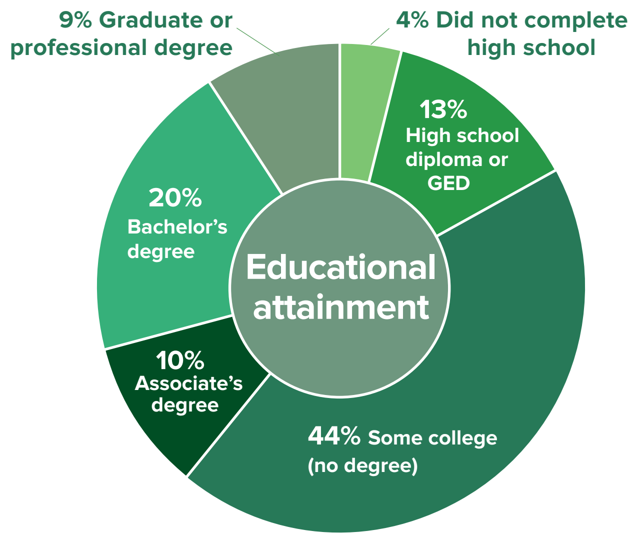
Figure 3: Location by region



Educational Attainment

Respondents were asked about the highest level of education that they had completed. Seventeen percent (17%) had a high school diploma or GED or did not complete high school. Forty-four percent (44%) had completed some college but had not obtained a degree, and 29% had received a bachelor's degree or a higher degree (Figure 4).

Figure 4: Educational attainment



Disability

Respondents received questions about their disability status based on questions from the American Community Survey (ACS) in order to compare the USTS sample to the U.S. population. Disabilities listed in the ACS included (1) being deaf or having serious difficulty hearing, (2) being blind or having serious difficulty seeing even when wearing glasses, (3) having serious difficulty concentrating, remembering, or making decisions because of a physical, mental, or emotional condition, (4) having serious difficulty walking or climbing stairs, (5) having difficulty dressing or bathing, and (6) having difficulty doing errands alone, such as visiting a doctor's office or shopping because of a physical, mental, or emotional condition. Forty percent (40%) of Latino/a respondents indicated that they had one or more disabilities listed in the ACS, similar to the rate in the USTS sample overall (39%). In contrast, only 15% in the U.S. population had a disability listed in the ACS.[8]

Respondents were also asked if they identified as a person with a disability to better capture disabilities that were not included in the ACS. One in four (25%)

Latino/a respondents identified as people with disabilities, compared to 28% in the USTS sample overall. The term "people with disabilities" used in this report refers to respondents who identified as people with disabilities.

Relationship Status

Twenty-seven percent (27%) of respondents were living with a partner, 20% were partnered and living separately, 51% were single, 1% were in a polyamorous relationship, and 1% had a relationship status that was not listed. Respondents were asked about their current legal marital status for the purpose of comparison to the U.S. population. Fourteen percent (14%) of Latino/a respondents were currently married, in contrast to 46% of Latino/a people in the U.S. population.[9] Eighty-one percent (81%) of respondents had never been married, which is nearly twice the rate among Latino/a people in the U.S. population (42%).

Sexual Orientation

Respondents were asked which terms best described their sexual orientation. Respondents were most likely to identify as queer (21%), straight (19%), or pansexual (19%). They also identified as gay, lesbian, or same-gender-loving (13%), bisexual (13%), and asexual (11%).

Citizenship and Immigration Status

Respondents were asked about their citizenship or immigration status. Ninety-two percent (92%) of Latino/a respondents were citizens, including 7% who were naturalized citizens. Latino/a respondents also reported a range of immigration statuses, including being permanent residents (3%), undocumented residents (2%), Deferred Action for Childhood Arrival (DACA) recipients (1%), and visa holders (1%).

Family Life and Faith Communities

Family Life

Eighty-seven percent (87%) of respondents were out as transgender to a current or former partner. Of those who were out to a current or former partner, 24% had a partner end their relationship solely or partly because they were transgender, including 10% who had a partner end their relationship solely because they were transgender. Nearly two-thirds (62%) of respondents who had children were out to one or more of their children, and 15% of those respondents had a child stop speaking to them or spending time with them after coming out as transgender.

Sixty percent (60%) of respondents who were out to at least some of the immediate family they grew up with reported that their family was generally supportive, 19% had unsupportive families, and 21% had families that were neither supportive nor unsupportive. Nearly one-half (49%) experienced at least one form of family rejection outlined in the survey, such as having a family member who stopped speaking to them for a long time or ended the relationship, experiencing violence by a family member, or being kicked out of the house for being transgender (Table 1).

Table 1: Forms of family rejection

(of those out to immediate family)	% of Latino/a people in USTS	% in USTS
Stopped speaking to them or ended relationship	28%	26%
Did not allow them to wear clothes that matched gender	32%	27%
Sent them to a professional to stop them from being transgender	16%	14%
Were violent towards them	12%	10%
Kicked them out of the house	11%	8%
One or more experiences listed	**49%**	**44%**

Transgender women (37%) were more likely to have an immediate family member stop speaking to them for a long time or end a relationship because they were transgender, compared to transgender men (30%) and non-binary people (14%). Transgender women (16%) were more likely to experience violence by a family member because they were transgender than non-binary people (13%) and transgender men (10%). Transgender women (15%) were also more likely to have been kicked out of the house than transgender men (10%) and non-binary people (6%).

Additionally, 12% of those who were out to their immediate family ran away from home because they were transgender, with transgender women (17%) being more likely to have run away than transgender men (10%) and non-binary people (10%).

Although approximately half of those who were out to their immediate family reported at least one experience of rejection from a family member, 81% reported that at least one immediate family member supported them through one or more specific acts, such as using their preferred name or pronouns, giving them money to support their transition, or helping them to change the name or gender on an identity document (Table 2).

Table 2: Supportive family behaviors

(of those out to immediate family)	% of Latino/a people in USTS	% in USTS
Told respondent they respect or support them	66%	65%
Used their preferred name	56%	58%
Used the correct pronouns	54%	55%
Stood up for them with family, friends, or others	38%	36%
Did research to learn how to best support them	29%	33%
Gave money to help with gender transition	19%	18%
Helped them change their name and/or gender on an identity document	11%	10%
Supported them in another way	10%	11%
One or more experiences listed	**81%**	**82%**

Faith Communities

Nearly two-thirds (62%) of Latino/a respondents had been part of a spiritual or religious community ("faith community") at some point in their lives. Of these, more than one in five (21%) left a faith community because they were rejected as a transgender person. That experience was more likely among transgender women (33%) than transgender men (22%) and non-binary people (13%). Thirty-seven percent (37%) of those who had been rejected by a faith community found a new faith community that welcomed them as a transgender person.

More than one-quarter (27%) of respondents who had ever been part of a faith community were part of one in the year prior to taking the survey. These respondents reported a range of experiences within their faith communities. Ninety-seven percent (97%) experienced one or more accepting behaviors from members of their faith community, such as having a community leader or member who accepted them or made them feel welcome as a transgender person or being told that their religion or faith accepts them as a transgender

person. However, 20% had one or more experiences of rejection, such as being asked to stop coming to services or faith community functions or having a community member tell them that being transgender is a sin or that their religion does not approve of them.[10]

Income and Employment

Unemployment

More than one in five (21%) Latino/a respondents were unemployed, compared to 15% in the USTS sample overall. The unemployment rate among Latino/a respondents was more than four times higher than the unemployment rate in the U.S. population overall (5%)[11] and three times the rate among Latino/a people in the U.S. population (7%) (Figure 5).[12] The unemployment rate differed by gender, with transgender Latinas (27%) being more likely to be unemployed (Figure 6). Respondents with disabilities (27%) were also more likely to be unemployed.

Figure 5: Unemployment

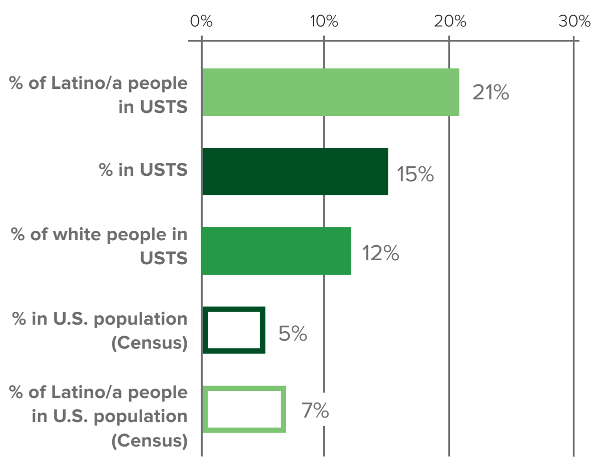
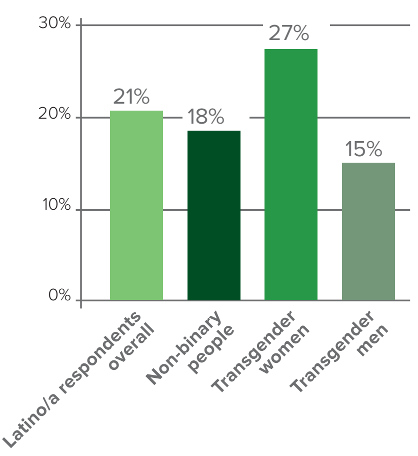


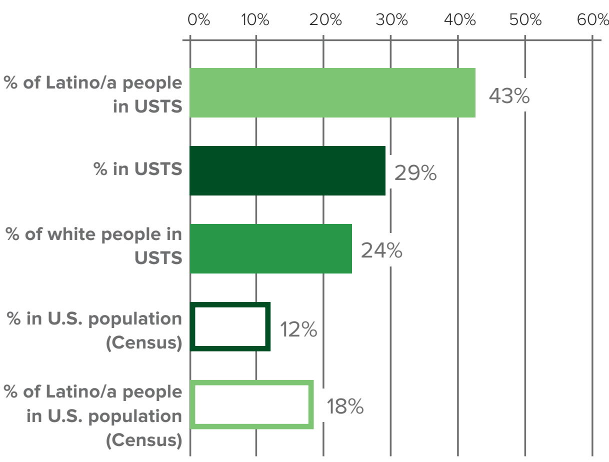
Figure 6: Unemployment (by gender)



Poverty

More than four out of ten (43%) Latino/a respondents were living in poverty,[13] compared to 29% in the USTS sample overall. This was substantially higher than the poverty rate in the U.S. population overall (12%)[14] and the poverty rate among Latino/a people in the U.S. population (18%) (Figure 7).[15] The poverty rate was higher among transgender women (45%) and non-binary people (43%) than among transgender men (36%).

Figure 7: Living in poverty



Sources of Income

Latino/a respondents' most common source of income was from their own employment or a partner's employment alone (40%), compared to those in the USTS sample overall (36%). More than one-third (35%) of Latino/a respondents reported that they received income from multiple sources, in contrast to 45% in the USTS sample overall. One in ten (10%) Latino/a respondents reported that their sole source of income was Supplemental Security Income (SSI) or disability benefits, compared to 9% in the USTS sample overall (Table 3).

Table 3: Current sources of income

Sources of income	% of Latino/a people in USTS	% in USTS
Employment only (from their own employment, partner's employment, or self-employment)	40%	36%
Supplemental Security Income (SSI) or disability benefits only	10%	9%
Pension or retirement income only	3%	3%
Unemployment benefits or public cash assistance program only	2%	1%
Pay from sex work, drug sales, or other work that is currently criminalized only	2%	1%
Other sources only	6%	3%
No income	2%	2%
Multiple sources	35%	45%

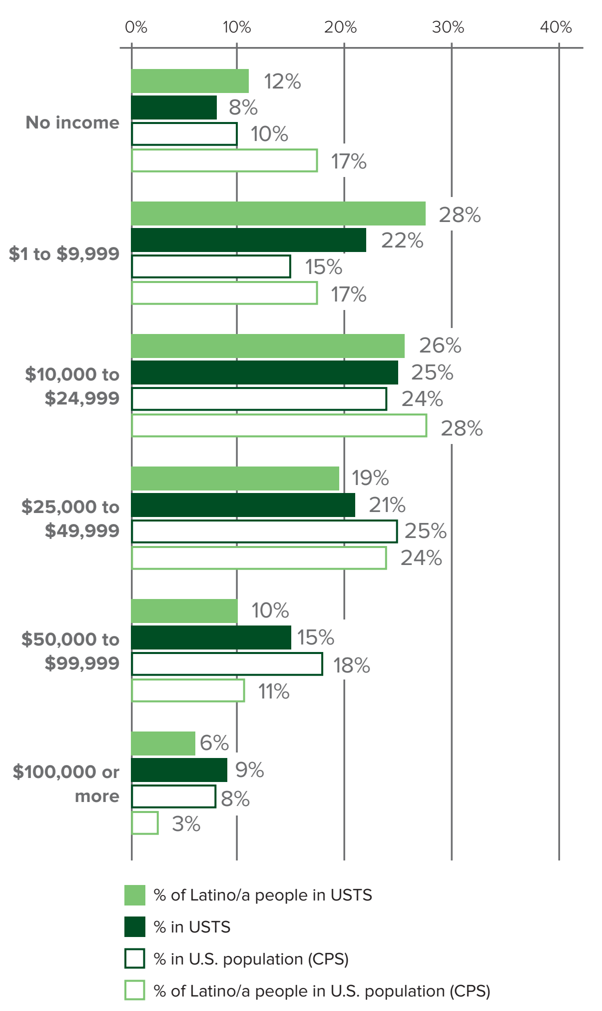
Military Service

Seven percent (7%) of Latino/a respondents have served in the military, including respondents who were currently serving in the military on active duty (<1%) and those who were currently on active duty for training in the Reserves or National Guard (1%). Six percent (6%) of respondents were veterans, similar to the rate in the U.S. population overall (8%), but higher than the rate among Latino/a people in the U.S. population (3%).[16]

Individual and Household Income

Respondents reported their annual individual and household income levels from 2014, the last full year prior to completing the survey. More than one-quarter (28%) of Latino/a respondents reported an *individual income* of $1 to $9,999, compared to 22% in the USTS sample overall.

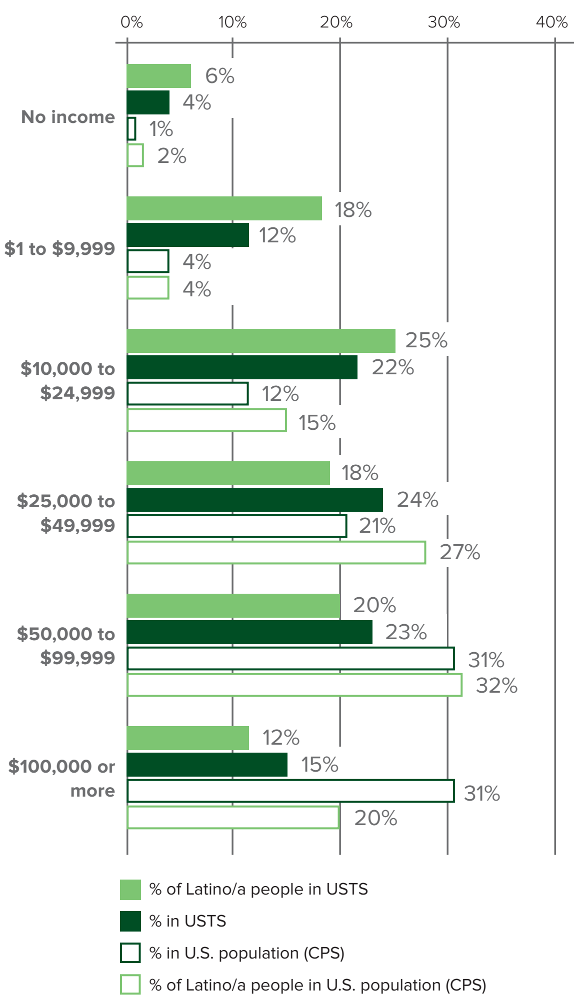
Figure 8: Annual individual income (2014)



Latino/a respondents were also substantially more likely to report this low individual income than Latino/a people in the U.S. population (17%)[17] (Figure 8).

Nearly one in five (18%) Latino/a respondents reported a *household income* of $1 to $9,999, compared to 12% in the USTS sample overall, and nearly five times the rate among Latino/a people in the U.S. population (4%) (Figure 9).

Figure 9: Annual household income (2014)

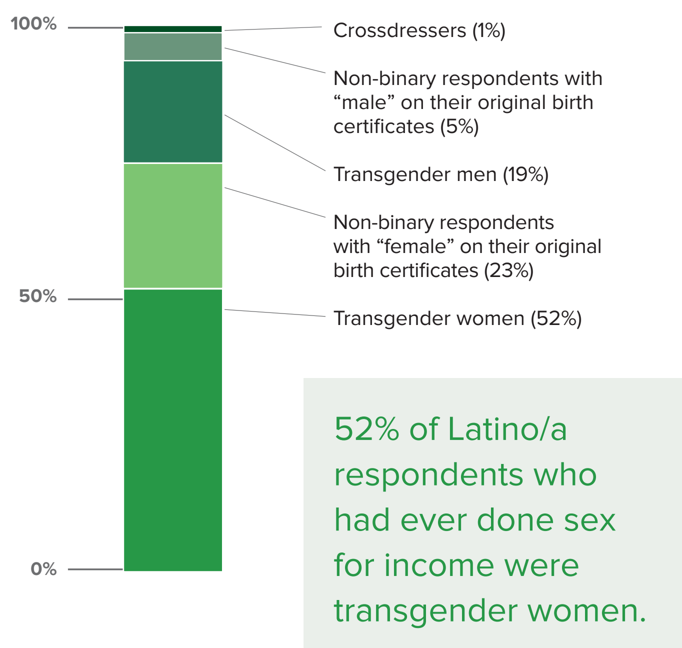


Sex Work and Other Underground Economy Work

Nearly one-quarter (22%) of Latino/a respondents have participated in the underground economy for income at some point in their lives, including in sex work, drug sales, and other currently criminalized work, similarly to 20% in the USTS sample overall. One in ten (10%) Latino/a respondents participated in the underground economy for income in the past year.

Thirteen percent (13%) of Latino/a respondents participated in sex work for income, compared to 12% in the USTS sample overall and 9% of white respondents. Examining the composition of those who have done sex work, transgender women represent more than one-half (52%) of Latino/a respondents who have done sex work for money in their lifetimes. Although Latinas represent a disproportionately high percentage of those who have done sex work, it is also important to recognize that non-binary people with "female" on their original birth certificates and transgender men account for a large proportion of those who have done sex work. Non-binary people with "female" on their original birth certificates represent nearly one-quarter (23%) of respondents who have done sex work for money in their lifetimes, and transgender men represent 19% (Figure 10).

Figure 10: Gender identity of those who have done sex work for income in their lifetimes



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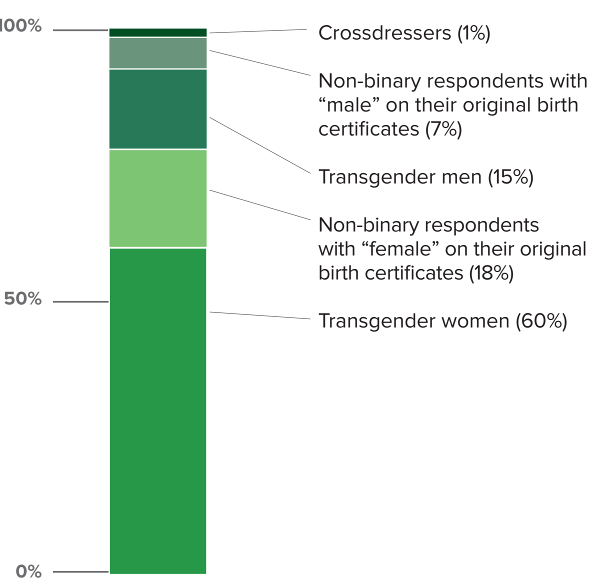
Six percent (6%) of Latino/a respondents participated in sex work for income in the past year. Examining the makeup of those who did sex work for income in the past year, transgender women represent more than one-half (60%), 18% were non-binary people with "female" on their original birth certificates, and 15% were transgender men (Figure 11).

Figure 11: Gender identity of those who have done sex work for income in the past year



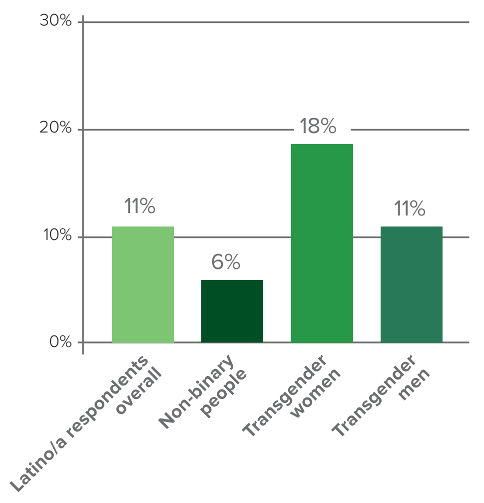
One in five (20%) respondents participated in sex work for money, food, a place to sleep, or other goods or services, compared to 19% in the USTS sample overall and 16% of white respondents.

Survey respondents were asked if they had ever interacted with police either while doing sex work or when police thought they were doing sex work. Of Latino/a respondents who had interacted with the police while doing or thought to be doing sex work, 84% reported some form of police harassment, abuse, or mistreatment, including being verbally harassed, physically attacked, or sexually assaulted by police, compared to 86% in the USTS sample overall and 82% of white respondents.

Experiences in the Workplace

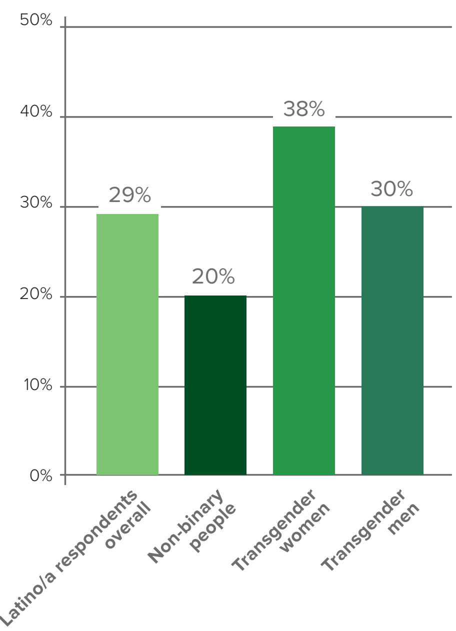
Fifteen percent (15%) of Latino/a respondents who have ever been employed reported losing a job at some point in their lives because of being transgender. This represents 11% of all Latino/a respondents, compared to 13% all respondents in the USTS. Transgender women (18%) were more likely to report being fired because of being transgender (Figure 12).

Figure 12: Ever lost job because of being transgender (by gender)



In the past year, 29% of those who held or applied for a job during that year reported being fired, being denied a promotion, or not being hired for a job they applied for because of being transgender, compared to 27% in the USTS sample overall. Transgender women (38%) were more likely to report this experience than transgender men (30%) and non-binary people (20%) (Figure 13).

Figure 13: Fired, denied promotion, and/or not hired in the past year because of being transgender (by gender)



Many respondents who had a job in the past year reported that they had been verbally harassed (14%), physically attacked (1%), and sexually assaulted (2%) at work during that year because of being transgender. More than one-quarter (27%) of respondents who were employed reported other forms of mistreatment based on their gender identity or expression during the past year, such as being forced to use a restroom that did not match their gender identity, being told to present in the wrong gender in order to keep their job, or having a boss or coworker share information about their transgender status with others without their permission.

Education

Nearly three-quarters (74%) of Latino/a respondents who were out or perceived as transgender at some point between Kindergarten and Grade 12 (K–12) experienced mistreatment, such as being verbally harassed, prohibited from dressing according to their gender identity, disciplined more harshly, or physically or sexually assaulted because people thought they were transgender. More than half (52%) of those who were out or perceived as transgender in K–12 were verbally harassed, 24% were physically attacked, and 16% were sexually assaulted in K–12 because of being transgender. Sixteen percent (16%) faced such severe mistreatment as a transgender person that they left a K–12 school, and 7% were expelled from school (Table 4).

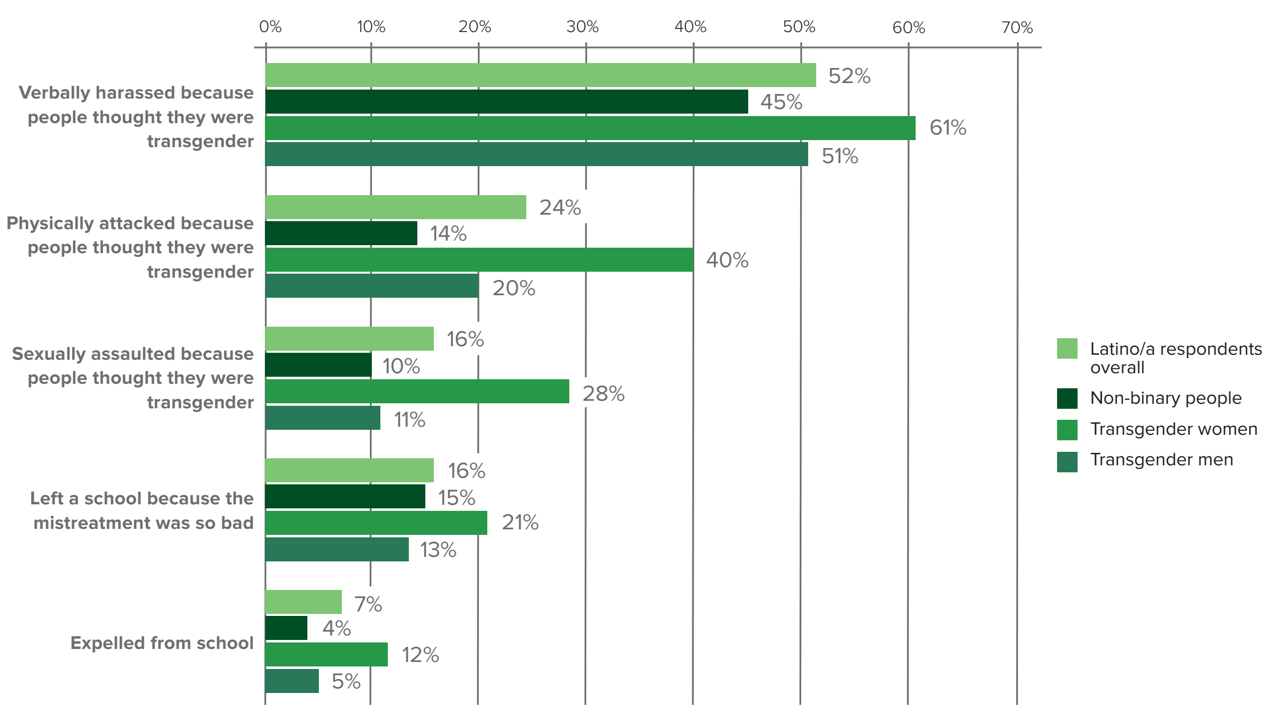
Table 4: Experiences of people who were out as transgender in K–12 or believed classmates, teachers, or school staff thought they were transgender

Negative experiences in school (out of those who were out or perceived as transgender)	% of Latino/a people in USTS	% in USTS
Not allowed to dress in a way that fit their gender identity or expression	55%	52%
Verbally harassed because people thought they were transgender	52%	54%
Disciplined for fighting back against bullies	35%	36%
Physically attacked because people thought they were transgender	24%	24%
Believe they were disciplined more harshly because teachers or staff thought they were transgender	24%	20%
Left a school because the mistreatment was so bad	16%	17%
Sexually assaulted because people thought they were transgender	16%	13%
Expelled from school	7%	6%
One or more experiences listed	**74%**	**77%**

Transgender women were more likely to have been verbally harassed (61%), physically attacked (40%), and sexually assaulted (28%) because people thought they were transgender in K–12. Transgender women were also more likely to have left a school because of mistreatment (21%) and to have been expelled from school (12%) (Figure 14).

Latino/a respondents also reported high levels of mistreatment in post-secondary schools. Nearly one-quarter (23%) of those who were out or perceived as transgender in college or vocational school were verbally, physically, or sexually harassed because of being transgender.

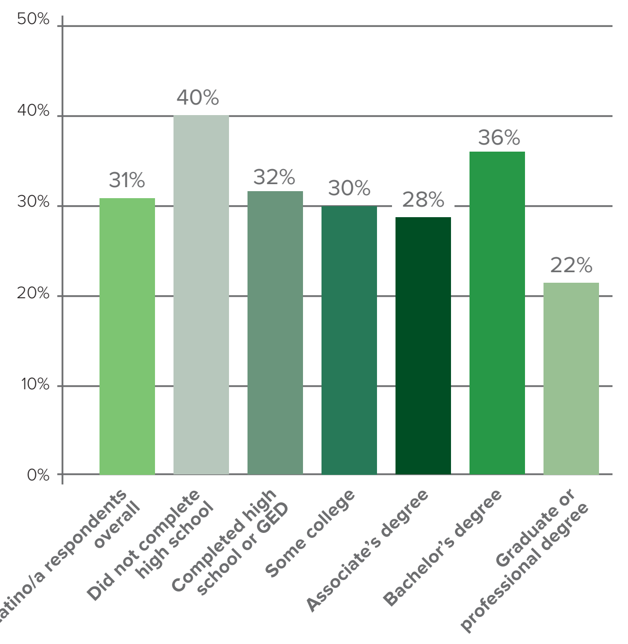
Figure 14: Experiences of people who were out as transgender in K–12 or believed classmates, teachers, or school staff thought they were transgender (by gender)



Housing, Homelessness, and Shelter Access

Nearly one-third (31%) of Latino/a respondents have experienced homelessness at some point in their lives. The rate of homelessness differed by educational attainment, with respondents who did not complete high school (40%) being more likely to have experienced homelessness (Figure 15). People with disabilities (39%) were also more likely to have experienced homelessness in their lifetimes.

Figure 15: Lifetime homelessness rate (by educational attainment)



In the past year, one-third (33%) of respondents experienced some form of housing discrimination or instability, such as being evicted from their home or denied a home or apartment because of being transgender.[18] Fourteen percent (14%) experienced homelessness in the past year because of being transgender, 6% were denied a home or apartment, and 6% were evicted because of being transgender (Table 5).

Table 5: Housing situations that occurred in the past year because of being transgender

Housing situation (out of those to whom situation applied)	% of Latino/a people in USTS	% in USTS
Had to move back in with family or friends	23%	20%
Slept in different places for short periods of time	17%	15%
Had to move into a less expensive home or apartment	16%	13%
Experienced homelessness	14%	12%
Denied a home or apartment	6%	6%
Evicted from a home or apartment	6%	5%
One or more experiences listed	**33%**	**30%**

More than one in five (22%) respondents who experienced homelessness in the past year avoided staying in a shelter because they feared being mistreated as a transgender person.

Public Accommodations

Respondents reported being denied equal treatment or service, verbally harassed, or physically attacked at many places of public accommodation—places that provide services to the public, like retail stores, hotels, and government offices. In the past year, out of respondents who visited a place of public accommodation where staff or employees thought or knew they were transgender, 30% experienced at least one type of mistreatment. This included 15% who were denied equal treatment or service, 23% who were verbally harassed, and 1% who were physically attacked because of being transgender (Table 6).

Transgender women (21%) were more likely to have been denied equal treatment or service compared to transgender men (11%) and non-binary people (12%). Transgender women (27%) and non-binary people (26%) were more likely to have experienced verbal harassment than transgender men (17%).

Table 6: Experiences in places of public accommodation in the past year due to being transgender

Experience at a place of public accommodation (out of those who believe staff knew or thought they were transgender)	% of Latino/a people in USTS
Denied equal treatment or service	15%
Verbally harassed	23%
Physically attacked	1%
One or more experiences listed	**30%**

Harassment and Violence

Overall Experiences of Unequal Treatment, Harassment, and Physical Attack

Nearly one-half (48%) of respondents reported being denied equal treatment, verbally harassed, and/or physically attacked in the past year because of being transgender. Fifteen percent (15%) were denied equal treatment or service in a public place and 45% were verbally harassed in the past year because of being transgender. Nearly one in ten (9%) were physically attacked in the past year because of being transgender (Table 7).

Transgender women (49%) and non-binary people (48%) were more likely to be verbally harassed in the past year because of being transgender than transgender men (40%). Transgender women (12%) and non-binary people (10%) were also more likely to be physically attacked in the past year because of being transgender, compared to transgender men (7%).

Table 7: Denial of equal treatment or service, verbal harassment, and physical attack in the past year because of being transgender

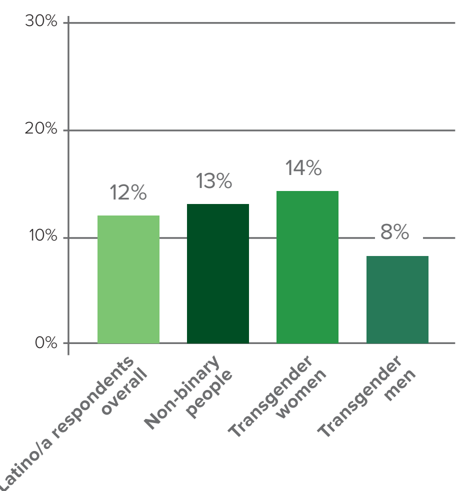
Experience in the past year due to being transgender	% of Latino/a people in USTS
Denied equal treatment or service	15%
Verbally harassed	45%
Physically attacked	9%
One or more experiences listed	**48%**

Sexual Assault

Nearly half (48%) of Latino/a respondents have been sexually assaulted at some point in their lifetimes, compared to 47% in the USTS sample overall and 45% of white respondents. People with disabilities (60%) reported a substantially higher rate of sexual assault in their lifetimes. Non-binary people with "female" on their original birth certificates (55%) were also more likely to have been sexually assaulted in their lifetimes (Figure 16).

Twelve percent (12%) of Latino/a respondents were sexually assaulted in the past year, compared to 10% in the USTS sample overall and 9% of white respondents. Transgender women (14%) and non-binary people (13%) were nearly twice as likely to have been sexually assaulted in the past year as transgender men (8%) (Figure 17). More than one-quarter (28%) of respondents who worked in the underground economy (such as in sex work, drug sales, and other currently criminalized activities) in the past year were sexually assaulted during that year.

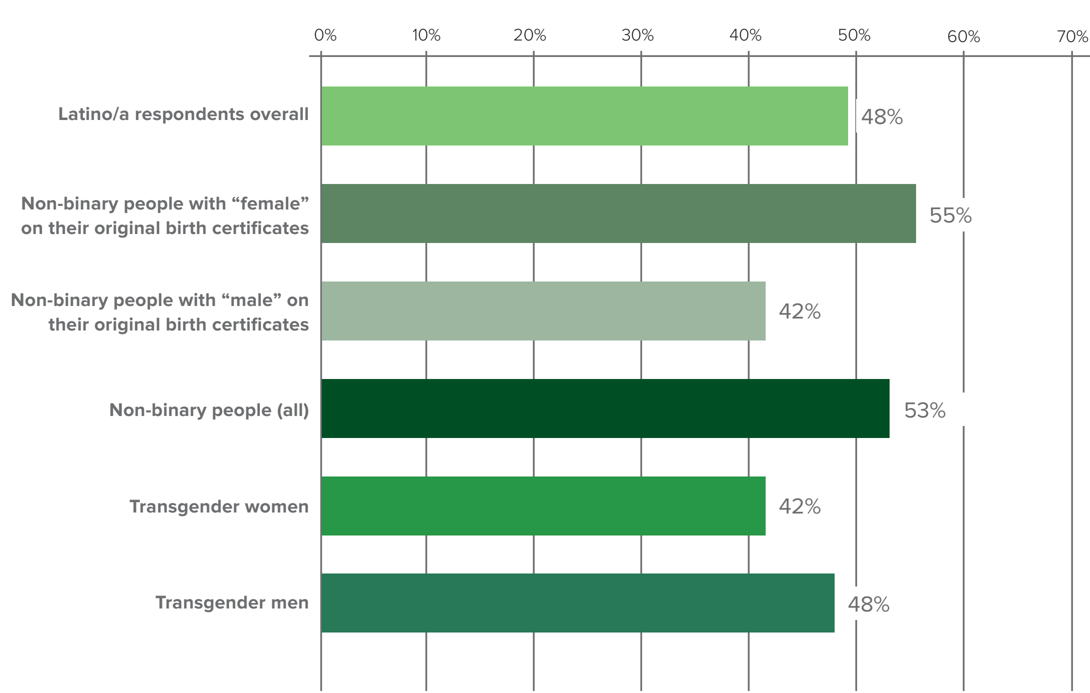
Figure 17: Sexual assault in the past year (by gender)



Intimate Partner Violence

Fifty-four percent (54%) of respondents experienced some form of intimate partner violence, including acts of coercive control[19] and physical violence. Transgender men (58%) were more likely to have experienced some form of

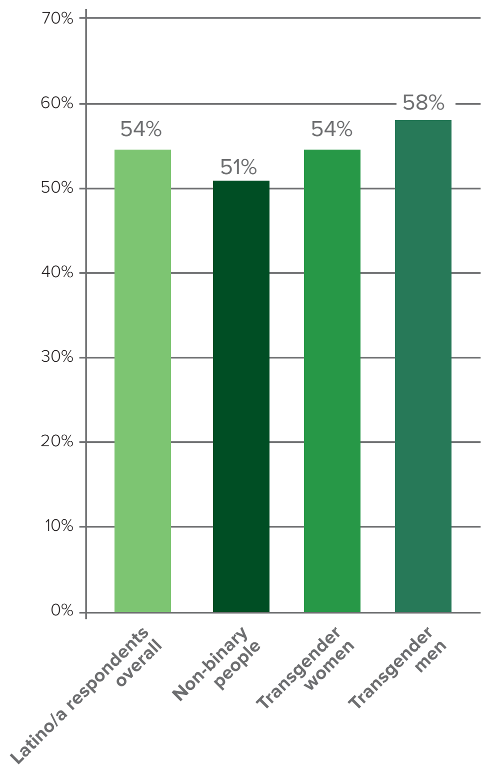
Figure 16: Sexual assault in lifetime (by gender)



intimate partner violence (Figure 18). Nearly three-quarters (74%) of respondents who have worked in the underground economy experienced intimate partner violence, and people with disabilities (62%) were also more likely to have experienced intimate partner violence.

More than one-quarter (27%) of respondents reported acts of coercive control by an intimate partner related to their transgender status, including being told that they were not a "real" woman or man, threatened with being "outed" by having their transgender status revealed to others, or prevented from taking their hormones. Forty-three percent (43%) experienced physical violence by an intimate partner.

Figure 18: Experienced intimate partner violence (by gender)



Police Interactions, Prisons, and Immigration Detention

Latino/a respondents experienced high levels of mistreatment and harassment by police. In the past year, out of respondents who interacted with police or other law enforcement officers who thought or knew they were transgender, 66% experienced some form of mistreatment, compared to 58% of USTS respondents overall and 55% of white respondents. This included being verbally harassed, repeatedly referred to as the wrong gender, or physically or sexually assaulted (Table 8).

Table 8: Mistreatment by police or other law enforcement officers in past year

Experience of mistreatment in the past year	% of Latino/a people in USTS	% in USTS	% of white people in USTS
Officers kept using the wrong gender pronouns (such as he/him or she/her) or wrong title (such as Mr. or Ms.)	55%	49%	46%
Verbally harassed by officers	29%	20%	17%
Officers asked questions about gender transition (such as about hormones or surgical status)	26%	19%	16%
Officers assumed they were sex workers	14%	11%	8%
Physically attacked by officers	5%	4%	2%
Sexually assaulted by officers	5%	3%	2%
Forced by officers to engage in sexual activity to avoid arrest	1%	1%	<1%
One or more experiences listed	**66%**	**58%**	**55%**

Fifty-nine percent (59%) of Latino/a respondents said they would feel somewhat or very uncomfortable asking the police for help if they needed it, compared to 57% of respondents in the USTS sample overall and 53% of white USTS respondents (Figure 19). Non-binary people (73%) were more likely to be uncomfortable asking the police for help, in contrast to transgender men (55%) and women (52%) (Figure 20). Nearly three-quarters (73%) of people with disabilities were uncomfortable asking the police for help.

Four percent (4%) of Latino/a respondents were arrested in the past year, compared to 2% in the USTS sample. Two percent (2%) of Latino/a respondents were incarcerated—held in jail, prison, or juvenile detention—in the past year, compared to 0.9% in the U.S. population overall.[20]

Latino/a respondents who were held in jail, prison, or juvenile detention in the past year faced high rates of physical and sexual assault by facility

Figure 19: Comfort asking the police for help

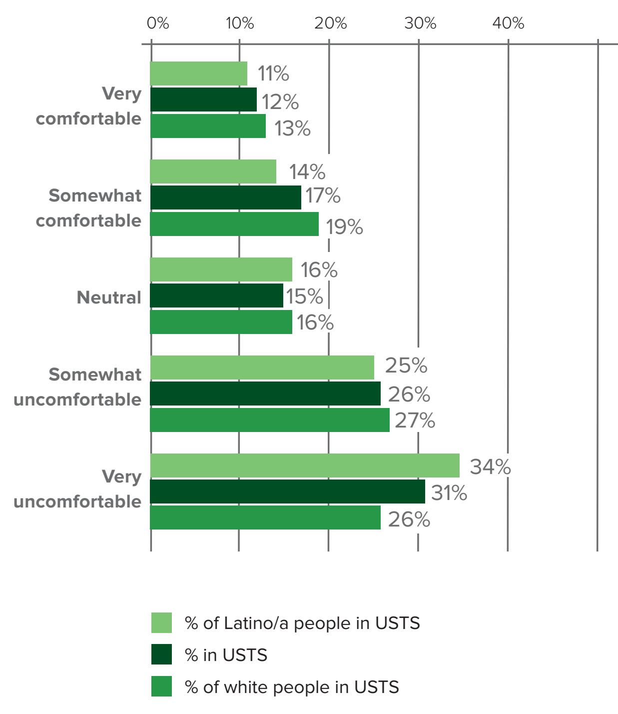
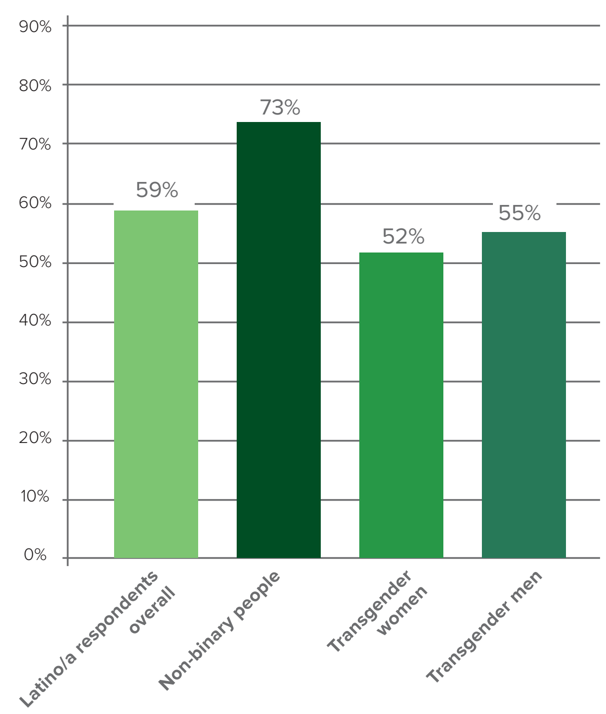


Figure 20: Somewhat or very uncomfortable asking the police for help (by gender)



staff and other inmates. In the past year, 18% were physically assaulted by *staff or other inmates*, compared to 23% in the USTS sample overall. More than one-quarter (27%) were sexually assaulted by *staff or other inmates*, compared to 20% in the USTS sample overall.

Fourteen percent (14%) of Latino/a respondents were sexually assaulted by *facility staff* in the past year during their time in jail, prison, or juvenile detention, compared to the rate in the USTS sample overall (11%). This was seven times higher than the rate in the incarcerated U.S. population in prisons (2%) and in jails (2%).[21]

Additionally, five percent (5%) of Latino/a respondents who were not U.S. citizens at the time of their birth have been held in immigration detention, such as in an Immigration and Customs Enforcement (ICE) detention center or a local jail just for immigration court proceedings. This represents 1% of all Latino/a respondents.

Health

Insurance

Seventeen percent (17%) of Latino/a respondents did not have health insurance, compared to 14% in the USTS sample overall and 12% of white respondents. This was higher than the rate in U.S. population overall (11%) but lower than the rate among Latino/a people in the U.S. population (25%).[22] The most common forms of insurance reported by Latino/a respondents included coverage they or a family member received through an employer (50%), followed by Medicaid (16%) (Table 9).

One-quarter (25%) of respondents experienced a problem in the past year with their insurance related to being transgender, such as being denied coverage for care related to gender transition or being denied coverage for other kinds of health care because they were transgender.

Experiences with Providers

Nearly one-third (32%) of respondents who saw a health care provider in the past year reported having at least one negative experience related to being transgender. This included being refused treatment, being verbally harassed, being

Table 9: Type of health insurance or health coverage plan

Health insurance source	% of Latino/a people in USTS	% in USTS	% in U.S. population (ACS)
Insurance through current or former employer or union (belonging to respondent or a family member)	50%	53%	56%
Medicaid	16%	13%	15%
Insurance they or someone else purchased directly from an insurance company or through a health insurance marketplace (such as healthcare.gov)	14%	14%	16%
Medicare	2%	5%	22%
VA	2%	2%	3%
TRICARE or other military health care	1%	2%	3%
Another type of insurance	6%	6%	---

physically or sexually assaulted, or having to teach the provider about transgender people in order to get appropriate care.

In the past year, more than a quarter (26%) of respondents did not see a doctor when they needed to because of fear of being mistreated as a transgender person, and 37% did not see a doctor when needed because they could not afford it.

HIV Status

Fifty-four percent (54%) of Latino/a respondents had been tested for HIV, a rate similar to the USTS sample overall (55%) but higher than in the U.S. population (34%).[23] Among those who had not been tested, 83% of Latino/a respondents said that it was primarily because they were unlikely to have been exposed to HIV. Latino/a respondents who had not been tested were slightly less likely to cite this reason than USTS respondents overall (86%) and those in the general U.S. population (86%).[24]

Among Latino/a respondents, 1.6% reported that they were living with HIV, compared to the rate in the USTS sample overall (1.4%) and among white respondents (0.4%). This was more than five times higher than the rate in the U.S. population (0.3%)[25] and more than three times higher than the rate among Latino/a people in the U.S. population (0.5%).[26] Transgender women (4.4%) were nearly three times more likely than Latino/a USTS respondents overall to be living with HIV (Figure 21) and respondents who did not complete high school (9.3%) were nearly six times more likely to be living with HIV (Figure 22). Additionally, 52% of Latino/a respondents were HIV negative, and 46% had not been tested or did not know the results of their HIV test.

Psychological Distress

Forty-five percent (45%) of Latino/a respondents experienced serious psychological distress in the month before completing the survey (based on

1.6% of Latino/a USTS respondents were living with HIV.

- **4X** higher than the rate among white USTS respondents (0.4%)
- **5X** higher than the rate in the U.S. population overall (0.3%)
- **3X** higher than the rate among Latino/a people in the U.S. population (0.5%)

4.4% of transgender Latinas were living with HIV, 15X the rate in the U.S. population (0.3%).

Figure 21: Living with HIV (by gender)

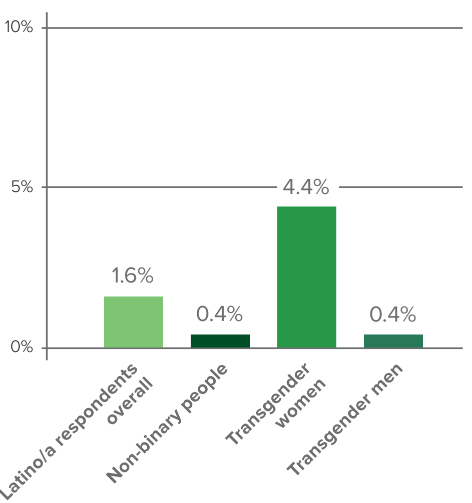
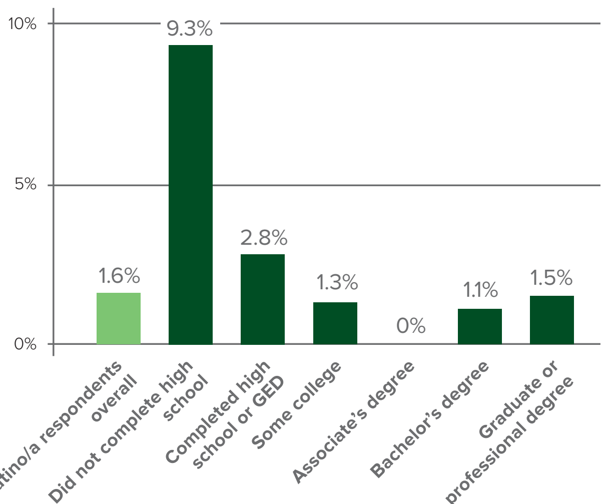


Figure 22: Living with HIV (by educational attainment)



the Kessler 6 Psychological Distress Scale),[27] nine times higher than the rate in the U.S. population (5%) and the rate among Latino/a people in the U.S. population (5%).[28]

Conversion Therapy

One in eight (12%) reported that a professional, such as a psychologist, counselor, or religious advisor, tried to stop them from being transgender.

Suicidal Thoughts and Behaviors

Nearly half (45%) of Latino/a respondents have attempted suicide at some point in their lives, compared to 40% in the USTS sample overall and 37% of white respondents. This rate was nearly ten times higher than the rate in the U.S. population (4.6%).[29] Latino/a respondents with disabilities (60%) were substantially more likely to have attempted suicide in their lifetimes.

Nearly one in ten (9%) Latino/a respondents attempted suicide in the past year, compared to 7% in the USTS sample overall and 6% of white respondents. This rate was fifteen times higher than the rate in the U.S. population (0.6%) and the rate among Latino/a people in the U.S. population (0.6%).[30] Latino/a respondents with disabilities (14%) were more likely to have attempted suicide in the past year.

Identity Documents

Only 10% of respondents reported that *all* of their identity documents (IDs) had the name and gender they preferred, while 71% reported that *none* of their IDs had the name and gender they preferred. The cost of changing IDs was one of the main barriers respondents faced, with 42% of those who have not changed their legal name and 38% of those who have not updated the gender on their IDs reporting that it was because they could not afford it.

More than one-third (35%) of respondents who have shown an ID with a name or gender that did not match their gender presentation were verbally harassed, denied benefits or service, asked to leave, or assaulted.

Experiences of Multiracial Latino/a Respondents

In addition to respondents who identified as Latino/a alone in the USTS, 549 respondents identified as multiracial and Latino/a or "a racial/ethnic identity not listed" and Latino/a. This section provides a brief overview of the experiences of these respondents, referred to here as multiracial Latino/a respondents. Additional research is needed to further examine the experiences of multiracial respondents.

- 21% of multiracial Latino/a respondents were unemployed.
- 50% were living in poverty.
- 23% of multiracial Latino/a respondents who have been employed reported losing a job at some point in their lives because of being transgender.
- In the past year, 34% of those who held or applied for a job during that year reported being fired, being denied a promotion, or not being hired for a job they applied for because of being transgender.
- In the past year, 17% were denied equal treatment or service in a public place and 57% were verbally harassed because of being transgender.
- In the past year, 12% were physically attacked because of being transgender and 15% were sexually assaulted. More than half (59%) have been sexually assaulted at some point in their lives.
- In the past year, out of respondents who interacted with police or other law enforcement officers who thought or knew they were transgender, 78% experienced some form of mistreatment. This included being verbally harassed, repeatedly referred to as the wrong gender, physically assaulted, or sexually assaulted.
- 80% of those who were out or perceived as transgender at some point between Kindergarten and Grade 12 (K–12) experienced some form of mistreatment, such as being verbally harassed (58%), physically attacked (31%), or sexually assaulted (16%) in K–12 because of being transgender.

Experiences of Multiracial Latino/a Respondents (continued)

- 42% of multiracial Latino/a respondents have experienced homelessness at some point in their lives.
- 20% experienced homelessness in the past year because of being transgender.
- In the past year, 29% of multiracial Latino/a respondents did not see a doctor when they needed to because of fear of being mistreated as a transgender person, and 43% did not see a doctor when needed because they could not afford it.
- 34% of those who saw a health care provider in the past year reported having at least one negative experience related to being transgender, such as being refused treatment, being verbally harassed, being physically or sexually assaulted, or having to teach the provider about transgender people in order to get appropriate care.

Endnotes

1. James, S. E., Herman, J. L., Rankin, S., Keisling, M., Mottet, L., & Anafi, M. (2016). *The Report of the U.S. Transgender Survey*. Washington, DC: National Center for Transgender Equality. Available at: www.USTransSurvey.org.
2. Throughout this report, respondents who identified as Latino/a or Hispanic are referred to as Latino/a. For additional information about terminology and conventions used throughout the report, see the *Guide to Report and Terminology* chapter in the full USTS report. The findings for Latino/a respondents reflect the experiences of respondents who identified as Latino/a alone and do not include the experiences of those who identified as multiracial and Latino/a. Some findings for respondents who identified as multiracial and Latino/a are included on page 22 of this report.
3. The U.S. Census Bureau defines and asks about race and ethnicity separately, with ethnicity being categorized as "Hispanic or Latino" and "Not Hispanic or Latino." U.S. Census Bureau surveys, such as the Decennial Census, American Community Survey, and Current Population Survey, first ask whether a respondent is of Hispanic or Latino origin to determine their ethnicity and then ask respondents their race. See e.g., U.S. Census Bureau. (2017). *Race and Ethnicity.* Available at: https://www.census.gov/mso/www/training/pdf/race-ethnicity-onepager.pdf. In contrast, USTS respondents received a question about their "racial/ethnic identity" and could select "Latino/a/Hispanic" as a racial/ethnic category. Therefore, comparisons to Latino/a people in the U.S. population presented throughout this report should be interpreted with caution.
4. The number of Latino/a respondents (n=1,473) is an unweighted value. All reported percentages are weighted to allow for comparison to the U.S. population when appropriate. Findings related to income, unemployment, and poverty are weighted differently than other reported percentages. For more information on the weighting procedures used to report 2015 U.S. Transgender Survey data, see the full survey report. Findings from statistical tests are not included in this report.
5. "Non-binary" is a term often used to describe people whose gender is not exclusively male or female, including those who identify with a gender other than male or female, as more than one gender, or as no gender.
6. Due to a low sample size, it was often not possible to include the experiences of crossdressers in gender-based comparisons in this report.
7. U.S. Census Bureau. (2015). *2015 American Community Survey 5-Year Estimates: Sex by Age.* Available at: https://factfinder.census.gov/faces/tableservices/jsf/pages/productview.xhtml?pid=ACS_15_SPT_B01001&prodType=table.
8. U.S. Census Bureau. (2015). *2015 American Survey 1-Year Estimates: Disability Characteristics.* Available at: http://factfinder.census.gov/faces/tableservices/jsf/pages/productview.xhtml?pid=ACS_15_1YR_ S1810&prodType=table. Calculations were completed by the research team.
9. U.S. Census Bureau. (2015). *2015 American Community Survey 1-Year Estimates: Sex by Marital Status by Age for the Population 15 Years and Over (Hispanic or Latino).* Available at: https://factfinder.census.gov/faces/tableservices/jsf/pages/productview.xhtml?pid=ACS_15_1YR_B12002I&prodType=table. These findings include adults who are currently married and living with a spouse and those who are married but separated, based on the ACS definitions. See the full report for more information. The percentage of Latino/a people in the U.S. who are currently married and who have never been married include those who are 15 years of age and older, in contrast to the USTS sample, which includes respondents who are 18 and older. Therefore, the comparison to USTS Latino/a respondents should be interpreted with caution.
10. Latino/a respondents' experiences of rejection also included being asked to meet with faith leaders or seek medical help to stop them from being transgender.
11. Bureau of Labor Statistics. (2015). *The Employment Situation—August 2015.* Available at: http://www.bls.gov/news.release/archives/empsit_09042015.pdf; Bureau of Labor Statistics. (2015). *The Employment Situation—September 2015.* Available at: http://www.bls.gov/news.release/archives/empsit_10022015.pdf.
12. The unemployment rate by race and ethnicity among adults in the U.S. population was calculated by the research team using CPS data available via the CPS Table Creator (http://www.census.gov/cps/data/cpstablecreator.html). CPS Table Creator data utilizes data from the March 2015 Current Population Survey Annual Social and Economic Supplement, in which the overall U.S. unemployment rate was 5.5%. See the full USTS report for more information about unemployment rate calculations and interpretation.
13. "Living in poverty" means living at or near the poverty line. The research team calculated the USTS poverty measure using the official poverty measure, as defined by the U.S. Census Bureau. USTS respondents were designated as living in poverty if their total family income fell under 125% of the official U.S. poverty line. See the full report for more information about this calculation.
14. Proctor, B. D., Semega, J. L., & Kollar, M. A. (2016). *Income and Poverty in the United States: 2015*. (p. 13). Washington, DC: U.S. Census Bureau. Available at: https://www.census.gov/content/dam/Census/library/publications/2016/demo/p60-256.pdf.

15. Proctor, B. D., Semega, J. L., & Kollar, M. A. (2016). *Income and Poverty in the United States: 2015*. (p. 55). Washington, DC: U.S. Census Bureau. Available at: https://www.census.gov/content/dam/Census/library/publications/2016/demo/p60-256.pdf.

16. U.S. Census Bureau. (2015). *American Community Survey 1-Year Estimates: Veteran Status*. Available at: https://factfinder.census.gov/faces/tableservices/jsf/pages/productview.xhtml?pid=ACS_15_1YR_ S2101&prodType=table.

17. U.S. Census Bureau (2014). *Current Population Survey Annual Social and Economic Supplement*. Available at: https://www.census.gov/data/tables/time-series/demo/income-poverty/cps-pinc/pinc-01.2014.html.

18. For each form of housing discrimination or instability listed, respondents could select “does not apply to me” if the housing situation could not have happened to them in the past year. For example, those who did not attempt to rent or buy a home in the past year could not have been denied a home or apartment, and were instructed to select “does not apply to me” for that question. The results for each form of discrimination or instability do not include those who answered “does not apply to me.”

19. Intimate partner violence involving coercive control included acts of intimidation, emotional and financial harm, and physical harm to others who were important to respondents.

20. Kaeble, D. & Glaze, L. (2016). *Correctional Populations in the United States, 2015.* (p. 4). Washington, DC: Bureau of Justice Statistics. Available at: https://www.bjs.gov/content/pub/pdf/cpus15.pdf.

21. Beck, A. J., Berzofsky, M., Caspar, R., & Krebs, C. (2013). *Sexual Victimization in Prisons and Jails Reported by Inmates 2011–12*. DC: Bureau of Justice Statistics. Available at: https://www.bjs.gov/content/pub/pdf/svpjri1112.pdf. Rates of physical assault by facility staff was not available. The Bureau of Justice Statistics (BJS) presents data separately for people incarcerated in state and federal prisons and people incarcerated in jails, but they do not present data for those held in juvenile detention facilities. Data from the U.S. incarcerated population in this section is provided as a benchmark for experiences among USTS respondents and should be interpreted with caution. See full report for more information about this comparison.

22. U.S. Census Bureau. (2015). *2015 American Community Survey 1-Year Estimates: Health Insurance Coverage Status by Age (Hispanic or Latino)*. Available at: https://factfinder.census.gov/faces/tableservices/jsf/pages/productview.xhtml?pid=ACS_15_1YR_B27001I&prodType=table.

23. Centers for Disease Control and Prevention. (2015). *BRFSS Prevalence & Trends Data.* Available at: http://www.cdc.gov/brfss/brfssprevalence.

24. Centers for Disease Control and Prevention. (2016). *2015 National Health Interview Survey: Sample Adult File.* Available at: https://www.cdc.gov/nchs/nhis/nhis_2015_data_release.htm.

25. Centers for Disease Control and Prevention. (2015). Diagnoses of HIV infections in the United States and dependent areas, 2015: Table 20b. *HIV Surveillance Report* (vol. 27). Available at: https://www.cdc.gov/hiv/pdf/library/reports/surveillance/cdc-hiv-surveillance-report-2015-vol-27.pdf. The HIV Surveillance Report provides data for those who were living with diagnosed HIV infection in the U.S. population in 2014. The U.S. population data includes those who are 15 years of age and older and does not include the rate for adults aged 18 and older alone, so it was not possible to exactly match the USTS sample with the U.S. population data. See the full report for more information on use of the U.S. population figure.

26. Centers for Disease Control and Prevention. (2015). Diagnoses of HIV infections in the United States and dependent areas, 2015: Table 20b. *HIV Surveillance Report* (vol. 27). Available at: https://www.cdc.gov/hiv/pdf/library/reports/surveillance/cdc-hiv-surveillance-report-2015-vol-27.pdf. See also note 25.

27. The Kessler Psychological Distress Scale, or K6, uses a series of questions to assess psychological distress based on how often in the past 30 days respondents felt so sad that nothing could cheer them up, nervous, restless or fidgety, hopeless, that everything was an effort, or worthless. See the National Health Interview Survey for additional information about the K6 mental health screening instrument and measure of serious psychological distress in adults (available at: http://www.healthindicators.gov/Indicators/Serious-psychological-distress-adults-percent_50055/Profile).

28. Center for Behavioral Health Statistics and Quality. (2016). *Results from the 2015 National Survey on Drug Use and Health: Detailed Tables.* Table 8.87B. Rockville, MD: Substance Abuse and Mental Health Services Administration. Available at: https://www.samhsa.gov/data/sites/default/files/NSDUH-DetTabs-2015/NSDUH-DetTabs-2015/NSDUH-DetTabs-2015.pdf.

29. Kessler, R. C., Borges, G., & Walters, E. E. (1999). Prevalence of and risk factors for lifetime suicide attempts in the National Comorbidity Survey. *Archives of General Psychiatry*, 56(7), 617–626.

30. Center for Behavioral Health Statistics and Quality. (2016). *Results from the 2015 National Survey on Drug Use and Health: Detailed Tables.* Table 8.73B. Rockville, MD: Substance Abuse and Mental Health Services Administration. Available at: https://www.samhsa.gov/data/sites/default/files/NSDUH-DetTabs-2015/NSDUH-DetTabs-2015/NSDUH-DetTabs-2015.pdf.

2015 U.S. Transgender Survey:
Report on the Experiences of Latino/a Respondents

by: Sandy E. James and Bamby Salcedo*

October 2017

The full report and Executive Summary of the 2015 U.S. Transgender Survey are available at www.USTransSurvey.org.

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*Bamby Salcedo is the President & CEO of the TransLatin@ Coalition. Sandy E. James is the Research Director at the National Center for Transgender Equality.

Updated November 2017

EXHIBIT B

The State of Trans Health: TransLatin@s and Their Healthcare Needs

THE STATE OF TRANS HEALTH

TRANS LATIN@S AND THEIR HEALTHCARE NEEDS

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ABOUT THE TRANSLATIN@ COALITION

THE VOICE OF TRANSLATIN@S IN THE USA

MISSION

The mission of TransLatin@ Coalition is to advocate for the specific needs of the Trans Latin@ community that resides in the U.S.A. and to plan strategies that improve our quality of life.

VALUES

- Altruism, respect, and dignity for everyone
- Transparency, integrity, and honesty
- Pluralism and diversity
- Collaboration, inclusivity, and social justice
- Good resource administration

VISION

The vision of TransLatin@ Coalition is to amplify education and resources to promote the empowerment of Trans leaders.

In this study, Trans Latin@ refers to: *a person over the age of 18 who was assigned male or female at birth and does not identify with that assigned sex and gender, and uses the term(s) Transgender, Trans, Transwoman, Transman, Transmasculine, or Transfeminine, and who reside in the southern part of the state of California, and identifies as Latin@.*

FOREWORD

California leads the country in anti-discrimination laws in employment, housing, and public accommodations; which include medical and health care. While anti-discrimination laws have been in place for over a decade in California, Trans individuals in the state continue to face high levels of unemployment, and discrimination in housing, and receiving health related care due to their gender identity and expression[1]. For Trans Latin@s who face transphobia and racism, marginalization is often exacerbated. In order to understand the needs of Trans Latin@s, TransLatin@ Coalition conducted the first ever study to shed light on the needs of Trans Latin@s in Southern California IN 2016.

It is important to survey the Trans community in order to understand the components of their lives that allow them to be physically, socioeconomically, and emotionally healthy individuals. Understanding these components and where they are lacking will allow service providers to help fill in the gaps that are inhibiting the health and well-being of this vulnerable community.

The TransLatin@ Coalition has begun to fill these needs through the creation of the Center for Violence and Transgender Wellness. The TransLatin@ Coalition seeks to improve the health outcomes of Trans people in California. This report will provide evidence of the specific healthcare needs of Trans Latin@s and what makes Trans Latin@s healthy individuals in the southern part of the golden state. California is recognized across the nation as a model state that provides the most comprehensive legislation and protections towards Trans people. However, there is still a lot of work that needs to be done to address the basic social supportive needs of Trans Latin@ people. We hope that this report provides a road map to assess what is it that supports trans Latin@s to fully realize their humanity, health, and happiness here in California.

JACQUELINE CARAVES, M.A.

Co-Principal Investigator
Ph.D. Candidate
Chicana and Chicano Studies
University of California, Los Angeles

BAMBY SALCEDO, B.A.

Co-Principal Investigator
President & CEO
TransLatin@ Coalition
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[1] Hartzell, E., Frazer, M. S., Wertz, K. and Davis, M. (2009). The State of Transgender California: Results from the 2008 California Transgender Economic Health Survey. Transgender Law Center

ACKNOWLEDGMENTS

A THANK YOU TO THOSE WHO HAVE HELPED US

This report became a reality thanks to the support from The California Endowment and the hard work and dedication of the members of the TransLatin@ Coalition.

Because of the members of TransLatin@ Coalition, we gathered 129 surveys with Trans Latin@ individuals in six different critical points in Southern California. We would like to give a special acknowledgment to those individuals and groups who were crucial to the success of this data collection and who organized people to participate in completing the surveys: Erika De La Cruz, Johanna Wallace and Maria Roman from TransLatin@ Coalition in Los Angeles; Madeline Ambrosini and Somos Familia Valle in the San Fernando Valley; Grupo Transgenero 2000 in San Diego, Alexa Castañon from TransLatin@ Coalition in Long Beach, Pastor Carol Jackson from Spiritual Truth Church in Long Beach, The Long Beach LGBT Center, Zulma Velasquez and Sasha Navarro TransLatin@ Coalition in El Monte, Adriel Rodriguez and Trans Union de OC in Orange County, Paolo Jara-Riveros (videographer), Steve Landaverde (graphic design – cucupan.com), Leisy Abrego, Feliz Quiñones, and Anisha Gandhi.

In addition, the research team would like to thank the anonymous respondents who shared their valuable time with us. Often reliving negative experiences to give voice to the continuous discrimination and marginalization they resist on daily basis in an effort to become healthy individuals. Through the sharing of the intimate details of their everyday lives and their experiences in relation to their mental, physical, and emotional health and well-being as Trans individuals living in Southern California we have been able to put together this very important and timely report. The results of this survey are dedicated to all of you and to the younger generations of Trans Latin@s in Southern California as well as those across the state and the nation.

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EXECUTIVE SUMMARY

THROUGHOUT THE COUNTRY, TRANS AND GENDER NON-CONFORMING INDIVIDUALS FACE DISCRIMINATION IN EVERY REALM OF THEIR LIVES.

Transgender and gender non-conforming individuals experience marginalization in employment, housing, health care, and education based on their gender identity and /or gender expression[2]. Transgender people of color in the U.S. experience racism and therefore experience heightened vulnerabilities in comparison to their white counterparts. For example, according to the National Center for Trans Equality, "Latino/a Trans people often live in extreme poverty with 28% reporting a household income of less than $10,000/year. This is nearly double the rate for Trans people of all races (15%), over five times the general Latino/a community rate (5%), and seven times the general U.S. community rate (4%). The rate for Latino/non-citizen respondents was 43%.[3]"

Given the urgent nature of these statistics, the TransLatin@ Coalition joined with researcher Jacqueline Caraves to conduct a more in–depth study focusing on the lives of Trans Latin@s who reside in Southern California and the social factors that support their health. Considering the vulnerabilities that Trans Latin@s experience, we identified the key areas that impact one's overall health, and asked questions related to their access and needs concerning gaps in those areas. Those areas include: housing, employment, health care, sexual health, mental health, and spiritual services.

The findings presented in this study were compiled from the surveys that were gathered from 129 Trans Latin@s living in different parts of southern California with greater concentration in Los Angeles, Orange County and San Diego Counties. While the survey was open to all Trans Latin@s, 91% of participants were assigned male at birth (transwomen) while 9% of participants were assigned female at birth (transmen). The surveys were anonymous. The surveys were composed of various forms of questions. There were dichotomous questions, Likert scale questions, as well as open-ended questions. This report shares the participants' views as to how these issues affect their lives as Trans Latin@s in Southern California. We hope that this report will serve as a tool to advance the rights of Trans Latin@s in the United States and informs policies that will improve the health and wellness needs of Trans Latin@s in the nation. We offer this report to the Trans community, the Latin@ community, and social service organizations as well as policy makers, service providers and scholars working toward social justice.

[2] Hartzell, E., Frazer, M. S., Wertz, K. and Davis, M. (2009). The State of Transgender California: Results from the 2008 California Transgender Economic Health Survey. Transgender Law Center.
[3] Harrison-Quintana, J., Perez, D., Grant, J. (2011). Injustice at every turn: A look at Latina/o respondents in the National Transgender Discrimination Survey. National Center for Transgender Equality.

RESEARCH TEAM

JACQUELINE "JACKIE" CARAVES, CO-PRINCIPAL INVESTIGATOR

Jackie is a gender non-conforming queer Latina and a Ph.D. Candidate in the César E. Chávez Department of Chicana and Chicano Studies at the University of California, Los Angeles (UCLA) where she also received her Master of Arts degree in Chicana/o Studies and is in the process of completing her graduate certificate in Gender Studies. Jacqueline holds a Bachelor of Arts degree in Latin American & Latino Studies and Politics form the University of California, Santa Cruz (UCSC). Jackie's dissertation work centers the experiences of Trans and gender non-conforming Latin@s and the role of family and spirituality in serving as spaces of empowerment and resistance. Jackie hopes to lend visibility to the Trans and gender non-conforming community and to show how this community survives and thrives in the most beautiful ways.

BAMBY SALCEDO, CO-PRINCIPAL INVESTIGATOR

Bamby is an internationally recognized leader and educator. Bamby is a proud Trans Latina woman whose commitment to the multiple communities that her life intersects has been the driving force of her success. Bamby is pursuing a master's degree in Latino/a Studies. Bamby is the President and CEO of the TransLatin@ Coalition, a national organization that focuses on addressing the issues of Trans Latin@s in the US. Bamby is currently developing the Center for Violence Prevention & Transgender Wellness, a multipurpose, multi-service space for Trans people in Los Angeles. Her powerful, sobering and inspiring speeches and her warm, down-to-earth presence have provided emotional grounding and perspective for diverse gatherings. She speaks from the heart, as one who has been able to transcend many of her own issues, to truly drop ways of being and coping that no longer served her, issues that have derailed and paralyzed countless lives. Her words and experience evoke both tears and laughter, sobriety and inspiration through the documentary made about her life called TransVisible: Bamby Salcedo's Story. Bamby has been featured in multiple media outlets such as People en Español, Latina Magazine, Cosmopolitan, the Los Angeles Times, Los Angeles Magazine and 2015 OUT 100 and featured in the 2016 Trans List with HBO among many other. Bamby has also been recognized for her outstanding work by multiple national and local organizations.

HOUSING

18.8 %

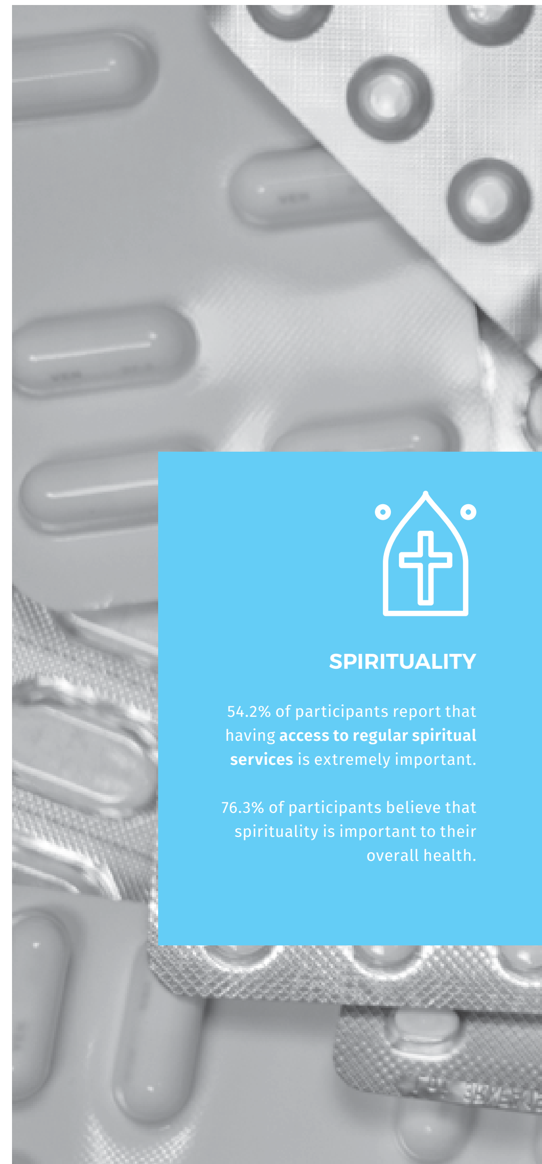
18.8% of participants are either **homeless or living in temporary housing** and 13.4% of participants rely on someone else to pay for their housing (i.e. spouse or partner, etc).

EMPLOYMENT

20 %

Only 20% of participants have **full-time employment**, while 80% of participants include participants who are self-employed (%), unemployed (26%), on disability (%) or other.

KEY FINDINGS

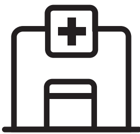


SPIRITUALITY

54.2% of participants report that having **access to regular spiritual services** is extremely important.

76.3% of participants believe that spirituality is important to their overall health.

HEALTH STATS



MEDICAL HEALTH

49.5 %

49.5% of participants are **covered under Medicare/Medicaid/Medi-Cal**.

While 28.1% of participants have no health insurance coverage.

31.2% of participants go to the Emergency Room when in need of health care.

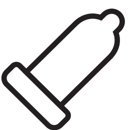
36% of participants strongly agree that it is because of a lack of personal resources that their medical needs are not being met, while 35% of participants agree that it is because of a lack of Trans sensitive health care providers that their medical needs are not being met.

MENTAL HEALTH

50.5 %

50.5% of participants **currently experience anxiety**, while 26.4% of participants report that they are currently experiencing depression.

46.7% of participants strongly agree that their mental health needs are not being met because of a lack of personal resources while 43.7% of participants strongly agree that their mental health needs are not being met because of a lack of support groups.

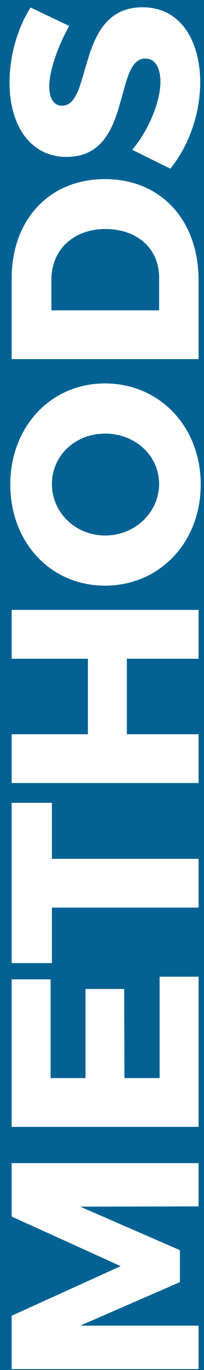


SEXUAL HEALTH

90 %

90% of participants report that they **practice safe sex**.

32.2% of participants reported being HIV positive and 97.4% of HIV positive participants are receiving treatment.



THIS REPORT IS ORGANIZED AROUND SIX CATEGORIES:

1. Access to Housing
2. Access to Employment
3. Access to Medical Care
4. Access to Sexual Health Care
5. Access to Mental Health Care
6. Access to Spiritual Services

THE RESEARCH METHOD THAT WAS USED TO CONDUCT THIS RESEARCH PROJECT WAS COMMUNITY-BASED PARTICIPATORY RESEARCH[4].

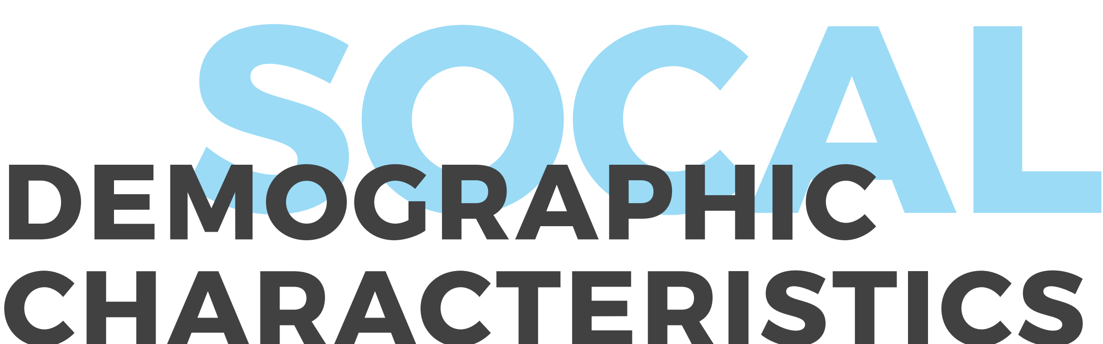
After consulting with members of the TransLatin@ Coalition (TLC), the members prioritized assessing the health care needs of Trans Latin@s was paramount. With this concept in mind, Bamby Salcedo approached Jackie Caraves to seek interest in partnering with the TLC to evaluate the needs of the Trans Latin@ community. After several conversations, Jackie agreed and understood the importance of having a community-engaged partnership. Jackie and Bamby formulated the type of questions that were relevant to collect, reviewed survey tools, and conducted pilot interviews with members of the target community.

After receiving feedback from community members about the survey instrument, the research team made modifications. The research team received Internal Review Board (IRB) approval from the University of California, Los Angeles, (Study #: 15-001883) went on to collect surveys between January 2016 and August 2016. The survey specifically targeted Trans Latin@s over the age of 18, who identify both as Trans and/or Transgender and Latin@. The survey was administered in cities and surrounding communities in El Monte, Long Beach, Los Angeles, San Diego, San Fernando Valley, and Santa Ana. These cities were chosen because of the established presence of Trans support groups that are linked and/or associated to TransLatin@ Coalition. The research team drew upon these six areas of concern to prepare the 70-question survey guiding this study.

8 MONTHS OF RESEARCH

70 SURVEY QUESTIONS

[4] Community based participatory research is a research approach that involves community members, organizational representatives in all aspects of the research process. All partners contribute their knowledge and expertise in the decision making process, in Wallerstein, N., & Duran, B. (2010). Community-based participatory research contributions to intervention research: the intersection of science and practice to improve health equity. American journal of public health, 100(S1), S40-S46.



DEMOGRAPHIC CHARACTERISTICS

THIS SECTION PROVIDES A DESCRIPTION OF THE DEMOGRAPHICS OF INDIVIDUALS WHO PARTICIPATED IN THIS NEEDS ASSESSMENT.

RECRUITMENT

Recruitment took place by members of the Trans Latin@ community throughout Southern California, with a specific focus in the areas where Trans Latin@ individuals thrive and are growing. The research team administered the surveys at each of these locations. The survey was available in both English and Spanish, and ninety-five participants answered the survey in Spanish. Participants took anywhere from half an hour to an hour to complete the survey. This report draws on the responses on 129 of survey participants who met the qualifications of being Trans, Latina@ and over the age of 18. Most participants were recruited during regular programing at local Trans support groups, or places where they frequently gathered. Survey participants who have no affiliation or connection to TransLatin@ Coalition were also recruited. The survey served an additional function as it connected these unaffiliated participants with Trans support groups. The surveys were distributed in private group settings on specific dates and times in each targeted city.

DATA ANALYSIS

Upon gathering all surveys, the research team used Statistical Software (SPSS) to analyze the data, and worked collaboratively to draft charts/graphs, write, and design this report. This report benefits from the input, revisions, and approval of the TransLatin@ Coalition.

LIMITATIONS

The TransLatin@ Coalition is made of up members that identify as Transwomen, Transfeminine, and Woman. The TLC research team recruited participants from all members of the Trans Latin@ community. Due to the membership base of TransLatin@ Coalition it is important to note that Transmen/Transmasculine make up 9% of the participants in this study. It is important to look at Transmen in future research.

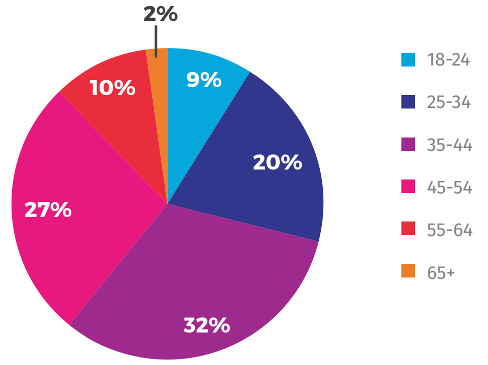
The 129 respondents of this study currently live in various regions throughout Southern California.

The following graph illustrates where interview participants geographic location based on the zip code or residence that they provided. As shown in the graph below, the largest percentage of Trans Latin@s in this needs assessment were from the city of Los Angeles, which accounted for 32% of the participants.

GENERAL FACTS

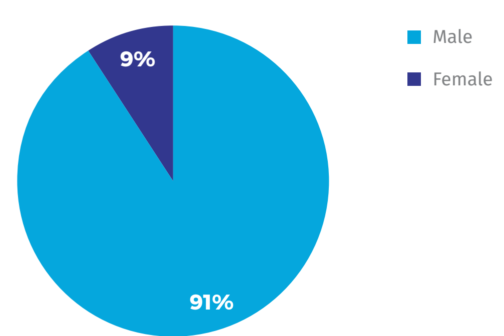
AGE

The following graph provides an overview of the age of Trans Latin@s who participated in the needs assessment.



BIRTH SEX

The following graph provides and overview of the sex assigned at birth of Trans Latin@s who participated in this needs assessment.



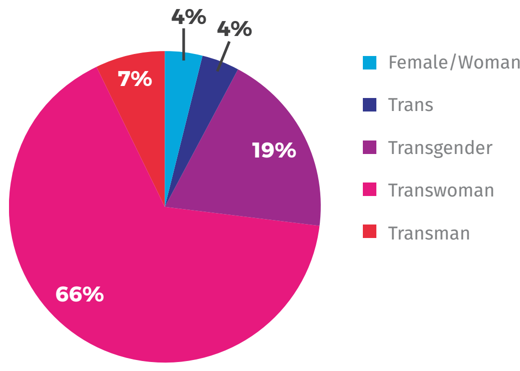
Age Data Analysis

A majority of the participants are between the ages of 35-54.

BACKGROUND

GENDER IDENTITY

The graph below illustrates the gender identity of Trans Latin@s who participated in this needs assessment.

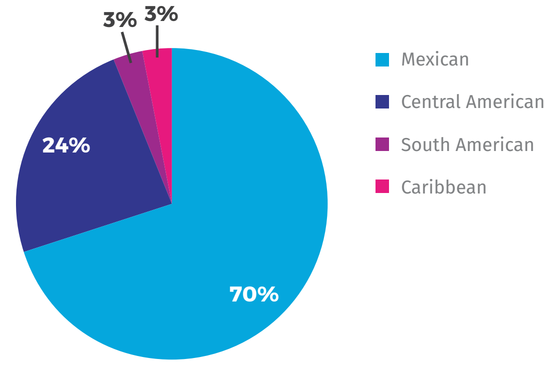


Gender Identity Data Analysis

The largest identity category for participants is Transwoman at 66% while Transman accounted for the smallest identity category at 7%. Twenty-three percent of participants identified as Trans or Transgender.

ETHNIC BACKGROUND

The following graph illustrates the ethnic background of Trans Latin@s who participated in this study.



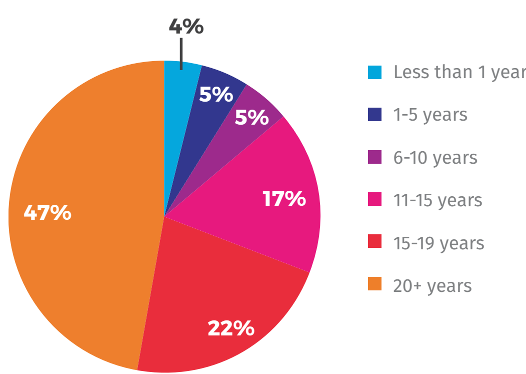
Ethnic Background Data Analysis

While Mexicans make up the majority of participants, Central Americans from El Salvador, Guatemala, and Honduras represent the second largest group.

IN THE USA

YEARS IN THE UNITED STATES

The following graph outlines the length of time that Trans Latin@s have been in living in the U.S.

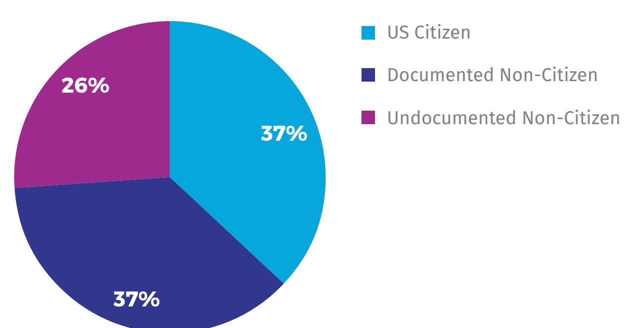


Years in US Data Analysis

A Total of 77% of participants reported having migrated to the U.S., 47% of those migrated reported living in the U.S. for over 20 years, and 4% percent of those living in the U.S. for less than one year.

CITIZENSHIP STATUS

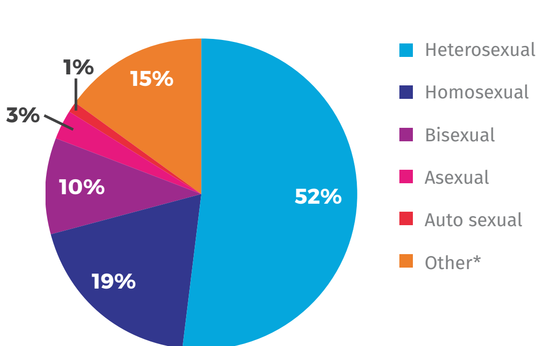
The graph below highlights the citizenship status of Trans Latin@s who participated in this needs assessment.



SEXUALITY & RELATIONSHIPS

SEXUAL ORIENTATION

The following graphs highlight sexual orientation and relationship status from participants.

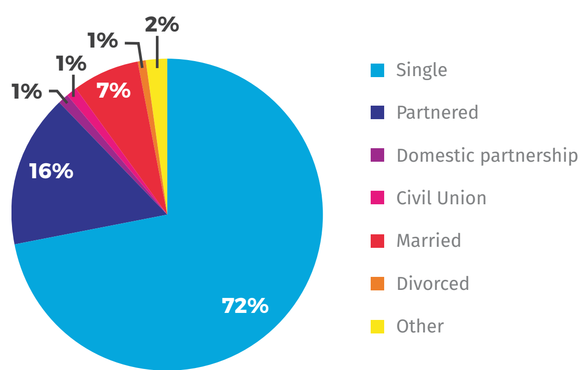


Sexual Orientation Data Analysis

Of those who answered “Other” for their sexuality, queer, pansexual and Transgender were among the most common responses.

RELATIONSHIP STATUS

The following graph highlights the relationship status of participants.

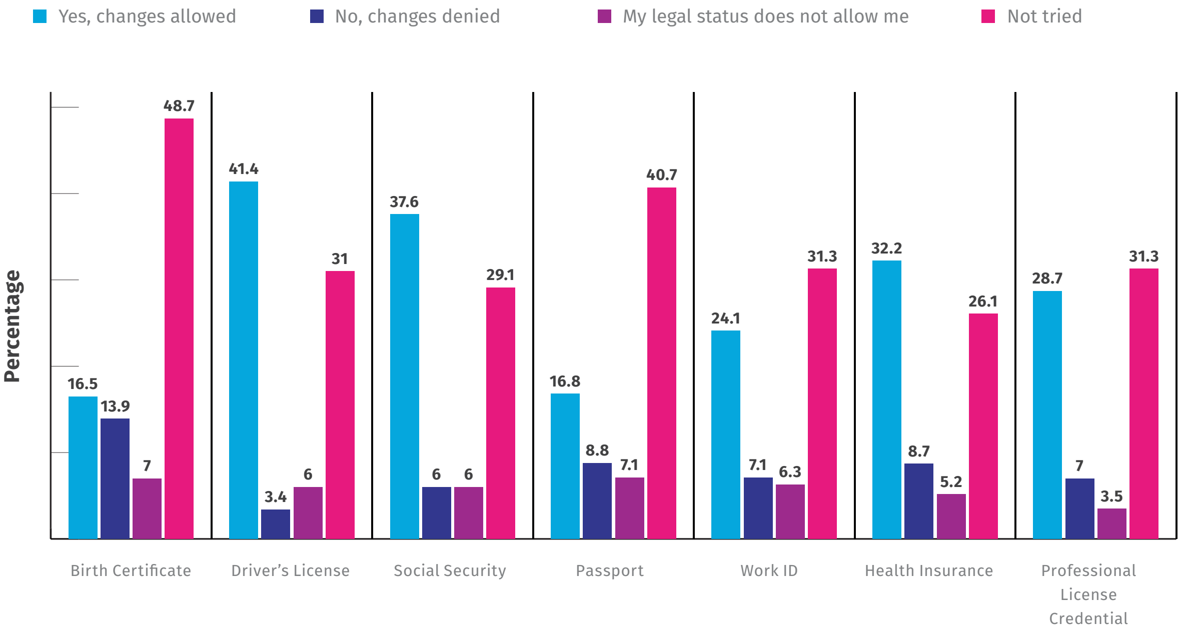


Relationship Status Data Analysis

Data shows a majority of participants who are single (72%), while 24% are either in a domestic partnership, partnered, civil union or married.

DOCUMENTS & RECORDS

HAVE YOU BEEN ABLE TO CHANGE THE DOCUMENTS OR RECORDS TO REFLECT YOUR CURRENT GENDER?



Documents/Records Gender Change Data Analysis

While many participants have been able to change their documents to reflect the gender they identify with, a great deal of Trans Latin@s have not tried at all. This may be due to the fact that there may be a lack of information on how to access these services/needs. There may be also a lack information and/or services in Spanish. It may have to do with lacking the time to access resources in order to begin processes that are time consuming. Because there is no streamlined process to access gender and name changes on all documents at once, it takes much time and money to make those changes.

SOCIOECONOMIC STATUS

INCOME DISTRIBUTION

The following section paints the picture of the social economic status of Trans Latin@s in Southern California.

Income	Percent
Less than $10,000	**57.4 %**
$10,000 - $19,999	20.9 %
$20,000 - $29,999	9.6 %
$30,000 - $39,999	7.8 %
$40,000 - $49,999	3.5 %
$70,000 - $79,999	0.9 %

Income Data Analysis

The **vast majority** of the people who participated in this needs assessment **live under the poverty level** making less than $10,000.00 per year.

EDUCATION DISTRIBUTION

The following graph describes the educational attainment of Trans Latin@s in Southern California.

Education	Percent
No formal education	3.9 %
Elementary school	21.3 %
Some high school	**23.6 %**
HS Diploma	18.1 %
Some college credit	11.8 %
Technical school	5.5 %
A.A. Degree	8.7 %
B.A. Degree	6.3 %
M.A. Degree	0.8 %

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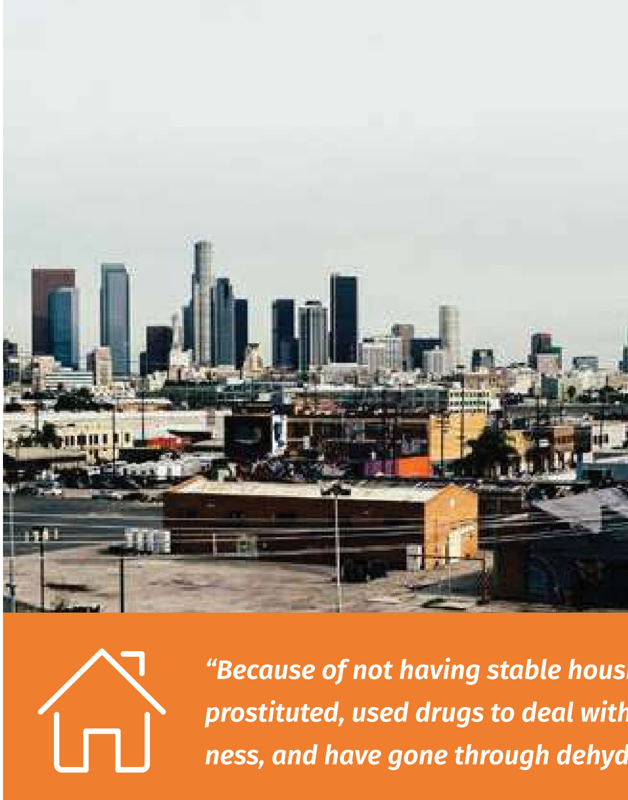
HOUSING

CURRENT HOUSING

The following section paints the picture of the housing situation of Trans Latin@s in Southern California.

Housing	%
Homeless	8.7 %
Shelter	3.1 %
Group home facility	3.9 %
Parents/family you grew up with	11 %
Temporary housing	3.1 %
Partner/spouse/other pays for housing	13.4 %
Rent alone/with others	**52 %**
Own alone/with others	4.7 %



"Because of not having stable hous... prostituted, used drugs to deal with... ness, and have gone through dehyd...

Housing is one of the basic needs that any individual within our society must have in order to be a stable person.

68%

of participants who do not have stable housing reported that they do not know of a shelter they can go to for help and feel safe as a Trans person.

98%

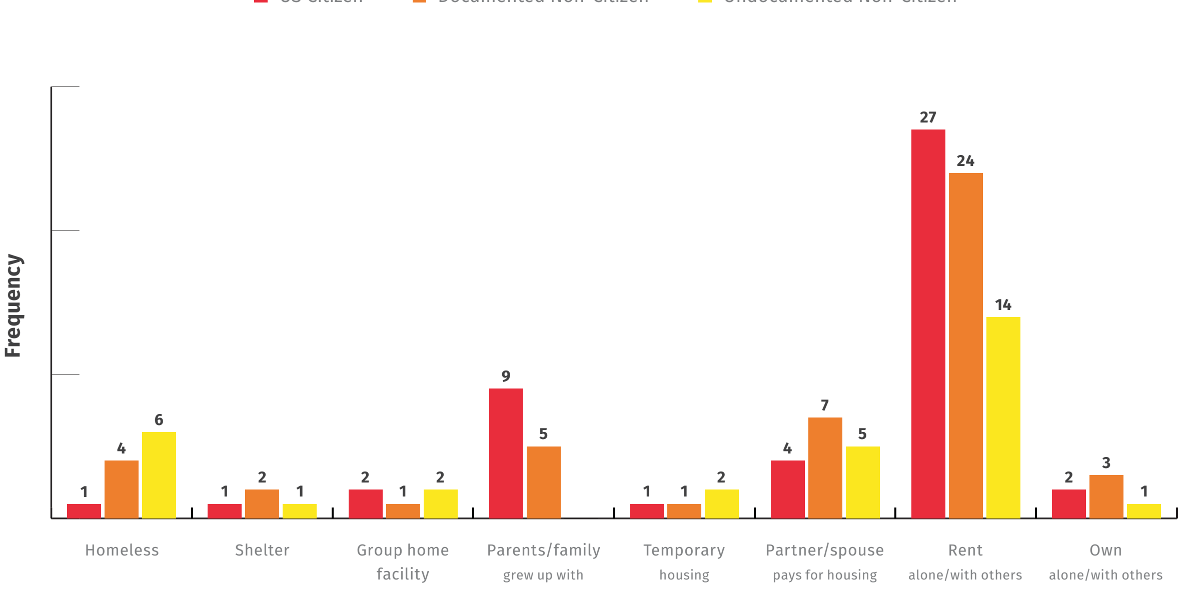
of participants acknowledged that housing is important to their overall health and well-being. The leading cause for participants who do not currently have stable housing is because they are unable to access work because of discrimination based on gender identity and/or their citizenship status.

*ing I have
n homeless-
ration"*

"THE REASON WHY I AM HOMELESS IS BECAUSE I WAS RECENTLY RELEASED BY ICE (IMMIGRATION) AND THEY DON'T CARE IF I HAVE A PLACE TO LIVE OR FOOD TO EAT."

HOUSING BY CITIZENSHIP STATUS

The graph below displays how citizenship status shapes housing outcomes for Trans Latin@s.



Housing by Citizenship Status Data Analysis

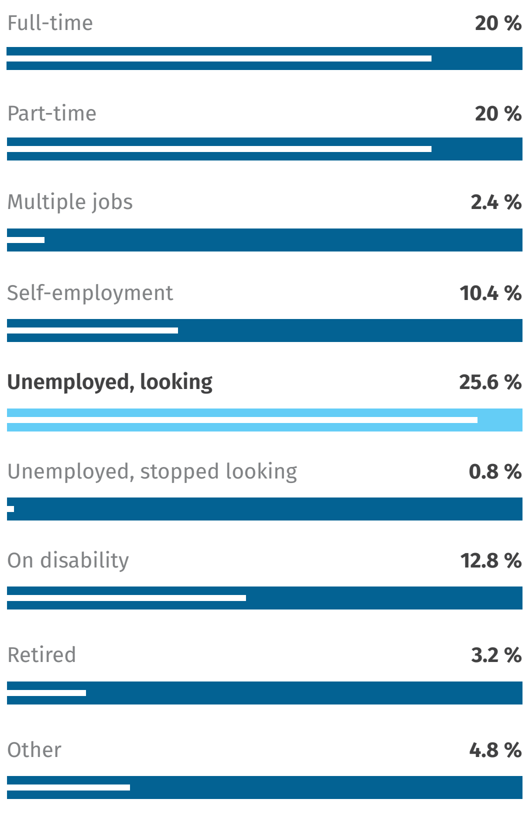
For all statuses, renting alone or with others is most common among participants. A total of 16 participants, from all statuses, reported being dependent on their partner or spouse for housing. For participants whom are U.S. Citizens or Documented Non-Citizens living with parents or family they grew up was prevalent. For Undocumented Non-Citizens who are vulnerable to being deported, housing especially of concern.

"I have feared and stressed out about my housing in the past due to fear of being accepted for my Trans identity. Stable housing is important because I need safety and a comfort zone after being out in the world, somewhere where I can be free to be myself."

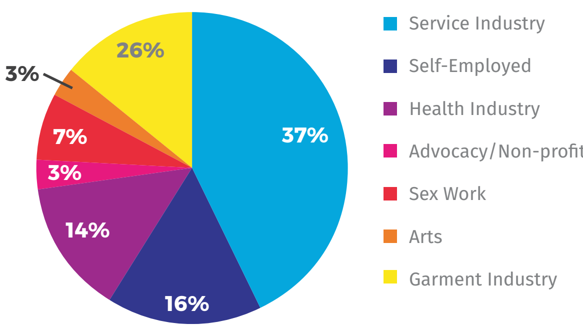
EMPLOYMENT

EMPLOYMENT STATUS

This section focuses on highlighting the employment needs of Trans Latin@s in Southern California.



EMPLOYMENT BY INDUSTRY



Employment Status Data Analysis

Only 20% of the participants reported having a full time job, and 20% have part time jobs. The largest portion of participants reported being "unemployed, but still looking for opportunities." There is much need of employment opportunities for Trans Latin@s in Southern California who often face discrimination. Additionally, as one participant notes below, other people whether partner, family member or friend are often dependent on Trans Latin@s income. Trans participants who reported "other" are qualify for Medicaid or General Relief (government assistance) due to their low-income status.

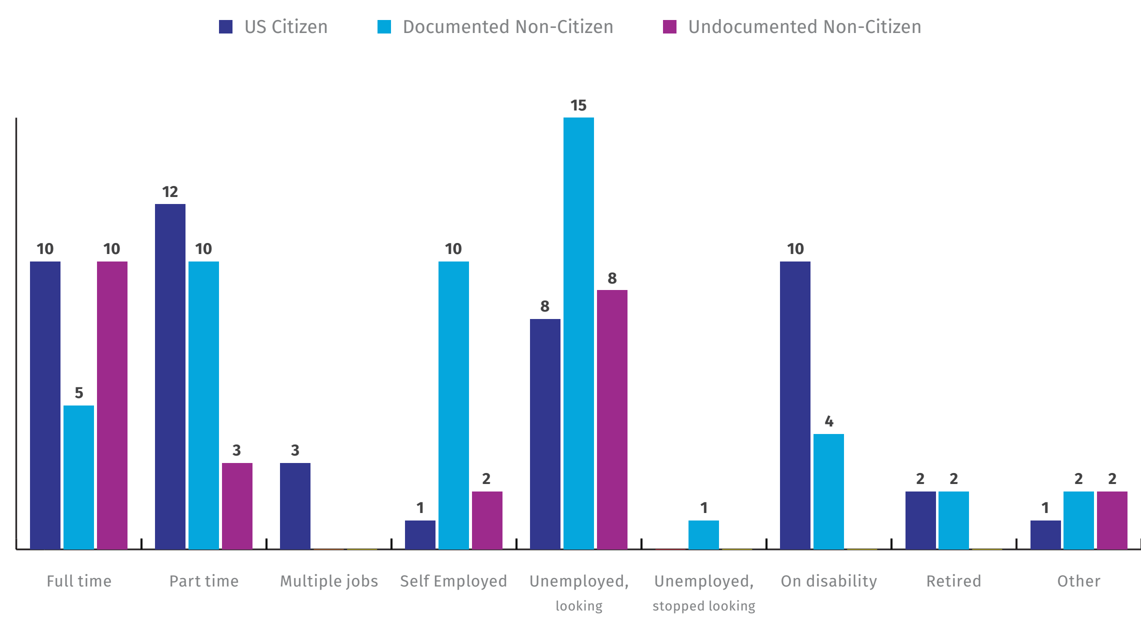
Employment by Industry Data Analysis

A large portion of participants mentioned working in the service industry included anything from being a stylist in a salon, to house keeping, and being cashier. For the 16% those are self-employed jobs varied from consulting to street vending.

"EMPLOYMENT IS IMPORTANT TO MY OVERALL HEALTH BECAUSE IT WOULD HELP STABILIZE ME AND GET ME ON MY FEET [AND] AWAY FROM PROSTITUTION AND DRUGS"

EMPLOYMENT BY CITIZENSHIP STATUS

The following graph below shows employment based on citizenship status.



Housing by Citizenship Status Data Analysis

For all statuses, renting alone or with others is most common among participants. A total of 16 participants, from all statuses, reported being dependent on their partner or spouse for housing. For participants whom are U.S. Citizens or Documented Non-Citizens living with parents or family they grew up was prevalent. For Undocumented Non-Citizens who are vulnerable to being deported, housing especially of concern.

"I support both myself and my partner financially, employment is necessary to be able to have a home, food, other necessities as well as to take care of my partner who is physically disabled and chronically ill."

MEDICAL CARE

HEALTH INSURANCE COVERAGE

The following section provides an overview of participant's status when it comes to accessing medical care.

Coverage	Percent
No health insurance	28.1 %
Insurance through employer	11.6 %
Insurance my family purchased	1.7 %
Medicare	10.7 %
Medicaid/Medi-Cal	**38.8 %**
Other public program	4.1 %
Other	5 %

Health Insurance Coverage Data Analysis

28.1 percent of participants have no health insurance coverage whatsoever. On the other hand, 53.6% of participants are covered by Medicare, Medicaid or other public insurance program, most commonly due to their low-income status. For some it is their low-income status along with being HIV positive that gains them access to health insurance.

LOCATION FOR MEDICAL CARE

The largest go to place for all Trans Latin@s is the emergency room.

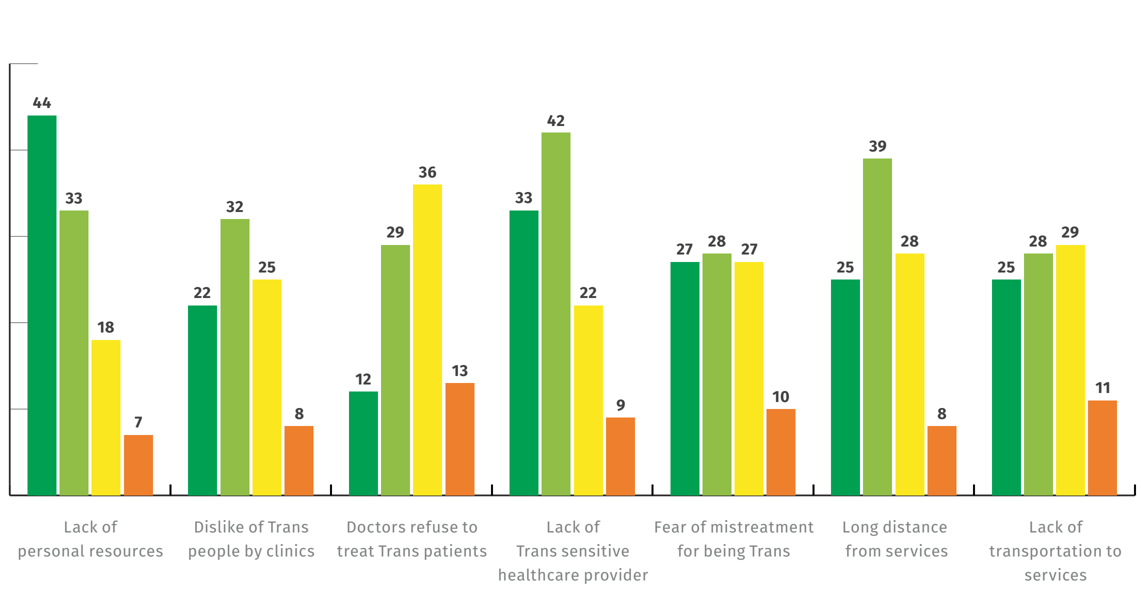
Location	Percent
Emergency room	**31.2 %**
Private doctor's office	9.6 %
Health clinic/center covered by insurance	23.2 %
Free health clinic	20 %
VA clinic or hospital	0.8 %
Alt. medicine (herbalist, acupuncture, etc.)	4 %
Not applicable	8 %
Other	3.2 %

Location for Medical Care Data Analysis

For those who may not have access to insurance, or face discrimination, the emergency room may be the only answer when pain is no longer the option.

REASONS WHY MEDICAL CARE IS NOT BEING MET

Participants were asked about the possible reasons why they were not receiving medical health. For Trans Latin@s lack of personal resources and lack of Trans sensitive health care providers, and long distance to services that are among the strongest reasons for why they may not be getting the health care they need.

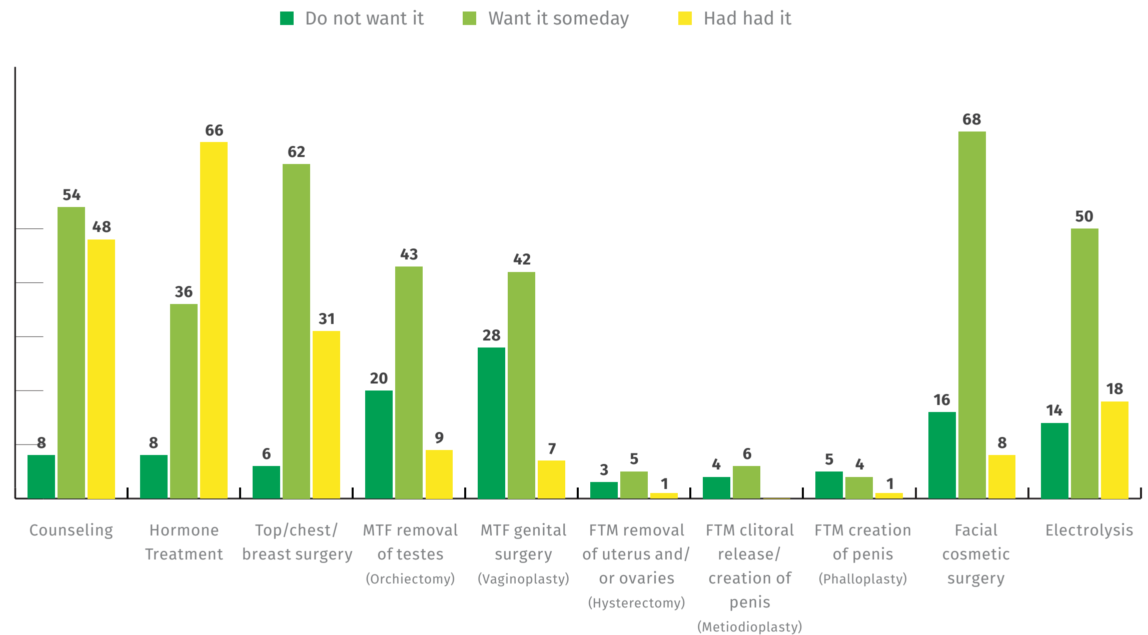


"Being physically and mentally healthy is important because that way I could function better within society."

MEDICAL CARE (CONTINUED)

TRANS RELATED CARE

The graph below addresses the Trans related care that participants have either had, want to have someday, or do not want at all.



Trans Related Care Data Analysis

About **15% of participants** mentioned having to **pay for Trans related care out of pocket**. Often times this included hormones and top surgery. For those who paid out of pocket, participants mentioned that the money they used came from their savings, financial help from family or friend or doing sex work. Some participants reported getting hormones from friends who were already on hormones and others discussed crossing the border in Mexico gain access to Trans Related care.

"Feeling aligned with oneself physically has a large impact mentally and socially for us to thrive."

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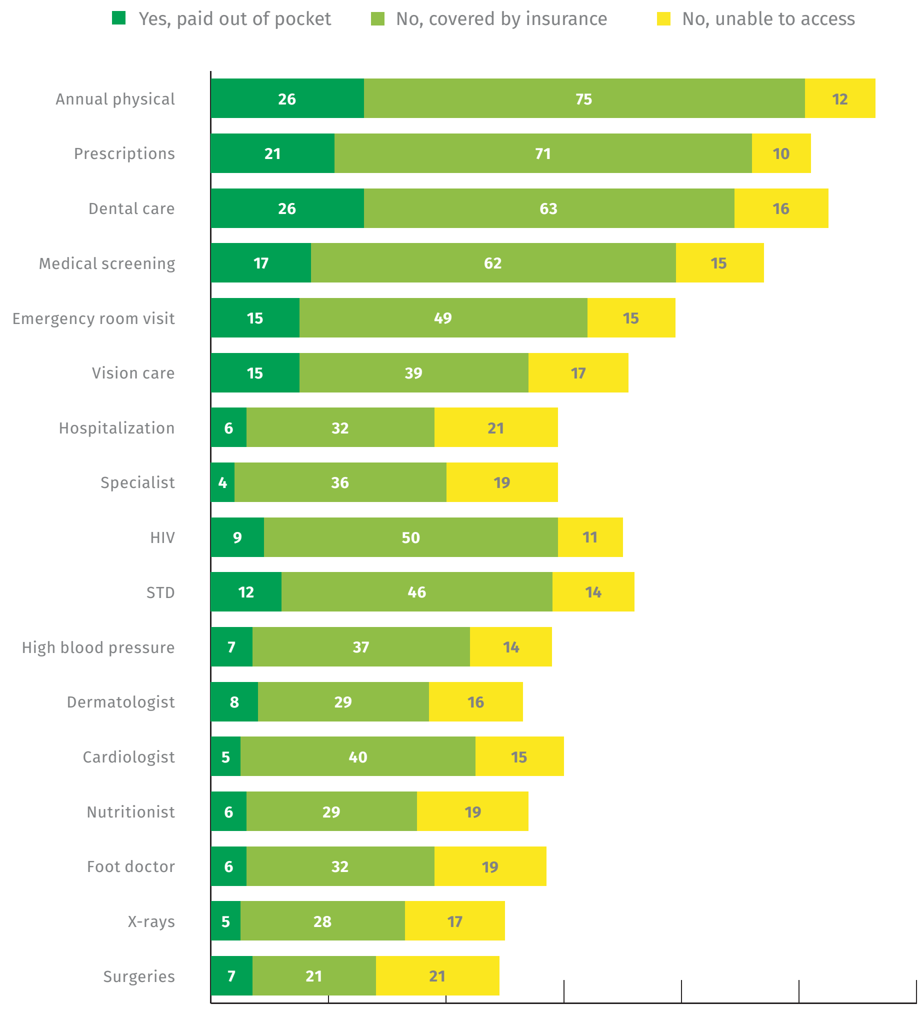
SERVICES ACCESSED IN THE LAST 12 MONTHS

The graph below shows the services that participants have accessed in the past 12 months.



Services Accessed (12 Months) Data Analysis

As mentioned above many participants have access to health care through Medi-Cal or Medicaid. A large amount of other participants have access to other forms of public health programs because of their HIV status. A total of 39 participants reported being HIV positive and receiving health insurance through Medi-Cal or another public program. For participants, who are not HIV positive or are not citizens, it may be very difficult to get the medical care you need.

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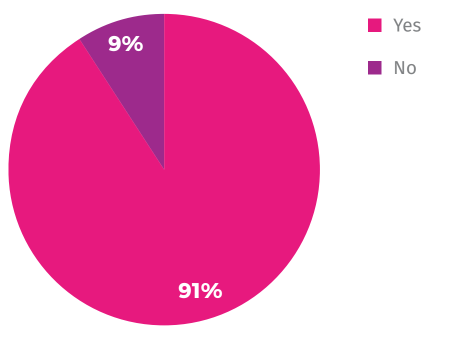
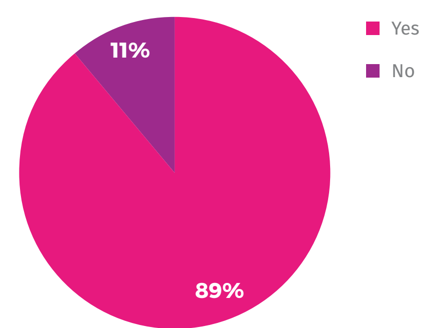
SEXUAL HEALTH

DO YOU USE PROTECTION WHEN ENGAGING IN SEXUAL ACTIVITY?

This section captures a snapshot of the sexual health of Trans Latin@s.



DO YOU KNOW WHERE TO LEARN ABOUT SAFE SEX PRACTICES?



Safe Sex Data Analysis

Participates where asked if they practice safe sex when they engage in sexuality activity, including penetration and oral, and over **90% of participants** reported that they do **use protection**.

92% of participants said that they feel knowledgeable about practicing safe sex.

89% of participants know where to learn about safe sex.

"By using protection I am respecting myself and my body."

HIV & STD TESTING FREQUENCY

Participants were asked how often they get tested for HIV and STDs.

Response	Percent
I've only been tested once	12.5 %
Every 6 months	**60.8 %**
Every year	11.7 %
Every time I am with a new intimate partner	5 %
Other	10 %

Testing Frequency Data Analysis

A **majority** of participants reported that they get **tested every six months**.

For those who reported other, most commonly they were tested every three months.

REASON FOR NOT GETTING TESTED FOR HIV

Participants were asked about possible reasons for why they may not be going to get tested for HIV.

Response	Percent
I feel healthy	**44.9 %**
I always practice safe sex	40.6 %
I don't know where I can get tested	1.4 %
I don't want to experience shame	2.9 %
I'd rather not know	1.4 %
Other	8.7 %

Reason for Not Getting Tested Data Analysis

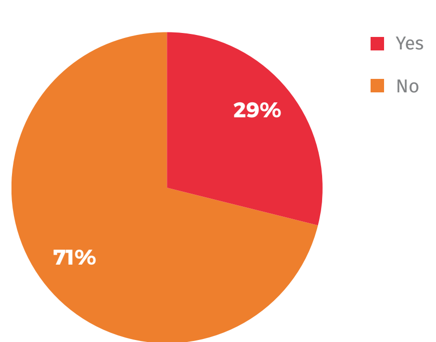
Majority of participants reported that they either felt healthy (44%) or they always practice safe sex (40.6%) so there would be no need to get tested.

A much smaller percentage mentioned not knowing where to get tested (1.4%), feeling shame (2.9%) and not wanting to know (1.4%).

MENTAL HEALTH

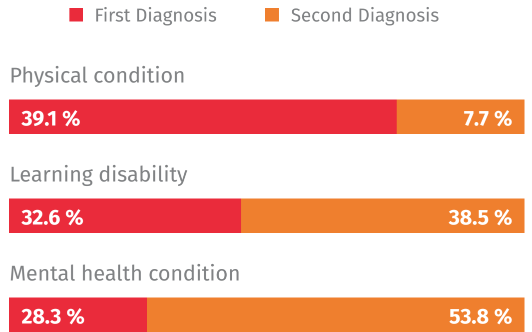
GENDER RELATED DIAGNOSIS

The section below is a snapshot of how Trans Latin@s fare when it comes to their mental health.



MENTAL/PHYSICAL DISABILITY

Participants were asked if they had any non-gender related diagnosis, including mental health condition, physical disability, or learning disability.



Mental Health Diagnosis Data Analysis

Mental health is important for our emotional, psychological and over all well-being. Getting the mental health care needs that Trans Latin@s need may be challenging to access due to their lack of health insurance, Trans sensitive care providers and groups, and financial resources.

Only 35 participants (28.7%) have been diagnosed with a gender related mental health issue. 87 participants (71.3%) mentioned that they have not been diagnosed with a gender related mental health issue.

Mental/Physical Disability Data Analysis

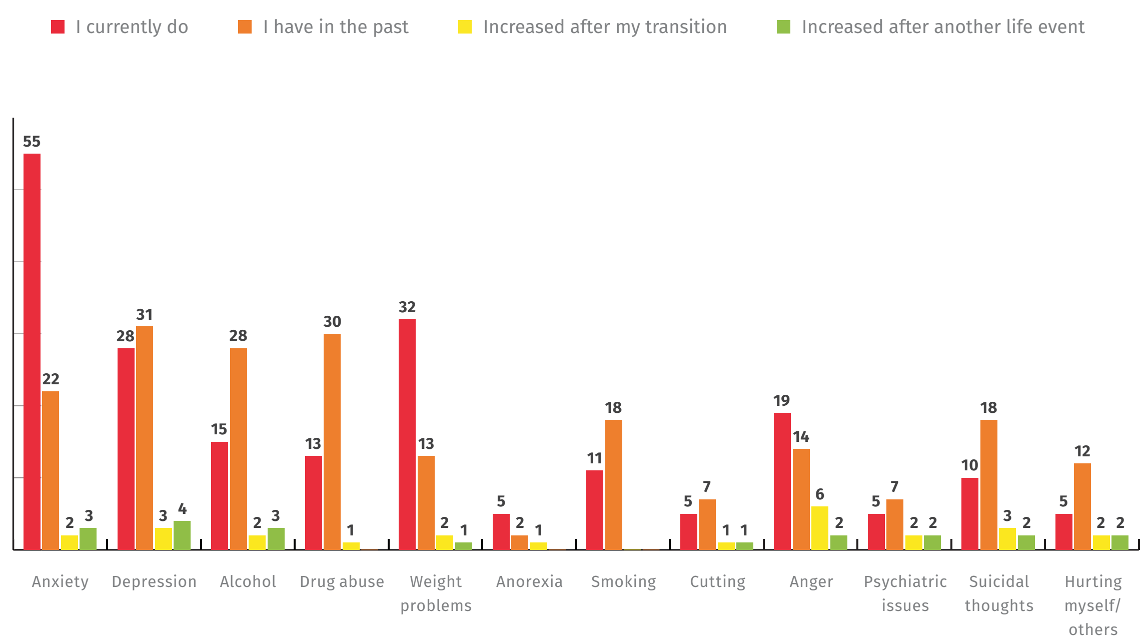
A total of 31% reported that they did have another diagnoses. Some participants have multiple diagnoses; the graph below shows percentage of first diagnoses, and second diagnoses for participants.

"It's important for me to have access to mental health, because I have depression, anxiety and many other things. Therapy and medication help me a great deal."

"HAVING ACCESS TO MENTAL HEALTH HELPS ME TO SEE, UNDERSTAND, AND ACCEPT THE DIFFERENT SITUATIONS AND ADVERSITIES IN MY LIFE. IT HELPS ME TO FIND AND REACH A PLACE OF BALANCE AND PEACE."

WHAT DO YOU STRUGGLE WITH?

Participants were asked if they were struggling with any of the following.



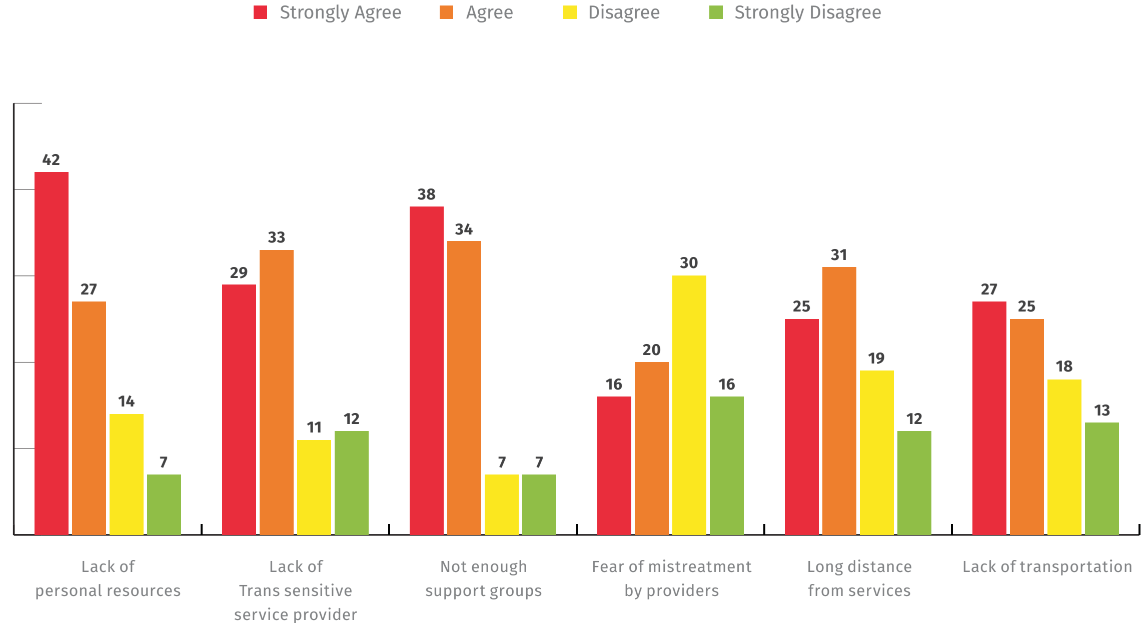
Struggles Data Analysis

A total of 42% participants reported that they currently struggling with anxiety. Overall, 49% of participants are reported receiving assistance for their current struggle listed below, while 51% are not getting the care they need.

MENTAL HEALTH
(CONTINUED)

REASONS WHY MENTAL HEALTH NEEDS ARE NOT BEING MET

Participants were asked about reasons for why they may not be getting the mental health care they need.



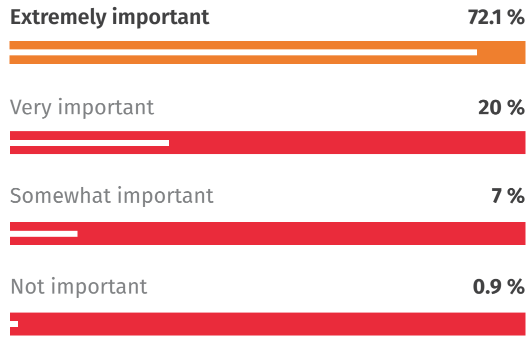
Mental Health Reasons Data Analysis

Lack of personal resources, not enough support groups available, and long distances to services stand out as the main reasons for why Trans Latin@s are not receiving the mental health care they need.

"It's important for me to have access to mental health, because I have depression, anxiety and many other things. Therapy and medication help me a great deal."

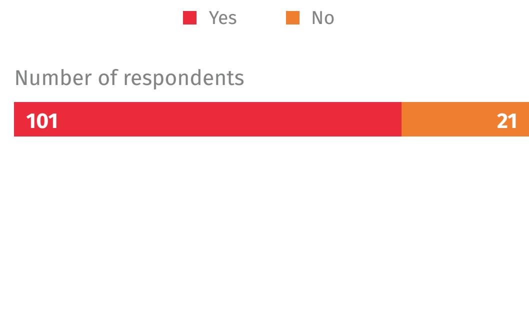
IMPORTANCE OF MENTAL HEALTH

Mental healthcare is either extremely important (72.1%) or very important (20%) the Trans Latin@ community.



DO YOU HAVE A SUPPORT SYSTEM?

We asked participants if they had a social support system, including friends, family, other Trans friends, etc that they could rely on.



"ACCESS TO MENTAL HEALTH SERVICES HELPS ME COPE WITH MY STRESS AND ANY DEPRESSION, DYSPHORIA, AND BAD THOUGHTS I MIGHT HAVE."

Support System Data Analysis

For the **82% of participants** that indicated they **had someone in their life they felt supported by**, most often it was a family member, partner, friends, Trans support group, another Trans friend(s), and/or co-workers.

or many participants reported that having a support system helps with their mental health. Often times support goes beyond emotional mental well-being, and support from friends and family entail providing a place to stay and food to eat.

SPIRITUAL SERVICES

SPIRITUAL AFFILIATION

The section addresses the role of spirituality in Trans Latin@s lives.

Affiliation	%
Christian	56.7 %
Other Non-Christian faith	16.7 %
Unaffiliated	23.3 %
Don't know	3.3 %

HOW IMPORTANT ARE SPIRITUAL SERVICES TO YOU?

Importance	%
Extremely important	54.2 %
Very important	18.3 %
Somewhat important	13.3 %
Not important	14.2 %

Spiritual Data Analysis

Spiritual services prove to be something that is very important for the Trans Latin@ community and it is often tied to their overall health and well being.

The majority of Trans Latin@s report being affiliated to a Christian faith, while 23.3 are unaffiliated to any religious institution.

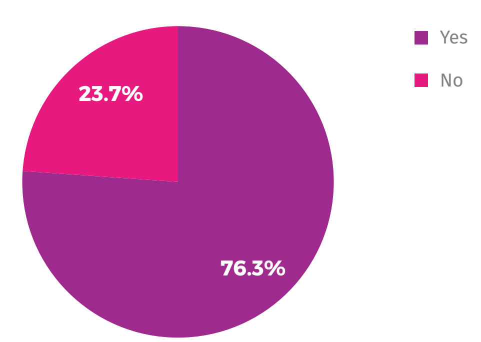
A total of 16.7% of participants reported practicing something other than Christianity, including Santeria, Native American practices, Buddhism and Judaism.

Close to 73% of participants reported that spiritual services are either extremely important or very important to them. Accordingly, 66.4% of participants mentioned that they do not need to hide who they are because of their religion.

Lastly, 68.2% participants feel welcome and accepted by their religion.

"MY BUDDHIST PRACTICE HAS EXTREMELY HELPED ME AND PULLED ME OUT OF MY DEPRESSION AND HAS LESSENED MY ANXIETY. IT HAS GIVEN ME THE CONFIDENCE AND ABILITY TO LOVE MYSELF."

IS SPIRITUALITY IMPORTANT TO YOUR OVERALL HEALTH?



Importance of Spirituality Data Analysis

When asked if spirituality is important to your overall health, a total of **90 participants** (76.3%) responded that **spirituality was important** to their overall health and well being.

"...[My church] gives me hope... I get all the support in this Church. I'm blessed with God and having people that care NOW...just the hugs we get, the conversations that picks me up and keeps me moving...So I'm okay."

RECOMMENDATIONS

HOUSING

HOUSING IS AN ESSENTIAL NEED FOR ANYONE TO BE ABLE TO HAVE A DECENT LIFE. EMERGENCY HOUSING THAT LEADS TO STABLE PERMANENT HOUSING IS SOMETHING THAT IS VERY MUCH NEEDED FOR TRANS LATIN@S. ACCESS TO STABLE AND PERMANENT HOUSING WILL ALLOW TRANS LATIN@S TO BE HEALTHY INDIVIDUALS, THEREFORE ENSURING A HIGHER QUALITY OF LIFE. THE FOLLOWING ARE OUR RECOMMENDATIONS FOR HOUSING:

- We recommend that legislators and policy makers fund an emergency shelter in key area(s). An emergency shelter will support Trans Latin@s in Southern California to start a path toward a healthy way of living. Having an emergency shelter will support Trans Latin@s in finding a safe place to deal with whatever they may be going through. Safe and secure housing for Trans Latin@s will reduce stress related to being homeless. It can eliminate other potential health risks such as the involvement in the sex trade for survival, and lessen the incidents of HIV and STDs among Trans Latin@s.

- Intentionally invest and develop transitional housing programs that will support Trans Latin@s to attain stability. A transitional housing program can provide the opportunity for Trans Latin@s to learn technical skills that will support them to get jobs and long term stability. These transitional housing programs should be of one to two years maximum depending on the needs of the individual. Transitional housing programs are a path for a permanent housing opportunities and programs and must be available for Trans Latin@s in key areas in Southern California.

- Government and service providing agencies, government elected officials and policy makers, must intentionally invest in permanent and affordable housing opportunities for Trans Latin@s residing in Southern California. Local Latin@, social justice, housing rights, immigrant and Trans organizing groups, must continue to organize and demand permanent housing opportunities to be met for Trans Latin@s in Southern California. In order for housing disparities to be addressed, organizing groups, agencies (both government and service providing) must work together to ensure Trans Latin@s become healthy through permanent housing.

EMPLOYMENT

EMPLOYMENT IS ONE OF THE BASIC NECESSITIES FOR PEOPLE TO HAVE A WAY TO SUSTAIN AND TO THEMSELVES AND ACQUIRE BASIC NEEDS. FOR TRANS LATIN@S, HAVING EMPLOYMENT OPPORTUNITIES IS VERY CHALLENGING BECAUSE OF THE CONTINUOUS DISCRIMINATION THEY FACE AS A COMMUNITY. THESE RECOMMENDATIONS ARE POSSIBLE WAYS TO ADDRESS THE EMPLOYMENT DISPARITIES AMONG TRANS LATIN@S IN SOUTHERN CALIFORNIA:

- The State of California Workforce Development Board must fund Trans led organizations and programs in Southern California to work with workforce development agencies to provide training and capacity building on Trans culture and inclusivity.
- The California State Workforce Development Board must mandate all workforce development centers and government agencies that they fund, (city and county) to take a minimum of eight (8) hours of Trans cultural sensitivity trainings to be able to understand issues related to Trans individuals. These trainings must be taken at least once a year and must receive some type of acknowledgment documenting that they had received this training. This should be part of their annual review and agency requirements to be able to obtain funding from the State of California Workforce Development Board.
- The California Workforce Development Board must allocate funding to work with Trans led groups and organizations to develop the work force and technical abilities in Trans Latin@ communities to gain skills and obtain jobs in different industry sectors.
- Local Workforce development agencies must obtain training on Trans sensitivity and inclusivity in the workplace. Local Workforce development boards have the ability to fund and contract with local Trans led groups and organizations to be able to do these trainings.
- Workforce development centers and nonprofit organizations must develop programs that support Trans Latin@s in attaining employment. These agencies must develop relationships with different industries to be able to have an array of employment options for Trans Latin@s in Southern California

MEDICAL HEALTH PERTAINS TO ONE'S OVERALL PHYSICAL HEALTH. HISTORICALLY, TRANS PEOPLE HAVE BEEN PATHOLOGIZED IN THE MEDICAL ESTABLISHMENT. AS A RESULT, TRANS PEOPLE HAVE OFTEN BEEN DISCRIMINATED AGAINST WHEN TRYING TO ACCESS BASIC MEDICAL NEEDS. THESE ARE OUR RECOMMENDATIONS RELATED TO THE MEDICAL HEALTH FOR TRANS LATIN@S:

- An individual's gender may not "align" with the patient's genitalia, we ask that medical practitioners and staff respect the dignity of each patient, and ask patients to identify their preferred gender identity.
- Develop and pass legislation that supports Trans Latin@s to cover expenses when accessing emergency rooms, clinics or hospitals.
- Intentionally allocate funding streams to provide training to doctors and staff on Trans health to be able to provide culturally competent healthcare to Trans Latin@s and their needs. We highly recommend that at least on person who is knowledgeable about Trans health care and is bilingual be scheduled to work at any given shift.
- Create and develop a statewide standard training curriculum to be used to train in medical schools, emergency rooms, and in hospitals about Trans Latin@s health.
- Educate and train Trans Latin@s in Southern California about their rights when it comes to medical care so that Trans Latin@s can empower themselves on how to advocate for themselves on their rights in the medical establishment
- Develop programs related to sexual health for Trans Latin@s that can be integrated into their HIV prevention programs.
- Create programs in clinics or medical services that provide transportation services to Trans Latin@s in Southern California so that they can have better accessibility to basic medical services.
- Develop programs that will support Trans Latin@s with dental health care and hygiene.
- Develop programs and services that could provide medicinal alternatives for Trans Latin@s in Southern California.

SEXUAL HEALTH

SEXUAL HEALTH IS AN IMPORTANT COMPONENT OF A PERSON'S QUALITY OF LIFE. IT IS SHAPED BY MANY FACTORS THAT INCLUDE PHYSICAL, SOCIAL AND MENTAL WELL-BEING. FOR TRANS LATIN@S SEXUAL HEALTH CAN BE PUT AT RISK DUE TO TRYING CIRCUMSTANCES .

- Sexual health care providers should be trained on cultural competence and non-discrimination. Clinics and sexual health providers should be trained in Trans appropriate care and inclusivity.
- Providers should create gender inclusive services to Trans individuals.
- An individual's gender may not "align" with the patient's genitalia, we ask that sexual health care providers and staff respect the dignity of each patient, and ask patients to identify their preferred gender identity.
- Intentionally allocate funding streams to provide training to sexual health care providers to provide culturally competent healthcare to Trans Latin@s and their sexual health needs. We highly recommend that at least on person who is knowledgeable about Trans sexual health and is bilingual be scheduled to work at any given shift.

MENTAL HEALTH

MENTAL HEALTH IS ONE OF THE ISSUES THAT AFFECT MANY PEOPLE. THE CALIFORNIA HEALTH CARE FOUNDATION STATES THAT AT LEAST 1 IN 20 INDIVIDUALS IN CALIFORNIA SUFFER FROM MENTAL HEALTH ILLNESS . ALTHOUGH THERE IS NO SPECIFIC INFORMATION ABOUT TRANS INDIVIDUALS IN CALIFORNIA AND ISSUES RELATED TO THEIR MENTAL HEALTH NEEDS, WE ARE PROVIDING RECOMMENDATIONS FOR CONSIDERATION BASED ON THE RESULTS OF THIS REPORT. THESE ARE OUR RECOMMENDATIONS:

- We recommend that legislators and policy makers intentionally allocate funding to pursue research on the mental health needs and issues related to Trans individuals in the state of California.
- Anxiety is one of the issues that affect Trans Latin@s in Southern California. We recommend that local mental health departments work with local Trans led groups and organizations to provide mental health services and counseling to Trans Latin@s.
- Look at alternatives programming that will support Trans Latin@s in lowering their levels of anxiety. Such as art programs like painting, theater, spoken word, etc.
- Creation of programs around smoking cessation targeting Trans Latin@s in Southern California. Programs should include culturally competent Trans Latin@ counseling sessions and providing strategies for reducing smoking habits.
- We recommend the creation of support groups that are Trans led by Trans led organizations so that members of the Trans Latin@ community can see themselves reflected. We need to develop Trans Latin@s leaders so that they can lead the proposed support groups. This is crucial because Trans Latin@s stated that having peer support is very important to them.
- Trans Latin@s need to have mental health services that are easily accessible to get to. Mental health services must be Trans competent and sensitive. Having easy access to mental health services would add to the support network that Trans Latin@s have.

[5] California Health Care Foundation: http://www.chcf.org/publications/2013/07/data-viz-mental-health

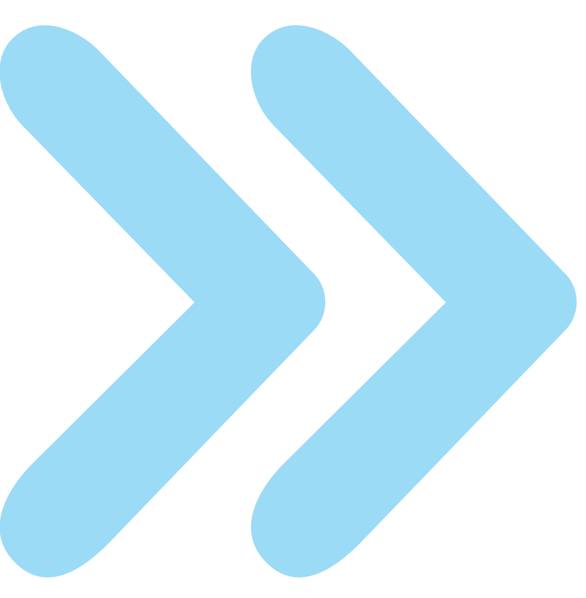
SPIRITUAL HEALTH

"RELATED TO SPIRITUALITY IS THE POWER OF HOPE AND POSITIVE THINKING."[6] IN THIS REPORT, SPIRITUAL SERVICES WERE EXTREMELY IMPORTANT TO TRANS LATIN@S. SPIRITUALITY IS OFTEN ASSOCIATED WITH HEALING AND EMPOWERING INDIVIDUALS WHO EXPERIENCE TRAUMA. THESE ARE SOME OF OUR RECOMMENDATIONS:

- Create and develop programs that have a spiritual component to them. Integrating spiritual components into social services and health care settings will support Trans Latin@s to see themselves represented in a different way.
- Trans Latin@s must be well informed about the spiritual services that exist and where they are welcome, such as LGBTQ specific churches, as well as other denominations. While a good percentage of Trans Latin@s feel welcome in their place of worship, many stated that they do not feel welcome.
- We recommend that service providers work together with LGBTQ spiritual leaders in the Southern California area to bridge their services to Trans Latin@s who feel marginalized or isolated from spirituality.

[6] Puchalski, Christina M. (2001) "The Role of Spirituality in Health Care." Proceedings (Baylor University. Medical Center) 14.4: 352–357. Print.

FUTURE RESEARCH



- We recommend that organizations and institutions of higher learning continue to provide support for additional research projects in order to access a wider range of Trans Latin@ participants. It is important to assess additional needs and perspectives of this diverse community so that service providers and policy makers get a better understanding of the needs of this community. Our hope is that members of the community can access much needed resources in order to improve their quality of life and health.

- We recommend that scholars conduct further research in areas such as family acceptance, HIV incidence and prevalence, matters that contribute to depression and suicide, the impact of sex work on the lives of TransLatin@s, the role of sexual health and pleasure in the lives of Trans Latin@s, reproductive health, as well as look to experiences of Latin@ transmen.

SURVEY APPENDIX

1. What is your age?
   - ☐18-24
   - ☐25-34
   - ☐35-44
   - ☐45-54
   - ☐55-64
   - ☐65+
2. What is your zip code?
   Zip: ____________
3. Do you consider yourself Latina/o?
   - ☐Yes
   - ☐No
   - ☐Other: ___________________________
4. What is your U.S. Citizenship status?
   - ☐U.S. Citizen
   - ☐Documented non-citizen
   - ☐Undocumented non-citizen
5. If you did migrate, how long have you been in the U.S.?
   __________years
6. If applicable, what country/countries did you or your families migrate from?
7. Which sex was assigned to you at birth, on your birth certificate?
   - ☐Male
   - ☐Female
8. How do you identify now?
   - ☐Male/man
   - ☐Female/woman
   - ☐Trans
   - ☐Transgender
   - ☐Transwoman
   - ☐Transman
   - ☐Other: __________________________
9. People can tell I am transgender/gender non-conforming even if I do not tell them?
   - ☐Always
   - ☐Most of the time
   - ☐Sometimes
   - ☐Occasionally
   - ☐Never
10. How many people know that you are transgender?

	None	A few	Some	Most	All	Not applicable
At home	☐	☐	☐	☐	☐	☐
On the job	☐	☐	☐	☐	☐	☐
At school	☐	☐	☐	☐	☐	☐
In private social setting	☐	☐	☐	☐	☐	☐
In public social settings	☐	☐	☐	☐	☐	☐
When seeking medical care	☐	☐	☐	☐	☐	☐

11. To the best of your ability, please estimate the following ages. If it does not apply to you, or you have no desire to transition, mark "N.A." for not applicable.

	Age in Years	N/A
a. Age you first recognized you were different in terms of your gender.		☐
b. Age you began to live part time as a transgender/gender non-conforming person		☐
c. Age you began to live full time as a transgender/gender non-conforming person.		☐
d. Age that you first got any kind of transgender-related medical treatment.		☐

12. For each of the following documents, please check whether of not you have been able (allowed) to change the documents or records to reflect your current gender. Mark "N/A" if you have no desire to change the gender on the document list.

	Yes, changes allowed	No, changes denied	My legal status does not allow me	Not tried	N/A
Birth certificate	☐	☐	☐	☐	☐
Drivers License and/or state issues non-driver ID	☐	☐	☐	☐	☐
Social security records	☐	☐	☐	☐	☐
Passport	☐	☐	☐	☐	☐
Work ID	☐	☐	☐	☐	☐
Military discharge papers (DD 214 or DD 215)	☐	☐	☐	☐	☐
Health Insurance Records	☐	☐	☐	☐	☐
Student records	☐	☐	☐	☐	☐
Professional licenses or credentials	☐	☐	☐	☐	☐

13. What is the highest level of education you have completed (either in the U.S. or country of origin)?
    - ☐ No formal education
    - ☐ Elementary School
    - ☐ Some high school
    - ☐ High school graduate –HS Diploma or equivalent (GED)
    - ☐ Some college credit
    - ☐ Technical school degree (such as cosmetology, computer technician, or mechanic)
    - ☐ Bachelor's Degree
    - ☐ Associate's Degree (AA, AS)
    - ☐ Master's Degree (MA, MS, ME, Med, MSW, MBA)
    - ☐ Professional Degree (Md, DDS, DVM, JD)
    - ☐ Doctorate Degree (PhD, EdD)
    - ☐ Other:___________________
14. What is your **individual** income (before taxes)?
    - ☐ Less than $10,000
    - ☐ $10,000 to $19,999
    - ☐ $20,000 to $29,999
    - ☐ $30,000 to $39,999
    - ☐ $40,000 to $49,999
    - ☐ $50,000 to $59,999
    - ☐ $60,000 to $69,999
    - ☐ $70,000 to $79,999
    - ☐ More than $80,000
15. How many individuals currently rely/depend on your income? (Mark all that apply)
    - ☐ My child/children, if so how many: _______________
    - ☐ My parent(s), if so, how many: __________________
    - ☐ My sibling(s), if so, how many: __________________
    - ☐ Other relatives under 18, if so how many: __________
    - ☐ Other relatives over 18, if so how many: ___________
    - ☐ Friend(s), if so how many: ______________________
    - ☐ Spouse/Partner

☐Other: ___________________________________

16. What is your sexual orientation?
    - ☐Heterosexual
    - ☐Homosexual
    - ☐Bisexual
    - ☐Asexual
    - ☐Auto sexual
    - ☐Other:_____________________
17. What is your relationship status?
    - ☐Single
    - ☐Partnered
    - ☐Domestic Partnership
    - ☐Civil Union
    - ☐Married
    - ☐Separated
    - ☐Divorced
    - ☐Widowed
    - ☐Other: ________________
18. What is your current living situation?
    - ☐Homeless (This includes if you are sleeping on a friends couch)
    - ☐Living in a shelter
    - ☐Living in a group home facility
    - ☐Living in a nursing/adult care facility
    - ☐Living on campus/university
    - ☐Living with parents or family you grew up with
    - ☐Staying with friends or family temporarily
    - ☐Living with a partner, spouse or other person who pays for housing
    - ☐Living in house/apartment/condo | RENT alone or with other
    - ☐Living in house/apartment/condo | OWN alone or with others
19. If you are currently homeless, do you know where there is a shelter where you feel you will be respected for who you are and will sleep at peace tonight?
    - ☐Yes
    - ☐No

    If yes, please tell us the name of this place
20. Have you been homeless in the past 12 months? (being homeless means sleeping at a friend's couch, or temporarily staying at someone's house that is not your permanent place of living)
    - ☐Yes
    - ☐No
21. If you have experienced homelessness in the past 12 months, please briefly tell us what caused you to be homeless: Please explain below
22. If you are or have experienced homelessness, what do you need order to secure stable housing? Please explain below
23. Do you believe that having stable housing is important to your health?
    - ☐Yes
    - ☐No

    Please explain why **it is** important or why **is not** important.
24. What is your current employment status? (Mark all that apply)
    - ☐Full-time
    - ☐Part-time
    - ☐More than one job
    - ☐Self-employed, own your business
    - ☐Unemployed but looking
    - ☐Unemployed and stopped looking
    - ☐On disability
    - ☐Retired
    - ☐Other, please specify:_________________
25. If you are currently employed please describe your work or vocation:
26. If you do not have what is typically called employment, please describe how you sustain yourself.
27. Do you have employment that provides you with health care insurance

☐Yes
☐No

28. If you do have health insurance through your employer, does your insurance and/or doctor provide trans-related care and coverage?
    ☐Yes
    ☐No
29. If yes, please explain what your insurance covers under trans related care.
30. Do you believe that having permanent employment is important to your overall health?
    ☐Yes
    ☐No
    Please explain why you think having employment **is important** to your health or why is **not important** to your health.
31. Please describe what would be the ideal job that you would like to have in the next three years.
32. What type of health insurance do you have? If you have more than one type of coverage, check the one that you usually use to cover doctor and/or hospital bills.
    ☐I have NO health insurance coverage
    ☐Insurance through a current or former employer (employee health plan, COBRA, retiree benefits)
    ☐Insurance through someone else's employer (spouse, partner, parents, etc.)
    ☐Insurance you or someone in your family purchased
    ☐Medicare
    ☐Medicaid/Medi-Cal
    ☐Military health care/Champus/Veterans/Tri-Care
    ☐Student insurance through college or university
    ☐Other public (such as state or county level health plan, etc.)
    ☐Other, please specify:_______________________________
33. Are currently enrolled in health insurance through Covered California?
    ☐Yes,
    ☐No
    If no, why not?
34. What kind of place do you go to most often when you are sick or need advice about your health?
    ☐Emergency room
    ☐Private Doctor's office
    ☐Health clinic or health center that my insurance pays for
    ☐Free health clinic
    ☐V.A. (veteran's) clinic or hospital
    ☐Alternative medicine provider (acupuncture, herbalist), specify: _______________
    ☐Not applicable, I do not use any health care providers
    ☐Other: ____
35. The following are a list of possible reasons why you may not get the health care you need. Based on your own situation, please rate your agreement or disagreement.

	Strongly agree	Agree	Disagree	Strongly disagree	N/A
a. Lack of personal resources	☐	☐	☐	☐	☐
b. Clinics having fear about Trans people or dislike of Trans people	☐	☐	☐	☐	☐
c. Lack of health professionals adequately trained to deliver healthcare to Trans people	☐	☐	☐	☐	☐
d. Long distances to Trans sensitive medical care facilities	☐	☐	☐	☐	☐
e. Doctors and other healthcare workers who refuse to provide services to Trans people	☐	☐	☐	☐	☐
f. Fear that if medical personnel find out I'm Trans, they will treat me different	☐	☐	☐	☐	☐
g. Lack of transportation to get to the services I need	☐	☐	☐	☐	☐

36. Please mark below the overall medical services that you have had access to in the past 12 months.

	Yes, I paid out of pocket	Yes, my insurance covers	No, Was unable to access	Do not know what this is
Annual Physical Exam				
Routine Prescriptions				
Dental Care				
Routine Medical Screening				
Emergency Room Visits				
Vision Care				
Routine Hospitalization				
Specialist Care				
Gynecological Care				
HIV Care				
High blood pressure				
Cardiologist				
STD testing				
Dermatologist				
Nutritionist				
Foot doctor				
X-Rays				
Surgeries (what type: write in below)				
Endocrinologist				

Other (please specify): ____

37. Please mark below if you received or want to receive health care related to being transgender/ gender non-conforming. If you have no desire to do so, please mark not applicable.

	Do not want it	Want it someday	Have had it	Not applicable
Counseling	☐	☐	☐	☐
Hormone Treatment	☐	☐	☐	☐
Top/chest/breast surgery (chest reduction, enlargement, or reconstruction)	☐	☐	☐	☐
Male-to-female removal of the testes (orchiectomy,	☐	☐	☐	☐
Male-to-female genital surgery (vaginoplasty; removal of penis and creation of a vagina, labia, etc.)	☐	☐	☐	☐
Female-to-male hysterectomy (removal of the uterus and/of ovaries)	☐	☐	☐	☐
Female-to-male genital surgery (clitoral release/metiodioplasty/creation of testes)	☐	☐	☐	☐
Female-to-male phalloplasty (creation of penis)	☐	☐	☐	☐
Facial cosmetic surgery	☐	☐	☐	☐
Electrolysis	☐	☐	☐	☐

38. If you have marked had any of the procedures done in Question 37, please tell us how you have/ or are you accessing those services:
39. Do you believe that having access to the procedures listed above (Question 37) are important for your overall wellbeing?
    ☐Yes
    ☐No
    a. Please explain why yes **it is important** or why not, is **not important**?
40. Do you believe that having access to a doctor on a regular basis is important to your health?
    ☐Yes

☐No

a. Please explain why yes **it is important** or why not, is **not important**?

41. How important is it to you to have a regular doctor that supports your health goals?
    ☐Extremely Important
    ☐Very Important
    ☐Somewhat important
    ☐Not important at all, I can be healthy even if I don't have a regular doctor
42. Do you use protection when engaging in sexual activity (penetration/oral)?
    ☐Yes
    ☐No
    a. Why or why not
43. Do you feel knowleagble about practicing safe sex?
    ☐Yes
    ☐No
44. Do you know where to learn about safe sex practices?
    ☐Yes
    ☐No
45. Have you ever been tested for HIV and STDs?
    ☐Yes
    ☐No
46. If yes, how often do you get tested for HIV and STDs?
    ☐I've only been tested once
    ☐Every six months
    ☐Every year
    ☐Every time I am with a new intimate partner
    ☐Other:______________________________
    a. If yes, where do you go get tested for HIV and STDs?
47. Have you not been tested for HIV because of any of the following reasons (mark all that apply.)
    ☐I feel healthy
    ☐I always practice safe sex
    ☐I don't know where I can get tested
    ☐I don't want to experience shame
    ☐I'd rather not know my status
    ☐Other:____________________
48. What is your HIV status?
    ☐HIV positive
    ☐HIV negative
    ☐Don't' know
49. If you are HIV positive, are you currently receiving treatment?
    ☐Yes
    ☐No
50. If you are receiving treatment, is it covered by your insurance?
    ☐Yes
    ☐No
51. If you don't have insurance, how are you obtaining HIV treatment/prescriptions?
52. Have you ever received a gender-related mental health diagnosis?
    ☐No
    ☐Yes. My diagnosis is:_____________________________
53. Not including a gender-related mental health diagnosis, do you have a disability (physical, learning, mental health) that substantially affects a major life activity?
    ☐Yes
    ☐NO
54. If yes, what is your disability? (Mark all that apply.)
    ☐Physical condition
    ☐Learning disability
    ☐Mental health condition
55. Have you ever been a victim of domestic violence or intimate partner violence because of being transgender?
    ☐Yes

☐No

56. Do you struggle with any of the following to cope?

	I currently do	I have in the past	This increased after my transition	This increased after another life event (job loss, death, etc)	Not applicable
Anxiety					
Clinical or severe depression					
Alcohol abuse					
Drug abuse					
Weight problems					
Anorexia					
Auto-immune problems					
Smoking					
Cutting					
Anger					
Psychiatric issues					
Thoughts of Suicide					
Hurting myself or others					
Other:					

57. For those boxes that you marked and you are currently struggling with, are you getting any assistance/ help?
☐Yes
☐No
58. If not, would you like to get a referral?
☐Yes
☐No
59. The following are a list of possible reasons why you may not get the mental health care you need. Based on your own situation, please rate your agreement or disagreement.

	Strongly agree	Agree	Disagree	Strongly disagree	N/A
a. Lack of personal resources	☐	☐	☐	☐	☐
b. Long distances to Trans sensitive mental health care facilities	☐	☐	☐	☐	☐
c. Fear that if mental health professionals find out I'm Trans, they will treat me different	☐	☐	☐	☐	☐
d. Lack of psychologists, social workers, and mental health counselors who can help Trans individuals with mental health issues	☐	☐	☐	☐	☐
e. Not enough psychological support groups for trans people	☐	☐	☐	☐	☐
f. Lack of transportation to get to the services I need	☐	☐	☐	☐	☐

60. Please let us know of any barriers that may keep you from accessing mental health help and support.
61. Do you currently have a social supportive system (including friends, family, other trans friends, etc.)?
☐Yes
☐No
a. If yes, please explain who is your social support system, if not please explain why you do not have a social support system currently
b. How does the social supportive system you have in place impact your overall wellness?
62. Do you believe that having access to Mental Health services on a regular basis is important to your health?
☐Yes
☐No
Please explain why yes, it **is important** or why you think is **not important**
63. How important is to you to have regular Mental Health services that supports you to be a healthy individual
☐Extremely Important

☐Very Important
☐Somewhat important
☐Not important at all, I can be healthy even if I don't have a regular mental health services

64. I partake in the following spiritual practices:
    ☐prayer
    ☐faith healing
    ☐homeopathy
    ☐magnetic therapy
    ☐numerology
    ☐astrology/horoscopes
    ☐gem-stone/crystals
    ☐Palmistry
    ☐Tarot
65. My religious affiliation is (Mark all that apply)
    ☐Christian
        ☐Protestant
        ☐Evangelical
        ☐Mainline
        ☐Catholic
        ☐Orthodox Christian
        ☐Mormon
        ☐Jehovah's Witness
        ☐Other Christian faith, please specify_______________________
    ☐Other Non-Christian Faiths
        ☐Santeria
        ☐Native American religions/practices
        ☐Buddhist
        ☐Jewish
        ☐Hindu
        ☐Muslim
        ☐Other non-Christian faith, please specify: ________________________
    ☐Unaffiliated
        ☐Atheist
        ☐Agnostic
        ☐Nothing in particular (believe in a higher power)
    ☐Don't know
66. Do you feel welcome and accepted by your religion and/ or place of worship?
    ☐Yes
    ☐No
67. Do you feel that you have to hide who you are because of your religion?
    ☐Yes
    ☐No
68. How important is to you to have regular spiritual/religious services?
    ☐Extremely Important
    ☐Very Important
    ☐Somewhat important
    ☐Not important at all, I can be healthy even if I don't have regular spiritual/religious services
69. Do you believe that having access to spiritual/religious services on a regular basis is important to your health?
    ☐Yes
    ☐No
    Please explain why yes or why not:
70. Anything else you'd like to tell us about your needs as a Latina/o trans/transgender person?

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www.translatinacoalition.org

/TRANSLATINACOALITION
@translatina_c

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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

WHITMAN-WALKER CLINIC, INC., *et al.*,

Plaintiffs,

v.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, *et al.*,

Defendants.

Case No. 1:20-cv-01630

DECLARATION OF ARIANNA INURRITEGUI-LINT, EXECUTIVE DIRECTOR OF ARIANNA'S CENTER

I, Arianna Inurritegui-Lint, hereby declare:

1. I am a 47-year-old transgender woman, an immigrant, and a person living with HIV.

2. I was born and raised in Lima, Peru, where I studied to become a lawyer. Seeking refuge from the discrimination I faced as an LGBTQ person in Peru, I immigrated to the United States in 1999. I initially settled in the New York metro area, before moving to Florida in November 2001.

3. English is my second language.

4. I am an individual member and the East Coast Co-Chair of the TransLatin@ Coalition.

5. I am also the founder and Executive Director of Arianna's Center.

6. Arianna's Center is a community-based 501(c)(3) nonprofit organization that provides advocacy, education and training, case management and linkage to care for transgender

Latinx men and women in South Florida and Puerto Rico. Our mission is to engage, empower and lift up the transgender community, with special emphasis on the most marginalized, including the transgender Latinx community, undocumented immigrants, people living with HIV and AIDS, and those who have experienced incarceration.

7. Arianna's Center is an affiliated organization of the TransLatin@ Coalition, meaning that as the leader of Arianna's Center, I serve on the board of the TransLatin@ Coalition. The Coalition is able to amplify its resources on a national basis by working closely with its affiliated, trans-led organizations across the United States that provide direct services to transgender and gender nonconforming Latinx people.

8. I founded Arianna's Center in 2015 to engage, empower, and uplift transgender and gender nonconforming Latinx people living in South Florida. Since its founding in 2015, Arianna's Center has expanded the reach of the organization to include transgender people living in Puerto Rico through the opening of a satellite office.

9. I currently live in South Florida and spend large amounts of time in Puerto Rico for my work. Neither the State of Florida nor the Commonwealth of Puerto Rico have state or territorial protections from discrimination on the basis of gender identity, transgender status, sexual orientation, or failure to conform with sex stereotypes in health care.

10. I am submitting this Declaration in support of Plaintiffs' Motion for a Preliminary Injunction to prevent the revised regulation under Section 1557 of the Affordable Care Act ("ACA"), published by the U.S. Department of Health and Human Services ("HHS") on June 19, 2020 (the "Revised Rule"), from taking effect. The Revised Rule eliminates explicit regulatory

protections for LGBT people in health care that were included in the 2016 Final Rule, which was promulgated under Section 1557 in May 2016.

11. Arianna's Center provides a variety of direct services to transgender and gender nonconforming Latinx people, with a focus on those who are most vulnerable to experiencing harm. This focus includes sex workers, people experiencing homelessness, persons living with HIV, people suffering from addiction, and transgender Latinx people who are immigrants or may be undocumented. Some of the Center's clients are also individual members of the TransLatin@ Coalition.

12. Arianna's Center provides free mobile testing for sexually transmitted infections and HIV and matches clients to follow-up health care and prevention services. The Center also connects clients to safe and affirming general medical and mental health care in the South Florida and Puerto Rico communities.

13. Arianna's Center also provides case management to help clients secure legal name changes, legal gender marker changes, and referrals for other legal support. The Center also provides emergency safe housing for transgender people in distress and those recently released from incarceration and Immigration and Customs Enforcement ("ICE") detention.

14. Arianna's Center also provides a 24/7 hotline number for community members to access whenever an emergency situation arises. This service allows the Center to meet crucial and time-sensitive needs, like access to post-exposure prophylaxis ("PEP") medication in cases of recent HIV exposure, or community crisis intervention services for situations of intimate partner violence.

15. Arianna's Center also provides education and employment services, including scholarships for GED completion programs and technical school certifications and coaching for transgender people preparing to enter the formal workforce.

16. Many of the people Arianna's Center serves have faced discrimination in trying to access gender affirming medical care and health care related to HIV management and prevention. These patrons have also been turned away from receiving health care because of their limited English proficiency or because of doctors' personal biases about transgender people. As an openly transgender woman living with HIV, I have experienced persistent discrimination from both health care providers and insurers during my life.

17. When I first moved to the New York metro area from Peru, I worked as a cashier because my license to practice law did not transfer to the United States. Despite being secure in my identity as a transgender woman, and knowing the medical transition steps I needed and desired to take, my health insurance did not cover hormone replacement therapy or gender confirming surgery – an exclusion that the 2016 Final Rule prohibited and is now seemingly permitted by the Revised Rule. Like many transgender people, I could not afford these treatments out-of-pocket on my cashier's salary.

18. As a result of the limited income available to me as a transgender Latinx immigrant and the discrimination I faced from my health insurance company, I had to work as an escort in order to make sufficient income so that I could afford the gender affirming medical care I needed, including informal treatments, like silicone injections.

19. I saved a great deal of money during my time doing sex work in New York City and was able to move to Orlando, Florida a few months after September 11, 2001.

20. After arriving in Orlando, I opened a construction company and was able to purchase a home but still could not afford health insurance or the out-of-pocket costs for gender affirming medical care through licensed providers.

21. Due to the lack of nondiscriminatory health insurance coverage and lack of access to affirming health care providers, I had to access gender affirming medical treatments through informal and unlicensed channels, where I could pay reduced prices for breast augmentation and additional silicone augmentation. I also continued to access hormone replacement therapy through these same channels because when I met a health care provider to discuss this treatment, I was told I would need a year's worth of psychotherapy before I would be prescribed hormones and I could not afford the out-of-pocket costs for a year's worth of therapy that insurance would not cover.

22. It was around this time I learned I was HIV positive. I believe I was exposed to HIV through the silicone injections I was accessing because I was diligent about safer sex practices.

23. I now have to live with HIV for the rest of my life, due in large part to discriminatory barriers in health care and health insurance for medically-necessary care for transgender people like myself.

24. I have found that being a transgender woman living with HIV carries a double dose of stigma when trying to access health care or utilize health insurance coverage. When I tried to access health care through public clinics, I found that health care providers would ask me uncomfortable questions about how I contracted HIV and my identity as a transgender woman.

25. In order to avoid issues related to discrimination in health care, I started working as a volunteer with a public health clinic in Orlando to allow me to educate providers about how to respectfully treat transgender people and ensure that I would not be subjected to as much discrimination myself.

26. I worked as a volunteer with an Orange County Health Department-run clinic in Orlando from 2006 to 2008 and was hired on as a full-time employee from 2008 to 2014.

27. During my time as a clinic volunteer and employee, I observed many instances of nursing staff and administrative employees not treating transgender people with the respect and dignity that they deserve. I often intervened in situations of discrimination against transgender people and worked to educate health care providers about how to respectfully treat transgender patients. This included explaining the impact of legal and financial barriers transgender patients face and the different forms of discrimination we encounter.

28. For example, a staff member often misgendered or called transgender patients by their birth name, rather than their preferred name, also known as “deadnaming.” “Misgendering” is when someone refers to a person as the wrong gender or uses language to describe a person that does not align with that person’s affirmed gender. “Deadnaming” occurs when someone calls or refers to a transgender individual by the name that the individual was assigned at birth even though that person has chosen a new name consistent with their gender identity. These are verbal acts of discrimination against transgender and gender nonconforming individuals that stigmatize, dehumanize, and even “out” the individual to others in the vicinity. These acts of discrimination cause significant distress, undermine a person’s identity and sense of self-definition, have negative impact on a person’s self-esteem and sense of self, and expose

people to risk of physical or bodily harm.

29. More systemically, only one of the five doctors in the clinic would prescribe hormones to transgender patients, as the other doctors refused to provide gender affirming treatment. As a result, there was a huge backlog and waiting list for transgender patients because only one doctor could properly care for them; they would have to wait as long as a year because the only doctor that prescribed hormones was overwhelmed.

30. I have also experienced discrimination in healthcare outside of that clinic, simultaneously because of my transgender identity, my HIV status, and my limited proficiency with speaking English.

31. For example, on one occasion at an emergency room, a health care provider misgendered me and had difficulty understanding me because of my limited English proficiency. When the provider understood that I was HIV-positive, the provider accused me of withholding the information from her, even though that I had been trying to explain it to her, and then threatened to call the police on me. As a transgender woman and immigrant, such threats carry even more weight because transgender people of color and immigrants face disproportionate rates of police violence and misconduct. Moreover, as an immigrant, any interaction with law enforcement can have significant immigration consequences.

32. For many immigrants like myself, the importance of having forms written in languages besides English, as well as qualified interpreters who speak languages besides English, can mean the difference between being able to access health care and not.

33. My personal experiences as an immigrant and a transgender woman who speaks English as her second language motivated in large part my founding of Arianna's Center in 2015

in Ft. Lauderdale, Florida. Arianna's Center exists to support other transgender Latinx people who are navigating barriers to health care like I did, but also to help ensure that no one else has to experience life-altering discrimination in health care and health insurance.

34. For these reasons, I am very concerned about the negative impacts the Revised Rule will have on transgender, gender nonconforming, and Latinx people. I fear that, as a result of the Revised Rule, I will experience even more discrimination by health care providers and insurers because of my sex, transgender status, national origin, disability, LEP status or some combination of these characteristics.

35. This fear is compounded because I live in Florida and spend considerable time in Puerto Rico, neither of which have state-level antidiscrimination protections for LGBTQ people in health care. Without federal protections like the regulatory protections being eliminated by the Revised Rule, transgender people like me will have little recourse to address the health care discrimination we will likely face and will be deprived of the clear nondiscrimination guidance the 2016 Final Rule provides to health care providers and insurers.

36. Not only do I worry about the personal harm I will experience as a result of the Revised Rule, but I worry about the significant harm to the transgender and gender nonconforming Latinx people Arianna's Center serves in South Florida and Puerto Rico, as well as the ability of Arianna's Center to carry out its activities on behalf the community it serves and the diversion of the Center's already limited financial resources in order to respond to those harms.

The Revised Rule's Negative Effects on the Transgender Latinx People

37. Arianna's Center clients are primarily transgender and gender nonconforming Latinx people, who are immigrants to the United States and/or who are currently residing in Puerto Rico. Many of our clients are also living with HIV/AIDS. The Revised Rule invites health care providers to discriminate against individuals served by Arianna's Center because of their sex, gender identity, transgender status, national origin, and/or LEP status.

38. Many of Arianna's Center clients live in communities in which English is not the primary language spoken and many individuals served in these communities speak, read or write English less than very well.

39. Arianna's Center clients have also experienced, or fear they may experience, discrimination from health care providers and insurers based on their sex, gender identity, transgender status, national origin, LEP, disability, or some combination of these characteristics.

40. The Revised Rule threatens these clients by inviting discriminatory behavior by healthcare providers and insurers based on sex, transgender status, national origin, disability, LEP status, or a combination of these intersecting characteristics.

41. The findings of a 2018 Human Rights Watch report published in collaboration with help from Arianna's Center entitled, "Living At Risk: Transgender Women, HIV, and Human Rights in South Florida," help explain how and why the Revised Rule will cause even more harm to our clients living in South Florida and Puerto Rico. The report "Living At Risk" is attached to this declaration as **Exhibit A**.

42. The researchers of "Living At Risk" administered surveys with 125 questions to transgender women living in Miami-Dade and Broward counties, two counties with the highest rates of new HIV infection in the United States. The study found that despite already substantial

and year over year increases in government funding for HIV prevention medication and treatments through the Ryan White Act programs, transgender women living with HIV in Miami-Dade and Broward counties face significant discrimination and lack of access to necessary health care.

43. Many of the transgender women surveyed, a significant proportion of whom are Latinx, reported experiencing disrespect, harassment, and denial of services in health care settings. They also reported such experiences often result in avoidance of health care altogether.

44. With the help of Arianna's Center, Human Rights Watch performed more than 100 interviews with transgender women, local HIV service providers, and advocates like myself, which demonstrated the reality in South Florida that transgender women of color experience higher rates of HIV infection due to the intersecting risk factors of poverty and lack of health insurance coverage.

45. Of the transgender women surveyed, 45% had no health insurance. More than 63% reported income of less than $10,000 a year, and more than half were unemployed.

46. Without a doubt, a contributing factor to the high rate of underinsured transgender women of color in South Florida, many of whom are clients of Arianna's Center, is the State of Florida's refusal to expand Medicaid coverage under the Affordable Care Act, which would extend Medicaid coverage to adults without dependents.

47. As the findings of the "Living At Risk" report demonstrate, the Revised Rule's invitation to health care providers and insurers to discriminate against Arianna's Center clients based on sex, gender identity, transgender status, national origin, disability, and LEP status will

worsen the health and wellbeing of transgender people and of transgender women of color in particular.

48. With the Revised Rule's removal of nondiscrimination protections on the basis of sexual orientation, gender identity, and transgender status, Arianna's Center's vulnerable clients risk even greater unmet health care needs. These transgender and gender nonconforming people will likely delay necessary health care and preventative screenings due to fear of discrimination and will face reduced access to care as a result of discrimination. In addition, they will face barriers to coverage of gender affirming care because of the Revised Rule's guidance that insurers may exclude such care from coverage.

49. As Arianna's Center's clients and other transgender and gender nonconforming people avoid necessary, routine, and preventative health care for fear of discrimination, they will face an increase in preventable health problems which will severely impede their ability to work, maintain housing, and afford other material necessities.

50. Under the Revised Rule, Arianna's Center's clients will be forced to pay considerable out-of-pocket medical expenses because insurers refuse to pay for life-saving and medically necessary care.

51. Because of the desire to avoid discrimination the Revised Rule invites and encourages, Arianna's Center's clients in South Florida and Puerto Rico will likely seek informal medical care from unlicensed providers. This inevitable reality will create another nexus of physical harm, for which people will again avoid seeking licensed medical care for fear of discrimination, until their physical condition is most dire, creating lasting physical and mental harm.

52. Arianna's Center's clients are not just transgender or gender nonconforming Latinx people but also immigrants, people living with HIV/AIDS, and people who speak, read, or write English less than very well. These intersecting characteristics position them to experience increased harm from the Revised Rule's elimination of a single legal standard to govern the intersectional discrimination they may face. Rather than being able to assert claims under a single legal standard, intersectional discrimination claims will be subject to different standards, enforcement mechanisms, and remedies based on which identities are at issue. This change will have a particularly harmful effect because discrimination based on sexual orientation, gender identity, transgender status, national origin, disability, and LEP status does not occur in an identity vacuum.

53. The Revised Rule's removal of language access protections, such as notice and tagline requirements, will also make it much more difficult for Arianna's Center's clients to be aware of their rights, which language services are available, how to access such services and how to handle discrimination and other complaints.

54. Arianna's Center has heard from clients that verbal and written interpretation services at medical appointments and in insurance coverage documents and communications remove an intimidating barrier to accessing preventative and necessary health care services.

55. The removal of language support services will likely cause individuals to delay seeking treatment for health conditions until they have attained a certain level of English proficiency, which will worsen underlying health issues as well as create additional complications requiring treatment.

56. Arianna's Center also understands that the Revised Rule attempts to change nondiscrimination regulations within the Center for Medicare and Medicaid Services ("CMS") to no longer prohibit discrimination on the basis of sexual orientation and gender identity.

57. This change, specifically to public health insurance programs, will significantly harm Arianna's Center's clients because many transgender and gender nonconforming people in South Florida and Puerto Rico rely on Medicaid or Medicare for their primary health insurance coverage. For example, according to a 2018 study, 39% of transgender women in South Florida receive health insurance coverage through Medicaid.

58. If nondiscrimination protections are removed from CMS through the Revised Rule, our clients who rely on public health insurance coverage through Medicare and/or Medicaid, will have reduced to no access to nondiscriminatory health care insurance coverage.

The Revised Rule's Harms to Arianna's Center

59. In addition to the harms to Arianna's Center's clients (some of whom are also individual members of the TransLatin@ Coalition), the Revised Rule will also harm Arianna's Center as an organization. As a small, community-based organization with only four staff members, Arianna's Center provides a panoply of services to the community with very limited resources. The discrimination the Revised Rule invites, the Revised Rule's direct harms, and the downstream effects of the Revised Rule will greatly affect our ability to meet our clients' needs and, given the resource diversion it will cause, undermine our ability to carry some of our critical programmatic services like our 24/7 emergency hotline, mobile sexual health testing, and providing safe emergency housing for transgender people in distress and those recently release from incarceration or immigration detention.

60. As a direct result of the Revised Rule, Arianna's Center will see a significant increase in requests for referrals to health care providers who will provide affirming and welcoming health care services. In turn, Arianna's Center will be required to divert additional resources, such as those used to provide for our GED and technical college scholarship programs to vet further additional health care providers, as the already-known affirming providers will become overwhelmed themselves.

61. This increase in referral requests for a limited number of providers who are affirming and welcoming will result in a substantial backlog in available providers and appointments. Many people whom Arianna's Center serves will therefore experience critical delays in receiving treatment for potentially serious health conditions because they will avoid seeing a provider who may discriminate against them based on their sex, transgender status, national origin, and/or LEP status.

62. Due to this delay in seeking treatment, many individuals will also face serious financial difficulties as they will have to pay for the expensive treatment required to address worsened health conditions and because of their inability to work while ill. As a result, Arianna's Center will be forced to divert significant financial resources away from other programs like our case management and employment coaching services to emergency support services, including housing support, mobile HIV testing and the 24/7 emergency hotline in order to meet increased and more serious demands. There is a real risk that Arianna's Center will run out of resources to provide these emergency services. These services will be necessary, however, given the increase in transgender people who will be out of work, and unable to pay rent or afford other material necessities as result of delayed treatment of serious or semi-serious health conditions.

63. Moreover, the COVID-19 pandemic has already put a severe strain on the long-term availability of Arianna's Center's fundamental programmatic services like emergency housing support. To accommodate the lack of employment and economic stability facing many members and individuals served by Arianna's Center, the organization already has been forced to shift resources. The effects of the Revised Rule will require Arianna's Center to provide additional emergency support services, further straining and burdening the Center.

64. While providing these emergency support services is an important programmatic component of Arianna's Center's work, it is only a part of the organization's overall activities. A significant redirection of funds required by the impact of the Revised Rule will impede Arianna's Center's ability to perform other programmatic activities like case management, legal name and gender marker change referrals, scholarships for GED completion and technical school tuitions, workforce development training programs, community research and education programs, and local and state advocacy campaigns for laws protecting the organization's clients.

65. The removal of language access measures from health care providers' offices and in health insurance bulletins and communications will make it much more difficult for Arianna's Center members and individuals with LEP to be aware of their rights; which language services are available, if any; and how to access such services; and how to handle discrimination and other complaints.

66. In addition to shifting much of our already limited budget to emergency services and services to support members and individuals with LEP, the impact of the Revised Rule will also require shifting an unexpected amount of limited resources to supporting our clients in finding nondiscriminatory health care providers, devising individual solutions for health

insurance exclusions for gender affirming care, and securing nondiscriminatory mental health treatment for the trauma that will occur because of widespread discrimination.

67. Arianna's Center will also be forced to devote a dwindling amount of resources to working with health care providers, insurers and other related organizations to educate and remind them of the importance of providing health care and insurance coverage to all patients on non-discriminatory terms.

68. The Revised Rule threatens to completely overwhelm the programs and activities Arianna's Center has been undertaking over the last few years to engage, uplift and improve the lives of transgender, gender nonconforming and intersex Latinx people in South Florida and in Puerto Rico. The harm to Arianna's Center will be long-lasting and difficult, if not impossible, to undo.

* * * * *

69. The Revised Rule poses serious and ongoing threats to the health and overall wellbeing of transgender and gender nonconforming Latinx people, like those served by Arianna's Center in South Florida and Puerto Rico. The Revised Rule also threatens the ability of Arianna's Center to fulfill its mission and provide critical programmatic services to the community it serves.

[*Signature on next page*.]

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Dated this 6th day of July, 2020.

Arianna Inurritegui-Lint

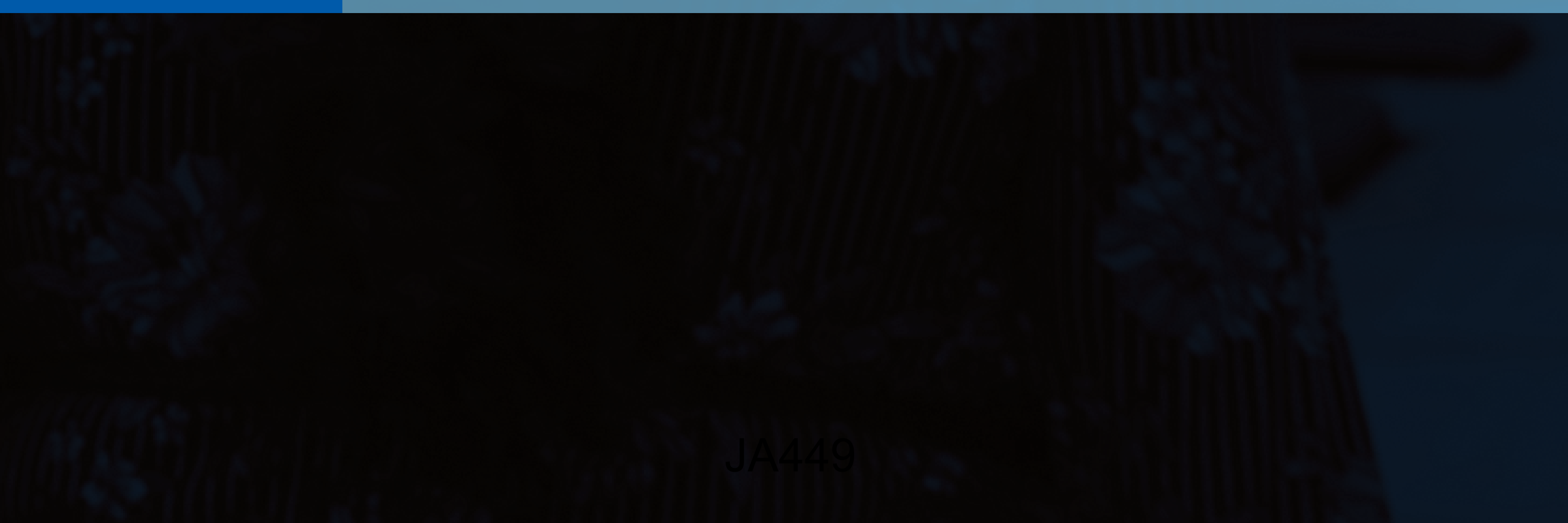
EXHIBIT A

Living at Risk: Transgender Women, HIV, and Human Rights in South Florida

HUMAN RIGHTS WATCH

LIVING AT RISK

Transgender Women, HIV, and Human Rights in South Florida



Living at Risk

Transgender Women, HIV, and Human Rights in South Florida

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Human Rights Watch defends the rights of people worldwide. We scrupulously investigate abuses, expose the facts widely, and pressure those with power to respect rights and secure justice. Human Rights Watch is an independent, international organization that works as part of a vibrant movement to uphold human dignity and advance the cause of human rights for all.

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Living at Risk

Transgender Women, HIV, and Human Rights in South Florida

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Summary

> This woman shouted for 'Kevin' to come to the desk. I shrunk in my seat, hoping she would see the note on the chart about my gender change. But she just kept yelling for Kevin. I finally had to get up and cross the room in a walk of shame. Will I ever go back there? No way.
>
> – Connie, 31, Miami, Florida

Connie is HIV-positive, one of many transgender women in Florida facing the challenge of finding health care that is safe, gender-affirming, and affordable. The 1.4 million transgender and gender-non-conforming people in the United States generally face multiple barriers, from family rejection to non-acceptance and abuse at school, and pervasive discrimination in employment, housing, and health care. Social and economic marginalization as a result of these factors lead to higher rates of suicide, poverty, violence, and incarceration, particularly for trans people of color. This is a severe and compound environment of risk for HIV that demands a robust response – one that the state of Florida, and the federal government, are failing to deliver.

Nationally, rates of HIV are declining as treatment becomes more effective and, if administered regularly, can eliminate the potential for transmission of the virus. Rates of HIV among transgender men appear to be low, though more study is needed. But among transgender women, rates of new HIV infection have remained at crisis levels for more than a decade. One of four trans women, and more than half of African-American trans women are living with HIV, rates that are far higher than the overall prevalence of HIV in the US of less than one percent. Transgender women are testing positive for HIV at rates higher than cisgender men or women, and racial disparities are stark: HIV prevalence is more than three times higher among African-American transgender women than their white or Latina counterparts.

Since 2010, the National HIV/AIDS Strategy has recognized trans women as a "key" population whose needs must be addressed. Trans people frequently experience disrespect, harassment, and denial of care in health care settings, and many avoid seeking health care as a result. HIV policymakers know what to do: ample evidence indicates that to be effective, health care services for trans individuals must be affordable, gender-affirming, and should be integrated with transition-related care. This is particularly important for HIV care. If forced to choose, trans women will frequently prioritize Hormone

Replacement Therapy (HRT) over HIV care, making it essential to combine these services in a "one-stop shop."

Numerous pilot programs across the country have demonstrated that providing integrated HIV care that engages and respects trans women is feasible and successful in reducing HIV risk and improving health outcomes. But this investigation of HIV prevention and care for trans women in south Florida found that trans women are navigating a difficult landscape that state and federal authorities have not done nearly enough to address. Services are fragmented, integrated care is limited, and cost and lack of insurance leave medical and mental health care out of reach. To the extent that such services exist, they are more a result of community demand and local advocacy efforts rather than federal or state policy, which contain no targeted requirements or standards to ensure that trans women are receiving the services they need.

The problem is not money. As a state with one of the country's highest rates of HIV infection, Florida receives hundreds of millions of dollars from the Ryan White program, the federal government's primary vehicle for funding HIV prevention and treatment services. The state HIV budget has increased more than 15 percent in the last three years. Nationwide and in Florida, more than half of people living with HIV receive care through a Ryan White funded program. Ryan White services are important for transgender women – when they stay in treatment in Ryan White programs, their health outcomes are significantly better than when they do not.

Despite a wide network of public and private providers in the metropolitan areas of Miami and Fort Lauderdale, only a handful of HIV clinics are consistently identified as providing what is recognized best practice, and to some experts, the standard of care, for transgender women. State HIV officials told Human Rights Watch that all Ryan White funded clinics "welcome" trans patients, but there was no systemic monitoring of the issue to determine whether this is the case, and evidence from the ground suggests otherwise. In fact, Human Rights Watch found that many transgender women experienced disrespect, harassment, and denial of services in health care settings, and that such experiences often result in avoidance of health care altogether.

The Ryan White program covers medications for patients under the AIDS Drug Assistance Program (ADAP). The federal government sets core criteria, but states can also cover medications for needs and conditions related to HIV, such as mental health and hepatitis C medications. In 21 states, ADAP covers hormone replacement medications for the purpose of gender transition – an important part of ensuring that HIV care meets the health

needs of transgender women. Florida is not one of these states, and federal policy does not require it to do so.

Underlying this lack of targeted government policy is the lack of accurate information about HIV risk and infection among trans women in Florida. The failure to collect accurate or complete HIV data among trans people is an ongoing problem. Decades into the epidemic, neither the state nor the federal government know how many trans women are living with HIV. Most states, including Florida, have only partially implemented federal recommendations for how to improve data collection for HIV among trans populations, and though Florida's data on trans women is improving, they remain incomplete. Estimates developed from other experts indicate that the number of transgender people living with HIV in Florida may be five to ten times higher than reported by the state.

Given that government response is driven by data, the undercounting of HIV prevalence means trans women are left out of many federal and state programs intended to monitor or improve HIV services. Often perceived by policymakers as a population too small to help, conditions for trans women on the ground remain unknown, unchanged, or inadequate. Over thirty years into the epidemic, the stark reality is that trans women are at an extremely high risk of HIV, but as a distinct population remain largely invisible to the federal and state HIV surveillance and monitoring systems that guide government response.

For this report, Human Rights Watch investigated access to health care, including HIV prevention and treatment, for women of trans experience in south Florida. We administered 125 survey questionnaires among trans women in Miami-Dade and Broward counties, two counties with the highest rates of new HIV infections in the country. These questionnaires, and the more than 100 interviews with trans women, their advocates, and HIV service providers indicated that many trans women in south Florida, particularly women of color, experience high HIV risk as a result of multiple factors, with poverty and lack of health insurance standing out as primary vulnerabilities. More than 63 percent of survey participants reported income of less than $10,000 per year, more than half were unemployed, and one of three were in "unstable" housing situations. This data is consistent with national surveys showing that many trans people live in extreme poverty and are three times more likely to be unemployed than those in the general population.

Nearly half of survey participants – 45 percent – had no health insurance. This alarming reality is tied to Florida's refusal to expand its Medicaid program under the Affordable Care Act, a decision that has left hundreds of thousands of low income and working Floridians

without access to health insurance. It is a decision that has a severe impact on transgender women, who are among the most impoverished residents of the state. Medicaid expansion could dramatically improve access to health care for trans individuals, many of whom would be included in its coverage of adults without dependents. Access to Medicaid could increase options for trans women as they attempt to locate gender-affirming health care in their community, providing vital access to HIV prevention and treatment.

Nationally, one of five trans women has been incarcerated, with African-American trans women three times more likely to face arrest than their white counterparts. Many trans women often turn to sex work in order to survive, leaving them vulnerable to police abuse and criminal charges that can begin, and perpetuate, a cycle of unemployment and lack of income. In the Human Rights Watch survey, more than half of respondents said they had been arrested at least once. Involvement in the criminal justice system increases HIV risk – even short jail stays have been shown to have negative health outcomes. Jails and prisons are also dangerous places for trans women, who report alarming rates of sexual assault in detention.

As trans women in Florida and throughout the US are struggling to access HIV prevention and care, the Trump administration has pressed forward with policies that will erode key LGBT rights protections and erect new barriers to their enjoyment of the right to health. The right to health does not guarantee to everyone a right to be healthy. Rather, its realization requires governments to implement policies that promote access to health care without discrimination, with particular attention to those facing the most barriers to care – low income persons, women, minorities, people with disabilities, and others.

Since Inauguration Day 2017, President Trump has moved in the opposite direction with a policy agenda that has sought repeal of the Affordable Care Act, restrictions on Medicaid access, and the rollback of regulations that protect LGBT Americans from discrimination. The rights of trans people are specifically threatened, with attempts to ban trans soldiers from the military, eliminate protections in federal law and policy that protect trans people from discrimination in employment and health care on the basis of gender identity, and weaken protections for transgender federal prisoners. For trans women, who face pervasive discrimination in employment and health care settings, the rollback of existing protections could have a particularly devastating impact.

In this increasingly hostile environment, trans women are in greater danger than ever and in greater need of federal and state support. For health officials, few questions remain

about what to do to reduce HIV infection among trans women. But without commitment by both federal and state policymakers to take these steps and remain accountable for doing so, the lives and health of trans women will remain at risk, and the crisis will continue.

Recommendations

To the President of the United States:

- Re-establish federal leadership addressing the HIV epidemic in the United States, including appointment of a director and staff for the Office of National HIV/AIDS Strategy and making appointments to the President's Advisory Council on HIV/AIDS comprised of public health experts, community leaders, and representatives of groups most heavily impacted by HIV, including trans women.
- Withdraw the executive order issued October 12, 2017 that permits unregulated health insurance plans inconsistent with the requirements of the Affordable Care Act.
- Withdraw the executive order issued May 4, 2017 instructing the Department of Health and Human Services to amend regulations for conscience-based objections to preventive care provisions of the Affordable Care Act.

To the Department of Health and Human Services:

- Protect and support expansion of the Medicaid program to ensure access to health care for low income people. Withdraw support for state waiver provisions that would reduce access to health services.
- Either defend the interpretation of section 1557 of the Affordable Care Act to protect against discrimination on the basis of gender identity, or introduce new legislation codifying those same protections.
- To the Health Resources and Services Administration (HRSA):
    - Implement policy regulations and guidance to states ensuring the protection of LGBT individuals from discrimination in insurance coverage. This includes the revision of Medicaid regulations to address denials on the basis of perceived gender incongruity.
    - Establish policies, monitoring, and evaluation procedures to promote gender-affirming care, including hormone replacement therapy, in all sites receiving Ryan White program funds, and support coverage of hormone replacement therapy in the AIDS Drug Assistance Program.

To the Centers for Disease Control and Prevention:

- Conduct a systematic review of implementation of the CDC Guidance for Working with Transgender HIV Data to ensure that states are taking effective steps to implement the Guidance and improve HIV data collection for trans communities.
- Identify states in need of technical assistance and prioritize provision of services accordingly.
- Report on steps taken and progress toward development of a national "indicator" for data collection on HIV among transgender communities as set forth in the National HIV/AIDS Strategy Update for 2020.

To the US Bureau of Prisons:

- Withdraw revisions to the Bureau of Prisons Transgender Offender Manual that weaken protections for transgender prisoners.
- Ensure that all regulations comply with Prison Rape Elimination Act requirements in order to reduce sexual assault in detention.

To the Congress of the United States:

- Stop attempts to repeal or further dismantle the Affordable Care Act without an adequate replacement.
- Support expansion of the Medicaid program to ensure access to health care for low income people.
- Pass legislation protecting LGBT persons from discrimination in health care, employment, and public accommodation.
- To the Senate: ratify the International Covenant on Economic, Social, and Cultural Rights.

To the State of Florida:

- To the Governor of the State of Florida:
  - Expand Medicaid under the Affordable Care Act to ensure access to health care for low income people including adults living in poverty with no dependents, and to reduce poverty in the state.
- To the Florida State Legislature:
  - Repeal HIV-specific criminalization laws.

  - Support criminal justice reform including alternatives to incarceration and decriminalization of consensual, adult sex work.
- To the Department of Health:
  - Issue a public report on progress to date and timelines for implementation of CDC Guidance for Working with Transgender HIV Data.
  - Establish policies, procedures, and monitoring systems to ensure that gender-affirming care is integrated with HIV care and services in all health care settings, including all sites receiving Ryan White funds.
  - Participate in the federal ECHO program to evaluate and improve the quality of HIV services for transgender people.
  - Ensure coverage for hormone replacement therapy in the AIDS Drug Assistance Program in all geographic areas and increase awareness of its availability.
- To the Office of Health Care Administration:
  - Develop explicit policy ensuring Medicaid coverage for transgender health care.

Methodology

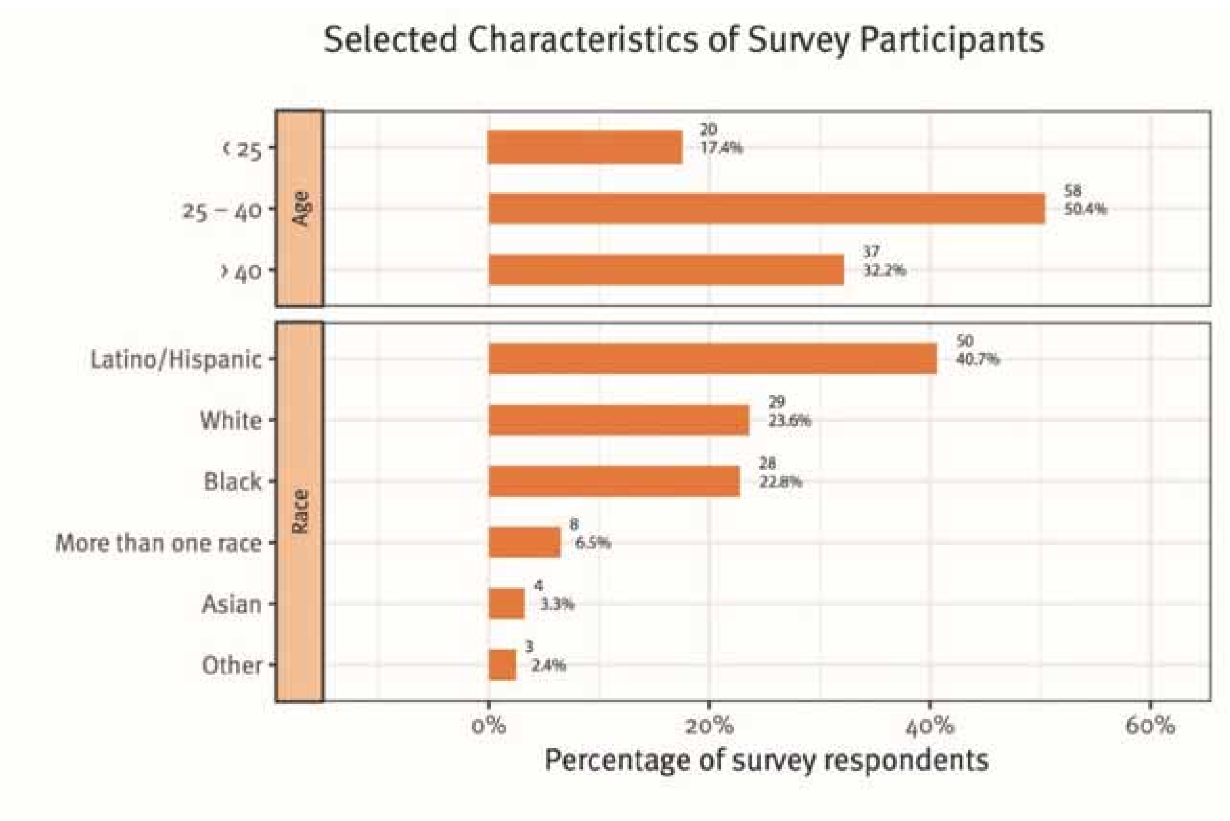
This report is based on research conducted between June 2017 and June 2018 in the south Florida counties of Miami-Dade and Broward. Human Rights Watch utilized a mixed-method approach that combined quantitative survey and qualitative interviews and legal and policy analysis. The research focuses on access to health care, including HIV prevention, for individuals who self-identified as women of trans experience – a term that was intended to reflect a variety of experiences and expressions – and that was left to the individual to define.

In addition to basic demographic information, the questions emphasized access to health care, including HIV care, access to HIV prevention, and interaction with the criminal justice system. Human Rights Watch identified respondents primarily through organizations providing social services to transgender people in the two counties and through the personal networks of peer interviewers. This approach produced a diverse group of respondents but should not be considered a representative sample of trans individuals in these counties, as survey participants were likely to be connected to health and HIV services.

For the quantitative component of the research, Human Rights Watch trained 15 peer interviewers in the administration of a survey, human rights documentation, and research ethics, including the importance of informed consent and confidentiality. Peer interviewers were diverse in age, gender identification, and ethnicity and were selected on the recommendation of, and in some cases were themselves representatives of, organizations providing services for transgender people in Miami-Dade and Broward counties. Of 125 questionnaires, 81 were administered by peer interviewers and 44 were administered directly by Human Rights Watch.

Survey participants were all Florida residents in Miami-Dade or Broward Counties who self-identified as women of trans experience; the survey tool made no inquiry into the definition of that term. The responses to the survey's demographic options showed that 41 percent identified as Latina/Hispanic, 24 percent as White/Caucasian, 23 percent as Black/African-American, 4 percent as Asian and 7 percent as other or as "more than one race;" ages reported ranged between 19 and 70 (see Graph I).[1]

[1] All survey results are on file with Human Rights Watch. Percentages may not total 100 due to rounding. Not all responses were valid for every question; percentages reflect total of valid responses. Latina/Hispanic women can be of more than one race.



Peer interviewers were paid a nominal stipend for their training time and administration of the survey. Gift cards were provided to interviewees to reimburse them for travel and related expenses.

All participants were informed of the purpose of the survey, its voluntary nature, and the ways in which the information would be used. All participants provided oral consent to be interviewed and consent was noted on each survey form. Participants were assured Human Rights Watch would not publish their names; all names of survey participants reported are pseudonyms. Survey results were tabulated and analyzed by Human Rights Watch.

Human Rights Watch also interviewed more than 100 advocates, health care providers, public defenders, sheriff and jail officials, members of state HIV planning councils, federal health and criminal justice officials, and national experts on transgender health. The Florida Department of Health HIV/AIDS Section responded to written questions in writing and responded on behalf of Miami-Dade and Broward County departments of health; Broward County Department of Health officials also met with Human Rights Watch in person. Documents were obtained from the Florida Department of Health, Broward County

Department of Health, Broward County Sheriff's Office, and Hollywood, Florida Police Department. All documents cited are publicly available or on file with Human Rights Watch. Pseudonyms are used for anyone not interviewed in their official capacity to protect privacy and confidentiality.

Background

Discrimination, Abuse, and Health Risks Among Transgender People

In the United States, an estimated 1.4 million people (0.6 percent of the population) identify as transgender. Transgender or "trans" is an umbrella term intended to be inclusive of the full range of nuance and diversity of gender expression and identity among those who may not identify with the sex they were assigned at birth.[2] Trans women were assigned male sex at birth but identify as women; trans men were assigned female sex at birth but identify as men.

Trans and gender-non-conforming people tend to face barriers in multiple aspects of life, from family rejection to non-acceptance and abuse at school, and pervasive discrimination in employment, housing and health care. Social and economic marginalization as a result of these factors are linked to higher rates of suicide, poverty, and incarceration, particularly for trans people of color. According to a survey conducted in 2015 by the National Center for Transgender Equality (NCTE), trans people were more than twice as likely as the US population as a whole to live in poverty and three times as likely to be unemployed.[3] A staggering 40 percent of respondents had attempted suicide, compared to 1.6 percent in the US population.[4] Violence was a fact of everyday life, with nearly half reporting having been sexually assaulted at one point and one in ten reporting sexual assault within the last year.[5]

In the national survey, African-American and Latino/a trans respondents fared worse than their white counterparts nearly across the board, reporting lower income, less access to health care and health insurance, as well as higher rates of homelessness, employment discrimination, and incarceration.[6] Trans people of color were more likely than white trans

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[2] National Center for Transgender Equality, "FAQs: Transgender People," https://transequality.org/issues/resources/frequently-asked-questions-about-transgender-people (accessed August 17, 2018).

[3] National Center for Transgender Equality (NCTE), *US Transgender Survey 2015,* https://transequality.org/sites/default/files/docs/usts/USTS-Full-Report-Dec17.pdf, (accessed August 17, 2018); see also National Center for Transgender Equality and National Gay and Lesbian Taskforce, *Injustice at Every Turn*, 2011, http://www.thetaskforce.org/static_html/downloads/reports/reports/ntds_full.pdf (accessed August 17, 2018).

[4] NCTE, National Transgender Survey 2015.

[5] Ibid.

[6] NCTE, *Black Respondent Report,* http://www.transequality.org/sites/default/files/docs/usts/USTSBlackRespondentsReport-Nov17.pdf (accessed August 17, 2018). The NCTE survey included "Black or African-American" and Latino/a or Hispanic" as racial/ethnic classification categories.

people to report abuse by the police as well as victimization while in jail or prison.[7] This is consistent with data collected under the federal Prison Rape Elimination Act indicating that African-American and Latina trans women report sexual assault in detention at higher rates than white women.[8] Violence and hate crimes against trans people have increased in recent years, though accurate data is hindered by lack of reporting and misinformation regarding the gender identity of victims.[9] FBI data show that reported hate crimes against trans people increased by 44 percent between 2015 and 2016.[10] At least 21 trans individuals, mostly women of color, have been killed in 2018, five of them in Florida.[11]

Barriers to Health Care and Services

Trans people in the US face both socio-economic barriers and discrimination in access to health care and services. Trans people are less likely than the general population to have health insurance and more likely to rely on publicly funded insurance than private or employer-provided coverage.[12] The 2015 US Transgender Survey indicated that one of three trans people had needed to see a doctor in the last year but could not afford to do so.[13] Trans people face outright denial of services as well as harassment in health care settings. A 2017 national survey by the Center for American Progress found that one in three trans respondents said that they had been turned away by a medical provider on the basis of their gender identity; one in five reported being subject to harsh or abusive language in a health care setting; and one in three reported unwanted physical or sexual contact by a medical provider.[14] A common response to these conditions is avoidance of health care altogether – one national survey found that one in four trans people stopped seeking health care as a result of bad experiences in health care settings.[15]

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[7] NCTE, Black Respondent Report; Sevelius and Jenness, "Challenges and Opportunities for Gender-Affirming Healthcare for Transgender Women in Prison," *Journal of Prisoner Health*, (2017) 13, pp. 32-40.

[8] Sevelius and Jenness; US Bureau of Justice Statistics, PREA Data Collection Activities 2015," https://www.bjs.gov/content/pub/pdf/pdca15.pdf accessed August 17, 2018.

[9] Astor, Maggie. "Violence Against Transgender People is on the Rise, Advocates Say," New York Times, November 9, 2017.

[10] Voice of America, " FBI: Hate Crimes Increased by 4.6 percent in 2016," November 13, 2017, https://www.voanews.com/a/fbi-hate-crimes-increased-in-2016/4112929.html (accessed October 3, 2018).

[11] Human Rights Campaign, "Violence Against the Transgender Community in 2018," (accessed October 3, 2018).

[12] Trudy Ring, "Trans People Less Likely to Have Needed Health Care," The Advocate, July 6, 2017, https://www.advocate.com/current-issue/2017/7/06/trans-people-less-likely-have-needed-health-care (accessed October 3, 2018).

[13] NCTE, *US Transgender Survey* 2015.

[14] Center for American Progress, "Discrimination Prevents LGBT People from Accessing Health Care," https://www.americanprogress.org/issues/lgbt/news/2018/01/18/445130/discrimination-prevents-lgbtq-people-accessing-health-care/ (accessed August 17, 2018).

[15]NCTE, *US Transgender Survey* 2015.

Health Care for Transgender People

As do all people, transgender individuals have diverse physical and mental health concerns, some that are related to their trans experience and some that are not. Standards of care for medical and mental health providers to treat transgender patients have evolved significantly in the last decade. The World Professional Association for Transgender Health (WPATH) takes care to distinguish gender non-conformity from the clinical diagnosis of gender dysphoria.[16] According to WPATH and the American Psychiatric Association, there is nothing inherently pathological about gender non-conformity; gender dysphoria is a mental health condition in which one is experiencing clinically significant distress or social/occupational impairment as a result of gender non-conformity.[17] This diagnosis remains controversial as it is perceived as stigmatizing and pathologizes distress which, in the view of many, originates largely from societal prejudice and discrimination.[18] However, the diagnosis remains relevant as a basis for medical and surgical interventions for transgender and gender non-conforming people who wish to pursue them, and in many cases, as a prerequisite for insurance coverage for these treatments.[19]

One principle that is widely accepted is that effective health care for trans people should be respectful, safe, and culturally appropriate – a large number of health experts, provider organizations, and transgender advocates have published detailed guidelines on how to provide "gender-affirming" services in health care settings.[20] Recommendations for best practices not only include clinical standards for care but emphasize the importance of respectful and knowledgeable staff interaction with patients – use of gender-affirming pronouns, avoiding assumptions about gender identity or expression, recognizing that a patient's official identity documents may not match their gender expression, and other considerations.[21] Underpinning these practices is a recognition of the evidence that failure to implement gender-affirming services will result in avoidance of health care for

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[16] World Professional Association for Transgender Health (WPATH), Standards of Care, https://www.wpath.org/media/cms/Documents/Web%20Transfer/SOC/Standards%20of%20Care%20V7%20-%202011%20WPATH.pdf (accessed August 17, 2018).

[17] WPATH; American Psychiatric Association, "What is Gender Dysphoria," https://www.psychiatry.org/patients-families/gender-dysphoria/what-is-gender-dysphoria (accessed August 17, 2018).

[18] Ibid; National LGBTQ Taskforce, "(In)validating Transgender Identities: Progress and Trouble in the DSM-5," http://www.thetaskforce.org/invalidating-transgender-identities-progress-and-trouble-in-the-dsm-5/ (accessed August 17, 2018); Aiken, J., "Promoting an Integrated Approach to Ensuring Access to Gender Incongruent Health Care," *Berkeley Journal of Gender, Law and Justice*, 31 (1), 2016.

[19] Ibid.

[20] Fenway Institute, "Meeting the Health Care Needs of Transgender People," http://www.lgbthealtheducation.org/wp-content/uploads/Sari-slides_final1.pdf (accessed August 17, 2018); University of California at San Francisco, Center for Excellence in Transgender Health (CETH), "Overview of Gender-Affirming Treatments and Procedures," http://transhealth.ucsf.edu/trans?page=guidelines-overview (accessed August 17, 2018).

[21] Ibid.

transgender patients. As stated by the University of California at San Francisco Center for Excellence in Transgender Health Care (CETH), "Providing a safe, welcoming, and culturally appropriate clinic environment is essential to ensure that transgender people not only seek care but return for follow up."[22]

An example of the importance of gender-affirming policies in health settings is provided by Connie, a 31-year-old trans woman living in Miami, Florida. Connie's driver's license does not yet reflect her transition to female, so in her first visit to a local health clinic she asked them to note her current name and gender identity on the chart. However, on her second visit she was in the waiting room with other patients, and she heard her birth name called out loudly to summon her to the reception desk. Connie recalled:

> This woman shouted for 'Kevin' to come to the desk. I shrunk in my seat, hoping she would see the note on the chart about my gender change. But she just kept yelling for Kevin. I finally had to get up and cross the room in a walk of shame. Will I ever go back there? No way.[23]

Transgender Women and HIV

Data are scarce and incomplete but alarming — both globally and domestically, trans women are heavily burdened by the HIV epidemic. According to the World Health Organization (WHO), existing studies show that nearly one of five transgender women around the world are living with HIV – this is a prevalence rate of 19 percent, compared to a rate of 0.8 percent in the general global adult population.[24] Globally, transgender women are 49 times more likely to acquire HIV during their lifetime than the general population of reproductive age.[25] HIV prevalence among trans men appears to be much lower, but data remain limited and more research is needed (see text box). WHO and UNAIDS, the leading international agencies charged with addressing the HIV epidemic worldwide, have designated transgender women as a "key population" along with men who have sex with men, prisoners, people who inject drugs, and sex workers. Because HIV among people within these groups (and their intimate partners) account for 40-50 percent of the global

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[22] CETH, "Creating a Safe and Welcoming Clinic Environment," http://www.transhealth.ucsf.edu/trans?page=guidelines-clinic-environment (accessed August 17, 2018).

[23] Human Rights Watch interview with Connie L., Miami, Florida, February 6, 2018.

[24] UNAIDS, "Transgender and HIV Risk,"http://www.unaids.org/en/resources/infographics/transgender-and-HIV-risk (accessed August 20, 2018); Avert https://www.avert.org/global-hiv-and-aids-statistics (accessed November 6, 2018).

[25] UNAIDS, "Transgender and HIV Risk."

HIV epidemic, WHO and UNAIDS have declared that "without addressing the needs of key populations, a sustainable response to HIV will not be achieved."[26]

In the United States, the National HIV/AIDS Strategy also designates transgender women as a "high-risk" and "key" population as studies indicate an HIV prevalence ranging from 22 percent to as high as 56 percent among transgender women of color.[27] This is grossly disproportionate to the overall prevalence of HIV in the US, which is under one percent.[28] In a recent survey of nine million HIV tests nationwide, transgender women had the highest percentage of positive results of any gender category.[29] Racial disparities are stark: HIV prevalence is more than three times higher among African-American transgender women than their white or Latina counterparts.[30]

HIV in the United States

More than 1.1 million people in the US are living with HIV, and one in seven are unaware of their infection.[31] Over the past decade, the number of people living with HIV has increased as treatment has become more effective. For the first time in the history of the epidemic, the number of new infections has begun to decrease overall, but still remains high among specific populations.[32]

In recent years, treatment has become the cornerstone of both HIV prevention and care. Public health and HIV experts have increasingly emphasized the importance of early and universal access to anti-retroviral medication not only to improve individual outcomes, but to reduce the risk of transmission to others. The approach characterized as "Treatment as

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[26] World Health Organization, "Consolidated Guidelines on HIV Prevention, Diagnosis, Treatment and Care for Key Populations,"2016 Update, http://apps.who.int/iris/bitstream/handle/10665/128048/9789241507431_eng.pdf;jsessionid=9261E742088B27F210C3747AB38F995B?sequence=1 (accessed August 22, 2018).

[27] US Centers for Disease Control, "HIV Among Transgender People," https://www.cdc.gov/hiv/group/gender/transgender/index.html (accessed August 22, 2018) and "HIV among Transgender People Fact Sheet," https://www.cdc.gov/hiv/pdf/group/gender/transgender/cdc-hiv-transgender-factsheet.pdf (accessed August 22, 2018); US Office of National HIV/AIDS Strategy, "National HIV/AIDS Strategy for the United States, Updated to 2020," https://files.hiv.gov/s3fs-public/nhas-update.pdf (accessed August 22, 2018).

[28] Avert, "HIV and AIDS in the United States of America," https://www.avert.org/professionals/hiv-around-world/western-central-europe-north-america/usa (accessed August 22, 2018).

[29] CDC, Morbidity and Mortality Weekly Report, "HIV Testing Among Transgender Women and Men- 27 States and Guam, 2014-15," https://www.cdc.gov/mmwr/volumes/66/wr/mm6633a3.htm (accessed August 22, 2018).

[30] AmfAR Issue Brief, "Trans Populations and HIV: Time to End the Neglect," http://www.amfar.org/uploadedFiles/_amfarorg/Articles/On_The_Hill/2014/IB%20Trans%20Population%20040114%20final.pdf (accessed August 22, 2018).

[31] CDC, "HIV/AIDS Basic Statistics," https://www.cdc.gov/hiv/basics/statistics.html (accessed August 22, 2018).

[32] US Department of Health and Human Services, "National HIV/AIDS Strategy for the United States 2017 Progress Report," https://www.hiv.gov/blog/2017-national-hivaids-strategy-nhas-progress-report-released (accessed August 22, 2018).

Prevention" has gained traction globally and in the US as research confirms that sufficient suppression of the virus through anti-retroviral therapy can effectively eliminate the risk of transmission from one person to another and in communities as a whole.[33] Key to the success of this approach is the ability of the person to become aware of their status and to sustain a lifetime course of anti-retroviral medication that must be taken on a daily basis.[34]

Increased access to treatment has reduced new infections nationwide, but rates of infection remain high among certain groups, including gay, bisexual, or other men who have sex with men; African-American men and women; Latino men and women; people who inject drugs; youth 13-24 years old; people in the southern United States; and transgender women.[35]

Race and Poverty

Many factors combine to place trans women, and particularly women of color, at high risk of HIV. In the United States, HIV has become a disease of social, economic, and racial exclusion. Trans women are disproportionately impacted by many of these forces of marginalization, facing what has been characterized by HIV experts as "multiple, concurrent HIV risks and underlying vulnerabilities."[36]

In the US HIV epidemic, racial disparities are extreme, with African-Americans comprising 12 percent of the US population, but 44 percent of new HIV infections. Though new infections have decreased among Americans overall, they continue to increase among African-Americans.[37] Indeed, African-Americans comprise the highest percentage of people living with HIV, people becoming newly infected, and people living with AIDS.[38]

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[33] CDC. "Evidence of HIV Treatment and Viral Suppression in Preventing the Sexual Transmission of HIV," December 2017, https://www.cdc.gov/hiv/pdf/risk/art/cdc-hiv-art-viral-suppression.pdf (accessed August 22, 2018).

[34] Ibid.

[35] US Department of Health and Human Services, "National HIV/AIDS Strategy for the United States 2017 Progress Report," https://www.hiv.gov/blog/2017-national-hivaids-strategy-nhas-progress-report-released (accessed August 22, 2018); US Office of National HIV/AIDS Strategy, "National HIV/AIDS Strategy for the United States, Updated to 2020," https://files.hiv.gov/s3fs-public/nhas-update.pdf (accessed August 22, 2018).

[36] Escudero, D.J. et al., "Inclusion of Trans Women in Pre-Exposure Prophylactis (PrEP): A Review, *AIDS Care*, 27 (5) 2015, pp. 637-641, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4336598/ (accessed August 22, 2018).

[37] Ibid.

[38] CDC, "HIV Among African-Americans," https://www.cdc.gov/hiv/group/racialethnic/africanamericans/index.html (accessed August 22, 2018).

African-American people in the US are more likely to be poor than white people, and poverty is one of the primary drivers of the HIV epidemic.[39] In contrast to sub-Saharan Africa's HIV epidemic affecting the entire population, HIV in the United States is concentrated in impoverished urban areas and small towns, with the highest concentration of people living with HIV and new HIV infections occurring in the US South.[40] In some impoverished areas of the US, HIV prevalence has been found to be higher than in many African countries where the HIV epidemic is severe.[41]

As noted above, many transgender people live in poverty – the 2015 US Transgender Survey indicated that nearly one in three had an income of less than $10,000 per year, with 55 percent living on less than $25,000 per year.[42] In their 2015 report, "Paying an Unfair Price: Financial Penalties for Being Transgender in America," the Center for American Progress found that discrimination in school, employment, housing and health care, as well as an inability to obtain gender-affirming identity documentation, combined to force many transgender people into poverty and into underground economies such as sex work for daily survival.[43]

Sex Work and Incarceration

People who exchange sex for money or life necessities are at increased risk for HIV, a risk that impacts some trans women who engage in sex work. This risk results from not only a higher number of sexual partners but, in many cases, from environmental factors such as poverty, homelessness, and substance use – all factors that have been independently associated with HIV risk and poor health outcomes.[44] In addition, Human Rights Watch and others have documented increased HIV risk to sex workers from the harmful consequences of criminalization: police harassment, arrest, and incarceration have been found to be

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[39] Kaiser Family Foundation, "Poverty Rates by Race/Ethnicity," https://www.kff.org/other/state-indicator/poverty-rate-by-raceethnicity/?currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D (accessed August 22, 2018); Wiewel, E., et al., "The Association Between Neighborhood Poverty and HIV Diagnoses Among Males and Females in New York City, 2010-2011, *Public Health Reports*, 131 (2), 2016, pp. 290-302; Denning, P and DiNenno, E., "Is there a generalized HIV epidemic in impoverished urban areas of the United States?" CDC 2014, https://www.law.berkeley.edu/files/DenningandDiNenno_XXXX-1.pdf (accessed August 22, 2018).

[40] Reif, S., et al., "State of HIV in the US Deep South," *Journal of Community Health*, 42 (5) 2017, pp. 844-853; for extensive research and materials on HIV in the US South, see Southern AIDS Strategy Initiative, https://southernaidsstrategy.org/deepsouthhiv/ (accessed August 22, 2018).

[41] Pellowski, J., et al., "A Pandemic of the Poor: Social Disadvantage and US HIV Epidemic," *American Psychologist,* 68 (4), 2013, 197-2019.

[42] NCTE, National Transgender Survey 2015.

[43] Center for American Progress, Paying an Unfair Price: The Financial Penalty for Being Transgender in America, 2015, http://www.lgbtmap.org/file/paying-an-unfair-price-transgender.pdf (accessed August 2018).

[44] CDC, National Center for HIV/AIDS, Viral Hepatitis, STD and TB Prevention, " Atlas Plus Social Determinants of Health Data" https://www.cdc.gov/nchhstp/dear_colleague/2018/dcl-061818-AtlasPlus.html (accessed August 22, 2018).

associated with higher HIV risk, less access to medical care, and impaired ability to manage HIV medications.[45] A criminal history after conviction on prostitution charges creates a significant barrier to employment that perpetuates poverty and the necessity of sex work in order to meet one's basic needs.

Trans women experience high rates of incarceration, with one in five trans women reporting having been in jail or prison.[46] The rate of incarceration for African-American trans women is three times as high as it is for white trans women – some studies indicate that half of African-American trans women report a history of incarceration.[47] Incarceration creates numerous barriers to HIV prevention and care – condoms are not available in the majority of prisons and jails in the United States; access to HIV medications and treatment is often inadequate or in many jails, non-existent; and linkage to medical care upon re-entry is uneven at best.[48]

In addition to incarceration itself as an HIV risk factor, transgender women experience alarming rates of sexual assault in prison. According to federal Prison Rape Elimination Act data for 2015, more than one-third of incarcerated trans women reported assault by other prisoners or staff.[49] African-American and Latina trans women are more likely to be victims of assault in jail or prison than their white counterparts.[50] Most HIV-positive prisoners were HIV-positive prior to their incarceration. However, a lack of HIV prevention measures and failure to provide safe environments for trans prisoners – such as the widespread practice

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[45] Human Rights Watch, Sex Workers at Risk: Condoms as Evidence of Prostitution in Four US Cities, July 2012, https://www.hrw.org/report/2012/07/19/sex-workers-risk/condoms-evidence-prostitution-four-us-cities; Human Rights Watch, Paying the Price: Failure to Deliver HIV Services in Louisiana Parish Jails, March 2016, https://www.hrw.org/report/2016/03/29/paying-price/failure-deliver-hiv-services-louisiana-parish-jails; Ginny Shubert, National Minority AIDS Council and Housing Works, "Mass Incarceration, Housing Instability and HIV/AIDS," 2013, https://www.hivlawandpolicy.org/resources/mass-incarceration-housing-instability-and-hivaids-research-findings-and-policy (accessed August 22, 2018); "HIV and Related Infections in Prisoners," *The Lancet*, Special Issue, July 2016.

[46] Reisner, S et al., "Racial/Ethnic Disparities in History of Incarceration, Experiences of Victimization, and Associated Health Indicators Among Transgender Women in the US," *Women and Health*, 54 (8) 2014, 750-767; Jae Sevelius and Valerie Jenness, " Challenges and Opportunities for Gender-Affirming Health Care for Transgender Women in Prison," *International Journal of Prisoner Health*," 13 (1) 2017, pp. 32-40.

[47] Ibid; Lambda Legal, "Transgender Incarcerated People in Crisis," https://www.lambdalegal.org/sites/default/files/2015_transgender-incarcerated-people-in-crisis-fs-v5-singlepages.pdf (accessed August 22, 2018).

[48] "HIV and Related Infections in Prisoners," *The Lancet*, Special Issue, July 2016.

[49] US Bureau of Justice Statistics, "PREA Data Collection Activities 2015," https://www.bjs.gov/content/pub/pdf/pdca15.pdf (accessed August 22, 2018).

[50] Reisner, S et al., "Racial/Ethnic Disparities in History of Incarceration, Experiences of Victimization, and Associated Health Indicators Among Transgender Women in the US," *Women and Health*, 54 (8) 2014, 750-767; Jae Sevelius and Valerie Jenness, " Challenges and Opportunities for Gender-Affirming Health Care for Transgender Women in Prison," *International Journal of Prisoner Health*," 13 (1) 2017, pp. 32-40.

of placing trans women in male prison facilities — increases HIV risk in correctional settings.[51]

Mental Health Issues and HIV

Trans people report experiencing high rates of mental health conditions including anxiety, depression, and substance use disorders. Many report anxiety, depression, and trauma resulting from societal factors – including stigma, discrimination, harassment, violence, and other mistreatment based on their gender non-conformity.[52] While cautioning against assuming that all mental health issues are related to gender identity, transgender health experts have identified distress and trauma from familial and societal non-acceptance as key to understanding and treating trans individuals.[53] Many transgender people seek mental health services to help them cope with the effects of prolonged concealment of their gender identity and harms resulting from attempts to express this identity in hostile environments.[54]

Mental health issues have been correlated with increased risk of HIV and poorer outcomes once infected. Depression, anxiety, low self-esteem, sexual abuse, post-traumatic stress disorder, and substance use disorders all have been associated with higher risk of acquiring and transmitting HIV in men who have sex with men, youth, people who use drugs, and transgender women.[55] People living with HIV experience higher rates of anxiety, depression, and substance use disorders than people without HIV, with trans women reporting higher rates of anxiety and depression, and reporting lower quality of life, than other groups living with HIV.[56]

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[51] Rubenstein, L., et al., "HIV, Prisoners and Human Rights," *The Lancet*, July 2016, pp. 44-56; Lambda Legal, "Transgender Incarcerated People in Crisis", https://www.lambdalegal.org/sites/default/files/2015_transgender-incarcerated-people-in-crisis-fs-v5-singlepages.pdf (accessed August 22, 2018).

[52] NCTE, National Transgender Survey 2015; National Center for Transgender Equality and National Gay and Lesbian Taskforce, *Injustice at Every Turn*, 2011, http://www.thetaskforce.org/static_html/downloads/reports/reports/ntds_full.pdf (accessed August 17, 2018).

[53] CETH, "Mental Health Considerations with Transgender and Gender Non-Conforming Clients," http://transhealth.ucsf.edu/trans?page=guidelines-mental-health (accessed August 22, 2018.); Sevelius, J., "Gender Affirmation: A Framework for Conceptualizing Risk Behavior Among Transgender Women of Color," *Sex Roles*, 68: July 2013, pp. 675-689.

[54] Rood, B, et al., "Identity Concealment in Transgender Adults: A Qualitative Assessment of Minority Stress and Gender Affirmation," *American Journal of Orthopsychiatry*, 87 (6): pp. 704-13.

[55] US Department of Health and Human Services, AIDS Info, "HIV and Mental Health," https://aidsinfo.nih.gov/understanding-hiv-aids/fact-sheets/27/92/hiv-and-mental-health (accessed August 22, 2018.)

[56] Ibid; http://www.apa.org/pi/aids/resources/exchange/2013/01/comorbidities.aspx; Mascolini, M., "More Depression, Worse Quality of Life In Transgender Women v. Men with HIV," 9th International AIDS Society Conference on HIV Science, July 2017, http://www.natap.org/2017/IAS/IAS_108.htm (accessed August 22, 2018.).

Anxiety, depression and other mental health issues reduce one's ability to adhere to a daily regimen of anti-retroviral medications, a key determinant of maintaining one's health and wellbeing while living with HIV. For this reason, access to mental health services is considered an integral component of HIV care.[57]

Transgender Men and Barriers to Health Care

Trans men face many of the same barriers to health care as trans women: a shortage of gender-affirming health settings, lack of knowledgeable providers, and denials of insurance coverage for basic health services – pap smears, mammograms and other services – that are perceived as "gender incongruent." Trans men are significantly more likely to live in poverty and to lack health insurance than cis-gender men.[58] Research on health issues for trans men, including HIV research, remains extremely limited.

The prevalence of HIV among trans men appears to be significantly lower than that among trans women – ranging from one to three percent in most studies – but still higher than in the general US population.[59] Many trans men have sex with cis-gender men who identify as gay or bisexual, placing them at increased risk of HIV infection.[60] Engaging in sex work and the use of alcohol or drugs also increase HIV risk. However, HIV testing among trans men remains low.[61] For trans men, sex with cis-gender men can be a complex issue, especially for those who are navigating the gay and bisexual community for the first time.

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57 National Institutes of Mental Health, "HIV/AIDS and Mental Health," https://www.nimh.nih.gov/health/topics/hiv-aids/index.shtml (accessed August 22, 2018.)

58 Lambda Legal, "When Health Care Isn't Caring,"2010, https://www.lambdalegal.org/publications/when-health-care-isnt-caring (accessed September 7, 2018); National Center for Transgender Equality (NCTE), US Transgender Survey 2015, https://transequality.org/sites/default/files/docs/usts/USTS-Full-Report-Dec17.pdf, (accessed August 17, 2018).

59 Herbst JH et al., "Estimating HIV Prevalence and Risk Behaviors in Transgender Persons in the United States: A Systematic Review," AIDS Behavior, 12(1) January 2008; McFarland, W., et al., "HIV Prevalence, Sexual Partners, Sexual Behavior and HIV Acquisition Risk Among Trans Men, San Francisco 2014," *AIDS Behavior*, 21(12) December 2017; Scheim, A., et al., "Inequities in Access to HIV Prevention Services For Transgender Men: Results of a Global Survey of Men Who Have Sex With Men," Journal of the International AIDS Society, 19 (Supp 2) 2016.

60 Scheim, A., et al., "Inequities in Access to HIV Prevention Services For Transgender Men: Results of a Global Survey of Men Who Have Sex With Men," *Journal of the International AIDS Society,* 19 (Supp 2) 2016; Rowniak, S., and Selix, N., "Attitudes, Beliefs and Barriers to PrEP Among Trans Men," AIDS Education and Prevention," August 2017.

61 CDC, "HIV Among Transgender People," https://www.cdc.gov/hiv/group/gender/transgender/index.html (accessed September 7, 2018).

Santi Aguirre is the director of transgender programs at Sunserve, a non-profit organization serving the LGBT community in Broward County. Aguirre told Human Rights Watch that many trans men are secretive about engaging in sex with cis-gender men, making HIV screening and referrals to prevention or treatment services difficult.

Lots of trans men are having sex with men, but they do not feel comfortable being open about it. The community is not that supportive of it. Some fear homophobia, and for others it contradicts the 'masculine' identity that they are working to develop.

> There are guys that I know that have a lot of sexual partners, some for money – they need PrEP and HIV testing but won't do it.[62]

In addition, many trans men having sex with men report preferring to get health services in settings that focus on men who have sex with men, but often feel excluded or unwelcome in these environments. This may contribute to lower HIV testing rates and lower access to condoms, lubricant, and other methods of HIV prevention among trans men than among cis-gender men.[63]

To date, HIV risk among trans men has not been accurately assessed or prioritized by federal or state HIV policymakers. Inadequate data as well as barriers to health care, including lack of access to affordable, gender-affirming care and HIV prevention services jeopardize the health of trans men.

Barriers to Access to Medical and Mental Health Care

Trans people generally face formidable barriers in accessing gender-affirming health care. For many trans women with HIV, medical and mental health services remain out of reach. A national survey published in 2016 by the Transgender Law Center's Positively Trans Project examined the health needs and concerns of trans people living with HIV. The majority (84 percent) of respondents were women, and 41 percent of respondents had a history of incarceration in prison, jail, or immigration detention. Forty-three percent reported income

[62] Human Rights Watch telephone interview with Santi Aguirre, Fort Lauderdale, FL, July 19, 2018.

[63] Scheim, A., et al., "Inequities in Access to HIV Prevention Services for Transgender Men: Results of a Global Survey of Men Who Have Sex with Men," *Journal of the International AIDS Society*, 19 (Supp 2) 2016.

of less than $12,000 per year.[64] The methodology of the survey skewed toward respondents who were likely to be connected with some type of health care rather than those who might be more isolated. Even so, 41 percent of respondents had not seen a doctor for six or more months following their HIV diagnosis.

The primary reason given for not seeing a doctor after their diagnosis was a previous or anticipated discrimination by a health care provider. Cost was also cited as a major factor in failing to access care. African-American and Latino/a respondents reported lower income and were less likely to have health insurance than white respondents. When asked to list their number one health concern, the top concern identified by more than 60 percent of respondents was a need for "gender-affirming and non-discriminatory health care." The next-highest concerns were hormone therapy and mental health care, including trauma recovery. HIV care was fifth on the list of concerns.[65]

For trans women with HIV, the first priority in addressing their needs is to ensure access to health care that provides them with fundamental respect and dignity. In 2017, a nationwide group of HIV-positive transgender leaders convened by AIDS United issued recommendations for best practices in health care. These leaders stated, "Due to the disproportionate impact of HIV on transgender and gender expansive communities, it is critical that clinics and support services are welcoming, inclusive and competent in serving this population."[66]

For trans people, services that support them in transition or maintenance of their gender identity are not optional aspects of health care – they are fundamental to affirming individual identity and meeting established standards of transgender health care. The World Professional Association for Transgender Health (WPATH), for example, includes as its core principles:

- Exhibit respect for patients with non-conforming gender identities
- Provide care that affirms patients' gender identities and reduces gender dysphoria, when present

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[64] Transgender Law Center, "Positively Trans Needs Assessment Reports 1-3," 2016, https://transgenderlawcenter.org/programs/positively-trans/research (accessed August 22, 2018). Categories utilized for racial classification included "African-American" and "Latino/a."

[65] Ibid.

[66] AIDS United, "Stepping Up: Best Practices In Providing HIV Medical Care, Support Services and Funding To Trans Communities," https://www.aidsunited.org/resources/stepping-up-a-consensus-statement-by-trans-leaders (accessed August 22, 2018).

- Become knowledgeable about the health care needs of gender non-conforming people
- Match the treatment to the specific needs of patients, particularly their gender expression and their need for relief from gender dysphoria
- Seek patients' informed consent before providing treatment[67]

Trans women frequently prioritize hormone replacement therapy over other health concerns.[68] For this reason, access to hormone therapy is of the utmost importance for trans women living with HIV.[69] Public health and HIV experts, experts in transgender HIV care and, most importantly, trans women living with HIV identify access to transition care, including HRT, as fundamental to effective HIV care for trans women. The Center for Excellence in Transgender Health recommends "bundling" HIV care with HRT and other health services sought by trans women.[70] The AIDS United statement emphasizes the importance of a "one-stop shop" where trans people can receive HIV care as well as comprehensive transgender-focused health services.[71] The WHO states that for transgender women living with HIV, "transition care was perceived as vital pre-requisite for subsequent health care" and recommends that governments prioritize gender-affirming care in developing their plans for addressing HIV in this key population.[72]

The availability of hormone replacement therapy is an essential component of the standard of care for transgender people, and HRT plays an important role in HIV prevention and treatment. As CETH states, "HIV and its treatment are not contraindications to hormone therapy. In fact, providing hormone therapy in the context of HIV care may improve engagement in and retention in care as well as decrease viral load and increase adherence."[73] Hormone therapy reduces anxiety and depression, factors known to increase

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[67] World Professional Association for Transgender Health, Standards of Care, https://www.wpath.org/media/cms/Documents/Web%20Transfer/SOC/Standards%20of%20Care%20V7%20-%202011%20WPATH.pdf (accessed August 17, 2018).

[68] Sevelius, J., et al., "The Future of PrEP among Transgender Women: The Critical Role of Gender Affirmation in Research and Clinical Practices," Journal of the International AIDS Society, 19 (7 Supp. 6) 2016, published online https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5071750/ (accessed August 22, 2018); Sevelius, J., "Gender Affirmation: A Framework for Conceptualizing Risk Behavior Among Transgender Women of Color," *Sex Roles*, 68: July 2013, pp. 675-689.

[69] CETH, "Transgender Health and HIV," http://transhealth.ucsf.edu/trans?page=guidelines-hiv (accessed August 22, 2018).

[70] Ibid; Sevelius, J., et al., "The Future of PrEP Among Transgender Women."

[71] AIDS United, "Stepping Up: Best Practices In Providing HIV Medical Care, Support Services and Funding To Trans Communities," file:///C:/Users/Megan%20McLemore/Downloads/Stepping_Up__A_Consensus_Statement_by_Trans_Leaders%20(2).pdf (accessed August 22, 2018).

[72] WHO Policy Brief, "HIV and Transgender People," http://www.who.int/hiv/mediacentre/news/transgender-hiv-policy-feature/en/ (accessed August 22, 2018).

[73] CETH, "Transgender Health and HIV," http://transhealth.ucsf.edu/trans?page=guidelines-hiv (accessed August 22, 2018).

HIV risk as well as to interfere with adherence to HIV medications.[74] The National Association of State and Territorial AIDS Directors stated, "Medication adherence among transgender people is heavily dependent on the availability of gender-affirming health services and continued hormone therapy."[75]

Evidence suggests that in addition to reducing anxiety and depression, access to HRT can be an important factor in reducing HIV-related risk behaviors for trans women. Transition therapy has been found to increase quality of life for trans people including improved employment prospects that may reduce the necessity to engage in sex work.[76] Moreover, for trans women, sex with men can provide gender validation.[77] Numerous studies among trans women indicate that HIV-related risk behaviors – including unprotected sex and sex work – are often related to what has been characterized as an "unmet need for gender affirmation."[78] Some trans women describe taking risks to have sex with men in order to confirm femininity and affirm their identity as women. Women also describe the relief obtained by access to HRT and other gender-affirming services, either under medical supervision or from street hormones for those who could not access health care.[79] For trans individuals, ensuring access to hormone replacement therapy is an indispensable element of the standard of care for both HIV prevention and treatment.

Federal Policies Contribute to HIV Risk for Transgender Women

Throughout the course of the HIV epidemic, federal agencies have been slow to respond to issues of HIV among transgender people. In 2010 the first US National HIV/AIDS Strategy announced its vision:

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[74] Ibid; Remien, R., "Addressing Mental Health: A Critical Component To Ending the HIV Epidemic," presentation at Conference on Retroviruses and Opportunistic Infections (CROI), 2018, http://www.natap.org/2018/CROI/croi_205.htm (accessed August 22, 2018).

[75] National Association of State and Territorial AIDS Directors, "Issue Brief: ADAP Considerations for Transgender Health," https://www.nastad.org/sites/default/files/Crossroads-Trans-Health.pdf (accessed August 22, 2018).

[76] Bockting, W., et al., "Adult Development and Quality of Life of Transgender and Gender Non-Conforming People," *Current Opinion in Endocrinology, Diabetes and Obesity*, 23(2): 2016, pp. 188-197 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4809047/ (accessed August 22, 2018).

[77] Poteat, T., et al., "HIV Risk and Preventive Interventions in Transgender Women Sex Workers," *The Lancet*, 385 (9964), 2015: pp. 274-286.

[78] Sevelius, J., "Gender Affirmation: A Framework for Conceptualizing Risk Behavior Among Transgender Women of Color," *Sex Roles*, 68: July 2013, pp. 675-689.

[79] Ibid; Poteat, T., "HIV Risk and Preventive Interventions in Transgender Women Sex Workers;" Keatley, J., et al., "Perceived Risks and Benefits of Sex Work Among Transgender Women of Color in San Francisco, *Archives of Sexual Behavior*, 36 (2007) 768-777.

> The United States will become a place where new HIV infections are rare and when they do occur, every person regardless of age, race/ethnicity, sexual orientation, gender identity or socio-economic circumstance, will have unfettered access to high-quality, life-extending care, free from stigma and discrimination.[80]

The Strategy established three primary goals: 1) reducing new HIV infections; 2) increasing access to care and optimizing health outcomes for people living with HIV; and 3) reducing health-related disparities. In 2015, the Office of National HIV/AIDS Policy released the National HIV/AIDS Strategy Updated to 2020, a document that reaffirms the vision of the original strategy and summarizes progress made toward the three goals using a group of 17 "indicators" for measurement of whether specific targets had been reached.[81] Overall, most people who stay in medical care are achieving viral suppression, but the failure to effectively link people to care after diagnosis and retain them in care for treatment adherence are recognized as key problem areas that are having a severe impact on continued high rates of HIV infection among certain groups. As a consequence, the Update identifies linkage to, and retention in, medical care as top priorities for agencies involved in the nation's HIV response.[82]

The Strategy identified HIV among transgender women as a serious concern and acknowledged the problem of inadequate access to gender-affirming health care:

> Transgender individuals are particularly challenged in finding providers who respect them and with whom they can have honest discussions about hormone use and other practices, and this results in lower satisfaction with their care providers, less trust and poorer health outcomes.[83]

Stating that "historically, efforts targeting this specific population have been minimal," the 2010 Strategy identified transgender women, particularly women of color, as a "high-risk" population and urged that Congress and relevant federal agencies fund and implement targeted programs for prevention, treatment and support services.[84]

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[80] National HIV/AIDS Strategy for the United States, 2010.

[81] National HIV/AIDS Strategy for the United States, Updated to 2020.

[82] Ibid.

[83] National HIV/AIDS Strategy for the United States, 2010, p 26.

[84] Ibid, pp. 15-20.

In this context, the needs of transgender women are addressed in numerous provisions of the Update, including a continuing recognition that the dearth of "culturally competent" care for transgender individuals that results in poor health outcomes and a call to establish a new "indicator" for improved data collection of HIV among the transgender population.[85]

But the reality is that despite ample, even overwhelming, evidence of the need to implement culturally competent care and how to do so effectively, implementation of these intentions on the ground is incomplete, fragmented and not incorporated into policy requirements, monitoring, or evaluation.

Some concrete steps were taken under the Obama administration to address trans health care and the alarming risk of HIV infection for trans women. Medicaid expansion was offered to states with the federal government footing most of the bill. The anti-discrimination protections in the Affordable Care Act were interpreted by the Department of Health and Human Services to include discrimination based on gender identity. The CDC issued technical guidance to states to improve their HIV data collection for trans populations and federally funded initiatives such as the Ryan White program, the nation's largest source of funding for HIV care and services, began to utilize a two-step gender identification process for its clients.[86] But implementation was incomplete, new HIV infections among trans women continued to rise, and the Trump administration is taking numerous steps to undo progress in increasing access to health care.

For example, Medicaid coverage, essential to access to health care generally as well as to HIV prevention, is being undermined by the Trump administration and Congress in a variety of ways. Government respect for transgender rights, including the right to health, is moving in the wrong direction. The burdens faced by transgender women in nearly every aspect of life are occurring in an environment of federal policy that not only remains insufficiently protective of LGBT people's rights but has also seen the rollback of many recent gains.

LGBT people are protected by a patchwork of laws and regulations that vary in scope and geography. There are no federal laws that explicitly protect persons from discrimination on

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[85] National HIV/AIDS Strategy for the United States, Updated to 2020.

[86] CDC, "Guidance for HIV Surveillance Programs: Working with Transgender Specific Data" Version 2.0, 2015; Health Resources and Services Administration, "Ryan White HIV/AIDS Program Annual Client-Level Data Report 2016," https://hab.hrsa.gov/sites/default/files/hab/data/datareports/RWHAP-annual-client-level-data-report-2016.pdf (accessed September 7, 2018).

the basis of either sexual orientation or gender identity. However, under the Obama administration, federal agencies issued a series of rules and regulations based on sexual orientation and gender identity to decrease discrimination in federally funded programs. The departments of Education, Justice, Housing and Urban Development, and Health and Human Services, among others, issued guidance or regulations clarifying that discrimination based on sexual orientation and/or gender identity is impermissible under federal law.[87]

Since 2017, the Trump administration has reversed many of those positions, withdrawing anti-discrimination protections and opposing inclusive interpretations of federal anti-discrimination laws in court.[88] Most recently, the administration has enacted two rules that significantly weaken anti-discrimination protections in federally funded health care activities and programs. These actions are likely to exacerbate health disparities for a population that is already significantly at risk. The first is proposed changes to the protections offered to LGBT people under the Affordable Care Act. Section 1557 prohibits discrimination in health care based on race, color, national origin, sex, age, or disability. In 2016, the Department of Health and Human Services issued a rule clarifying that discrimination based on "sex" includes discrimination based on gender identity and pregnancy status.[89]

The rule would have ensured that transgender people could not be denied care or coverage – including for transition-related services – because of their gender identity. However, shortly after the rule was introduced, eight states and religiously affiliated health care providers challenged it in court, and a federal judge in Texas enjoined it from taking effect.[90] Reversing the Obama administration's decision to defend this interpretation in court, the Trump administration has indicated that it no longer considers section 1557 to protect against discrimination based on gender identity or pregnancy status.[91] Though the text of section 1557 has not changed, the administration's re-interpretation of the rule has left transgender people without legal protection and signaled that federal agencies will no longer advance trans-inclusive interpretations of provisions prohibiting discrimination on

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[87] White House, "Obama Administration's Record and the LGBT Community," June 9, 2016, https://obamawhitehouse.archives.gov/the-press-office/2016/06/09/fact-sheet-obama-administrations-record-and-lgbt-community (accessed August 29, 2018).

[88] Dan Diamond, "Trump Administration Dismantles LGBT-Friendly Policies," *Politico*, February 19, 2018, https://www.politico.com/story/2018/02/19/trump-lgbt-rights-discrimination-353774 (accessed August 29, 2018).

[89] "Nondiscrimination in Health Programs and Activities; Final Rule," 45 CFR 92, Federal Register Vol. 81, No. 96, May 18, 2016, https://www.gpo.gov/fdsys/pkg/FR-2016-05-18/pdf/2016-11458.pdf (accessed August 29, 2018).

[90] *Franciscan Alliance v. Price*, US District Court, Northern District of Texas, (7:16-cv-00108).

[91] US Department of Health and Human Services, "Section 1557: Frequently Asked Questions," https://www.hhs.gov/civil-rights/for-individuals/section-1557/1557faqs/index.html (accessed August 29, 2018).

the basis of sex. In October 2018, the New York Times reported that the administration is considering narrowing the definition of "sex" to male and female for all federal agencies, a move that could eliminate protection against discrimination for transgender and intersex people in employment, education, health care and other areas of life.[92]

The Department of Health and Human Services issued a proposed rule that would give sweeping discretion to providers to discriminate against LGBT people on the grounds of moral and religious belief.[93] The regulation would broaden existing protections for religious objectors by codifying vague, open-ended definitions that would invite discrimination against LGBT people, women and others.[94] In the absence of any provisions that would mitigate harm, these redefinitions risk greatly exacerbating discrimination and barriers to access women and LGBT people already experience. Other actions by the Trump administration include attempts to bar transgender persons from military service and weakening protections for transgender prisoners in the federal Bureau of Prisons. Passage of laws in numerous states that invite discrimination against LGBT persons in health care, adoption, and public accommodations combine with federal action to create a hostile environment that jeopardizes the health of transgender women.[95]

JoAnne Keatley, Director Emeritus of the UCSF Center for Excellence in Transgender Health, is concerned that any momentum for trans women with HIV that did exist will be lost as the Trump administration creates, what she calls, an environment that is "hostile to LGBT rights, but particularly hostile to transgender people."[96]

In June 2018, the Trump administration released a report on the National HIV/AIDS Strategy indicating that on several key fronts progress had been made and reaffirming the commitment to end the nation's HIV epidemic.[97] But, as noted by leading HIV advocacy

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[92] Erica L. Green, Katie Benner and Robert Pear, "Transgender Could Be Defined Out of Existence Under Trump Administration," *New York Times*, October 21, 2018.

[93] "Protecting Statutory Conscience Rights in Health Care; Delegations of Authority," 45 CFR 88, Federal Register Vol. 83, No. 18, January 26, 2018, https://www.gpo.gov/fdsys/pkg/FR-2018-01-26/pdf/2018-01226.pdf (accessed August 29, 2018).

[94] Human Rights Watch, "Human Rights Watch Letter to US Secretary of Health and Human Services Alex Azar," March 27, 2018, https://www.hrw.org/news/2018/03/27/human-rights-watch-letter-us-secretary-health-and-human-services-alex-azar

[95] Human Rights Watch, "All We Want is Equality": Religious Exemptions and Discrimination Against LGBT People in the United States," February 2018, https://www.hrw.org/report/2018/02/19/all-we-want-equality/religious-exemptions-and-discrimination-against-lgbt-people; National Center for Transgender Equality, "The Discrimination Administration: Trump's Record of Action Against Transgender People," https://transequality.org/the-discrimination-administration (accessed November 6, 2018).

[96] Human Rights Watch telephone interview with JoAnne Keatley, Director Emeritus, Center for Excellence in Transgender Health, San Francisco, CA, June 28, 2018.

[97] US Department of Health and Human Services, "National HIV/AIDS Strategy for the United States 2017 Progress Report," https://www.hiv.gov/blog/2017-national-hivaids-strategy-nhas-progress-report-released (accessed August 22, 2018).

organizations, the administration report did not acknowledge the major policy shifts that threaten continued progress, from attacks on Medicaid to the failure to appoint a director for the Office of National HIV/AIDS Strategy or members to the President's Advisory Council in HIV/AIDS (PACHA). As noted in an AIDS United press release, "HIV policy does not occur in a vacuum."[98] Cecilia Chung is a trans woman, national HIV policy advocate, and former member of PACHA. Chung told Human Rights Watch, "Without health care, and without respect for trans people's rights, we will never end the HIV epidemic in this country.[99]

The federal response has produced some visibility for HIV risk among trans women as well as a patchwork of initiatives and grants. But the crucial issue of whether HIV care is integrated with trans health care and provided in a gender-affirming setting has not been translated into federal policy.

This policy void is most problematic in relation to the Ryan White HIV/AIDS program, a statutory program that since 1996 has provided the majority of national funding for medical care, medication and support services for people living with HIV.[100] Administered by HRSA and implemented by the states, Ryan White is a safety net program – eligibility for Ryan White programs, including the AIDS Drug Assistance Program (ADAP) that helps pay for medications, is based on income and availability of health insurance. Ryan White patients must have an HIV diagnosis and income of less than 400 percent of the federal poverty level.[101] Ryan White is intended to be the provider of last resort – the program is available for those who have no insurance, but it can also supplement services that are left uncovered by insurance and, in the case of medications, help pay some premium costs and co-pays to ensure access to HIV medications.[102] Care and services offered through Ryan White funded programs are critical to the US HIV response: an estimated 52 percent of people living with HIV — 550,462 people in 2016 — utilize Ryan White. Ryan White patients have significantly better health outcomes, as these services have proven to be vital to their health; 85 percent of Ryan White patients have achieved viral suppression compared to 49 percent nationwide.[103]

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[98] AIDS United, "A Promising Progress Report on the National HIV/AIDS Strategy Only Tells Half of the Story," https://www.aidsunited.org/Blog/?id=3746 (accessed August 29, 2018).

[99] Human Rights Watch interview with Cecilia Chung, Orlando, FL, September 7, 2018.

[100] Ryan White Comprehensive AIDS Resources Emergency Act, P.L. 101-381, 104 Stat. 576, Enacted August 18, 1990.

[101] Florida Department of Health, HIV/AIDS Patient Care Programs, "Core Eligibility Requirements," http://www.floridahealth.gov/diseases-and-conditions/aids/patient-care/_documents/eligibility-information/attachment-c1-brochure-englishc.pdf (accessed August 30, 2018).

[102] National Association of State and Territorial AIDS Directors, "National RWHAP Part B and ADAP Monitoring Project: 2018 Annual Report," https://www.nastad.org/PartBADAPreport (accessed August 30, 2018).

[103] AIDS Watch, "Access to Care," file:///C:/Users/Megan%20McLemore/Downloads/Health_Care_Acess.pdf (accessed August 30, 2018).

The purpose of the Ryan White program is to ensure care for those who have no other options, and in states like Florida with limited access to Medicaid, the program is of lifesaving importance for trans women living with HIV. According to HRSA's annual Ryan White report for 2016, there are 7,166 transgender clients in Ryan White programs nationwide, 355 of whom reside in Florida. Most are trans women (93 percent) and African-American (54 percent). An overwhelming majority live in extreme poverty: 78 percent live at or below the federal poverty level, earning less than $12,000 per year.[104] Though lower than for Ryan White clients overall, viral suppression rates for transgender clients are high (79 percent), much higher than the national average of viral suppression of 49 percent, illustrating the importance of the Ryan White program to transgender women living with HIV. Ryan White-funded clinics clearly help trans women once they enter and stay in the program – but as with other key groups impacted by the US HIV epidemic, there are troubling gaps in engagement and retention in care.

The necessity of gender-affirming care to engage and keep trans women in HIV care is well established, as is the feasibility of implementing this approach. In 2012, HRSA began funding a Special Project of National Significance (SPNS) project called the Transgender Women of Color Initiative (TWOC). TWOC was a demonstration project for improving HIV care at nine sites – both health facilities and community organizations. One of the primary elements of this project was the integration of trans-related health care, including HRT, with HIV care at several of the sites. None of the TWOC sites was in Florida, but for more than five years this project has demonstrated how a focus on providing gender-affirming care — from putting posters with images of trans people on the wall in a clinic to helping with documentation to ensuring availability of HRT — can improve HIV outcomes for trans women of color, and full results are expected to be published in fall of 2018.[105]

The quality of HIV care for trans individuals is included in one federal demonstration project, but participation by states and clinical providers is optional. HRSA is funding a project to offer technical assistance to state health departments and Ryan White-funded health care providers to improve the quality of HIV care to high-risk populations. The project, called the ECHO project, commenced in July 2018, and is designed to respond to

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[104] Health Resources and Services Administration (HRSA) , Ryan White HIV/AIDS Program Clients, Transgender Clients 2016, on file with Human Rights Watch; HRSA, Ryan White HIV/AIDS Program Client Level Data Report 2016, https://hab.hrsa.gov/sites/default/files/hab/data/datareports/RWHAP-annual-client-level-data-report-2016.pdf (accessed August 22, 2018).

[105] Human Rights Watch interview with Dr Greg Rebchook, Principal Investigator, San Francisco, CA, June 27 2018 and https://hab.hrsa.gov/sites/default/files/hab/data/biennialreports/2016_HRSA_Biennial_Report.pdf and https://ajph.aphapublications.org/doi/full/10.2105/AJPH.2016.303582 , full results to be published in a special issue of AIDS and Behavior in the fall 2018.

requests for assistance from clinics whose data indicate health disparities for any of four groups, including transgender people. Transgender HIV experts will be available to consult on ways to increase trans engagement and retention in care. But whether entities will reach out for assistance with trans clients remains to be seen. According to one administrator for the HRSA ECHO program, response from providers is uncertain:

> We are not sure that trans issues will be addressed. It is a time commitment to participate – ten hours of training a month, data reports monthly, consultant involvement – this is a lot of time for a very small population.[106]

Another HRSA-funded project commencing in 2018 will support 26 clinics around the US to implement evidence-based approaches to HIV care for high risk populations, including transgender people. Yet no policies or standards require federally funded HIV care to be provided in a gender-affirming setting and there is no systematic monitoring or evaluation of this issue by the federal government.

JoAnne Keatley has published extensively on the importance of integration of care and provided technical assistance for the TWOC project. According to Keatley, "Even before the TWOC project, we had the evidence we need – we know what to do to improve HIV outcomes for trans women. We have been working for decades to incorporate these findings into federal policy."[107]

In the absence of federal standards or guidance, integration of HIV care with trans health care remains aspirational, limited, and incomplete in many states such as Florida. As discussed in detail below, Florida HIV officials provide funding to clinics that promote and offer gender-affirming care, but information from the ground indicates that they are also funding sites that do not. The AIDS Drug Assistance Program (ADAP) provides HIV medications to those without health insurance, but in many states, including Florida, medications necessary for gender transition care are missing. Although millions of federal dollars are being administered, states implement Ryan White funding without policy guidance or compliance standards from the federal government for ensuring that gender-affirming care is implemented. According to Florida Department of Health HIV program officials:

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[106] Human Rights Watch telephone interview with Kevin Garrett, Senior Quality Manager, HRSA Ryan White HIV/AIDS Program Center for Quality Improvement and Innovation, New York, NY, June 21, 2018.

[107] Human Rights Watch telephone interview with JoAnne Keatley, Director Emeritus, Center for Excellence in Transgender Health, San Francisco, CA, June 28, 2018.

After a thorough search we could find no HRSA or Ryan White regulations that addressed gender-affirming care for transgender women living with HIV.[108]

HIV in Florida

The state of Florida, along with the rest of the US south, lies at the center of the nation's HIV epidemic. With more than 116,000 people known to be living with HIV, Florida accounts for 11 percent of HIV cases in the US.[109] Florida has the nation's third highest rate of new HIV infections, and the epidemic is concentrated in urban areas of the state. The cities of Miami, Fort Lauderdale and West Palm Beach accounted for 47 percent of the state's new HIV infections in 2016.[110] The rates of HIV infection in Miami-Dade and Broward counties are the highest in the nation. In 2017, the metropolitan areas that included Miami-Dade and Broward counties ranked first and second in the US in the rate of new HIV infections.[111]

Racial disparities are stark. In Florida, one in every 151 adults is known to be living with HIV; one in 295 whites, one in 49 African-Americans and one in 155 Hispanics.[112] African-Americans are 15 percent of the state's population, but account for 42 percent of adult HIV infection cases and 50 percent of adult AIDS diagnoses. Hispanic people comprise 24 percent of Florida's adult population but represent 31 percent of HIV infection cases and 24 percent of AIDS cases.[113] The rate of HIV infection in Florida is five times higher for Black men than white men, and 12 times higher for Black women than white.[114]

Florida surveillance data indicate that male-to-male sexual contact is the primary mode of transmission for both those living with HIV and new infections, followed by heterosexual

[108] Human Rights Watch email communications with Devin Galetta, Interim Communications Director, Florida Department of Health, June 22, 2018 and July 25, 2018 ("FDOH Responses").

[109] State of Florida Integrated HIV Prevention and Care Plan 2017-21"; Washington DC's rate of new infections is higher than any state; Florida's rate of new HIV infection is third behind Georgia and Louisiana. Florida Department of Health, HIV/AIDS Section, "State of the Epidemic in Florida, 2017.

[110] CDC. "HIV in the United States by Geography," https://www.cdc.gov/hiv/statistics/overview/geographicdistribution.html (accessed August 30, 2018); Florida Department of Health, "State of Florida Integrated HIV Prevention and Care Plan 2017-21," http://www.floridahealth.gov/diseases-and-conditions/aids/Prevention/_documents/State-of-Florida-Integrated-HIV-Prevention-and-Care-Plan-09-29-16_FINAL-Combined.pdf (accessed August 30, 2018).

[111] Florida Department of Health, HIV/AIDS Section, "State of the HIV Epidemic in Florida, 2017." State HIV data utilize "Black" and "Hispanic" as categories for racial classification.

[112] Ibid.

[113] Ibid.

[114] Florida Department of Health, "State of Florida Integrated HIV Prevention and Care Plan 2017-21."

contact and injection drug use.[115] As discussed in detail below, this data does not accurately reflect either cases or transmission modes among the transgender population.

State Response to HIV

In the US, the federal government is the primary source of funding for state HIV response, and the severity of the epidemic in Florida has resulted in what the statewide HIV Prevention and Care Plan calls "one of the nation's most comprehensive programs for HIV/AIDS surveillance, education, prevention, counseling, testing, care, and treatment."[116] In fiscal year 2017-2018, Florida's HIV budget totaled nearly $300 million, mostly from federal sources. This budget has increased in the last three years by 15.6 percent. [117]

In Florida, lack of other insurance options has resulted in a significant reliance on Ryan White. One in five people in Florida is uninsured, the third-highest percentage in the nation.[118] More than half of people living with HIV in the state rely on care and services from the Ryan White Program.[119] Florida has a very restrictive Medicaid program and many people cannot afford to purchase private insurance, do not receive it from their employer, or are not eligible for federally subsidized insurance premiums under the Affordable Care Act. An estimated 384,000 people fall into this "coverage gap" in the state.[120] In Florida, the majority of Ryan White clients are African-American men, have incomes under 100 percent of the federal poverty level (less than $13,860 per year for an individual), and have no insurance.[121]

Florida's extensive public HIV program has produced mixed results. Significant improvement has occurred over the last decade: Between 2008 and 2017, there was an 18

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[115] Florida Department of Health, HIV/AIDS Section, "State of the HIV Epidemic in Florida, 2017."

[116] Florida Department of Health, "State of Florida Integrated HIV Prevention and Care Plan 2017-21."

[117] FDOH Responses.

[118] David K. Jones and Paula S. Atkinson, "At Stake in the 2018 Midterms: Medicaid Expansion in Florida and Maine," Health Affairs Blog, July 27, 2018, https://www.healthaffairs.org/do/10.1377/hblog20180726.267396/full/?utm_campaign=Health+Affairs+Today+Newsletter&utm_medium=email&utm_content=email&utm_source=Act-On_2018-07-27&cm_mmc=Act-On+Software-_-email-_-Medicaid+Expansion+and+The+2018+Midterms%3B+Hospital+OPPS+Proposed+Rule-_-At+Stake+In+The+2018+Midterms%3A+Medicaid+Expansion+In+Florida+And+Maine&utm_term=At+Stake+In+The+2018+Midterms%3A+Medicaid+Expansion+In+Florida+And+Maine (accessed August 30, 2018).

[119] Health Resources and Services Administration, "Ryan White HIV/AIDS Clients Served by State, 2015" https://hab.hrsa.gov/stateprofiles2015/#/ (accessed August 30, 2018).

[120] David K. Jones and Paula S. Atkinson, "At Stake in the 2018 Midterms: Medicaid Expansion in Florida and Maine,"; Southern AIDS Strategy Initiative," Medicaid Expansion in the South," https://southernaids.files.wordpress.com/2016/03/medicaid-expansion-in-the-south-report-final1.pdf (accessed August 30, 2018.)

[121] Health Resources and Services Administration, "Ryan White HIV/AIDS Clients Served by State, 2015" https://hab.hrsa.gov/stateprofiles2015/#/ (accessed August 30, 2018).

percent decline in HIV cases diagnosed, a 51 percent decline in AIDS cases diagnosed, and a 47 percent decline in HIV-related deaths.[122] Some recent trends are promising. Between 2014 and 2016, more Floridians with HIV entered medical care, remained in care, and became virally suppressed.[123] In the state ADAP program, 9 of 10 clients have achieved viral suppression.[124]

However, new infections have increased since 2013. Rates of new infection are highest among men who have sex with men (a category that erroneously includes many trans women), particularly young men of color.[125] The number of patients who fail to remain in treatment for HIV is concerning; of persons diagnosed with HIV, 92 percent are linked to care, but only 66 percent remain in care and 60 percent become virally suppressed.[126] Despite improvement in some areas, Florida is still struggling to bring its HIV epidemic under control.[127] In 2018, state HIV officials reported that many of the targets set in the previous year – including reducing new HIV infections, reducing new infections among African-American and Hispanic people, and reducing rates of infection among Hispanics – had not been met.[128]

Florida faces many challenges in effectively managing HIV. With 20 million people, it is the fourth most populous state in the US, a vast geographical area both urban and rural. Floridians are multi-ethnic (17 percent African-American and 24 percent Hispanic or Latino, according to 2017 census estimates) and there is a considerable transient population comprised of migrant workers as well as seasonal and part-time residents.[129] Its fiscal policy is conservative, with a constitution that prohibits state income taxes – the last tax increase occurred in 1988 and increased the sales tax by one percent.[130] Under Republican

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[122] Florida Department of Health, HIV/AIDS Section, "State of the HIV Epidemic in Florida, 2017,"; Florida Department of Health, "State of Florida Integrated HIV Prevention and Care Plan 2017-21."

[123] Ibid.

[124] Ibid.

[125] Ibid.

[126] Ibid.

[127] Cohen, J. "We're In a Mess'- Why Florida Is Struggling With an Unusually Severe HIV/AIDS Problem," *Science*, June 13, 2018.

[128] Florida Department of Health, HIV/AIDS Section, "Agency Performance Management Council Meeting, Performance Review," April 12, 2018, on file with Human Rights Watch.

[129] United States Census Bureau, "State of Florida Quick Facts," https://www.census.gov/quickfacts/FL (accessed August 30, 2018). The Census utilizes "Latino" as a classification category.

[130] George Mason University, Mercatus Center, "Florida Fiscal Policy: Responsible Budgeting in a Growing State," https://www.mercatus.org/publication/florida-fiscal-policy-responsible-budgeting-growing-state (accessed August 30, 2018).

Governor Rick Scott, health and education budgets have experienced deep cuts.[131] In 2017, public health funding in Florida as a percentage of the budget ranked 40th in the nation; effective health care policy, comprised of factors such as percent uninsured, health spending, and vaccination coverage, ranked 46th among 50 states.[132]

In 2018, the legislature failed to pass a bill that would have permitted syringe exchange programs to operate statewide, leaving Miami-Dade as the only county with a syringe exchange program. Rejection by conservative legislators of proven public health and harm reduction approaches to injection drug use are problematic as the state, and the US, faces an unprecedented epidemic of drug overdose and increasing rates of HIV, hepatitis C, and other illnesses from injection drug use.[133]

The policy most detrimental to Florida's ability to manage its HIV epidemic is the state's failure to expand its Medicaid program. Under the Affordable Care Act, states have the option to expand eligibility guidelines for their Medicaid programs with payment largely covered by the federal government.[134] Florida is one of 18 states that have rejected this option despite Florida's very restrictive Medicaid eligibility guidelines for its state program. Florida limits Medicaid eligibility both categorically (one must be disabled, parents of dependent children, a pregnant woman, or in need of long-term care) and income (for example, parents and caretakers' income cannot be higher than 29 percent of the federal poverty level, or more than $7,380 per year).[135]

Medicaid expansion has benefited people living with HIV, primarily by ensuring coverage for a core group of comprehensive medical services without exclusion for pre-existing

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[131] Ryan Benk, "Lawmakers Unveil Budget Proposals Containing Punishing Cuts to Hospitals," *Health News Florida*, March 29, 2017, John Kennedy, "At Height of Opioid Crisis, Some Florida Treatment Programs Face Deep Cuts," *Sarasota Herald Tribune*, May 8, 2018; Kate Santich, "Cuts to Mental Health Care Could Leave Thousands Without Help, Advocates Say," *Orlando Sentinel*, August 7, 2017.

[132] United Health Foundation, "America's Health Rankings, Florida in 2017," https://www.americashealthrankings.org/explore/annual/state/FL (accessed August 30, 2018).

[133] CDC, "Increasing Rates of Hepatitis C Linked to Worsening Opioid Crisis," https://www.cdc.gov/nchhstp/newsroom/2017/hepatitis-c-and-opioid-injection-press-release.html (accessed August 30, 2018).

[134] Center for American Progress, "10 Frequently Asked Questions About Medicaid Expansion," https://www.americanprogress.org/issues/healthcare/news/2013/04/02/58922/10-frequently-asked-questions-about-medicaid-expansion/ (accessed August 30, 2018).

[135] Florida Policy Institute, "Medicaid Premiums and Work Requirements: A Prescription for Higher Costs and Lower Health Insurance Coverage," https://www.fpi.institute/wp-content/uploads/2017/11/MedicaidWorkReq.pdf (accessed August 30, 2018).

conditions.[136] In Medicaid expansion states, Medicaid coverage for people living with HIV rose 11 percent, with the most significant gains in coverage experienced by people with the lowest incomes and people of color.[137] Medicaid expansion has the potential to significantly mitigate HIV risk as well; expansion has been shown not only to increase access to comprehensive health services but to reduce poverty, a primary driver of HIV risk in the US.[138] Because Medicaid expansion regulations incorporate the anti-discrimination provisions of the Affordable Care Act, expansion is particularly important for LGBT people and other groups experiencing discrimination in health care.[139]

Broader eligibility under Medicaid expansion extends not only to working people with higher incomes, but to adults without dependent children. For Floridians, and for many trans women, this is a key factor as the Florida Medicaid program is limited to adults with dependent children, pregnant women or people with disabilities. In Florida, 87 percent of people who fall into the health insurance "coverage gap" as a result of failure to expand Medicaid are adults without dependent children, and 47 percent are people of color.[140]

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[136] Center for American Progress, "The Medicaid Program and LGBT Communities," https://www.americanprogress.org/issues/lgbt/reports/2016/08/09/142424/the-medicaid-program-and-lgbt-communities-overview-and-policy-recommendations/ (accessed August 30, 2018).

[137] Kaiser Family Foundation, "ACA Medicaid Expansion Drove Nationwide Increase in Health Coverage for People with HIV, First National Analysis Finds," https://www.kff.org/health-reform/press-release/aca-medicaid-expansion-drove-nationwide-increase-in-health-coverage-for-people-with-hiv-first-national-analysis-finds/ (accessed August 30, 2018).

[138] Chicago Policy Review, "Reducing Poverty: How Medicaid Does More Than Just Improve Access to Health Care in Cities," http://chicagopolicyreview.org/2014/01/20/reducing-poverty-how-medicaid-does-more-than-just-improve-access-to-healthcare-in-cities/ (accessed August 30, 2108).

[139] Center for American Progress, "The Medicaid Program and LGBT Communities," https://www.americanprogress.org/issues/lgbt/reports/2016/08/09/142424/the-medicaid-program-and-lgbt-communities-overview-and-policy-recommendations/ (accessed August 30, 2018).

[140] Kaiser Family Foundation, Medicaid Issue Brief, "The Coverage Gap: Uninsured Poor Adults in States That Do Not Expand Medicaid," https://www.kff.org/medicaid/issue-brief/the-coverage-gap-uninsured-poor-adults-in-states-that-do-not-expand-medicaid/ (accessed August 30, 2018).

Findings

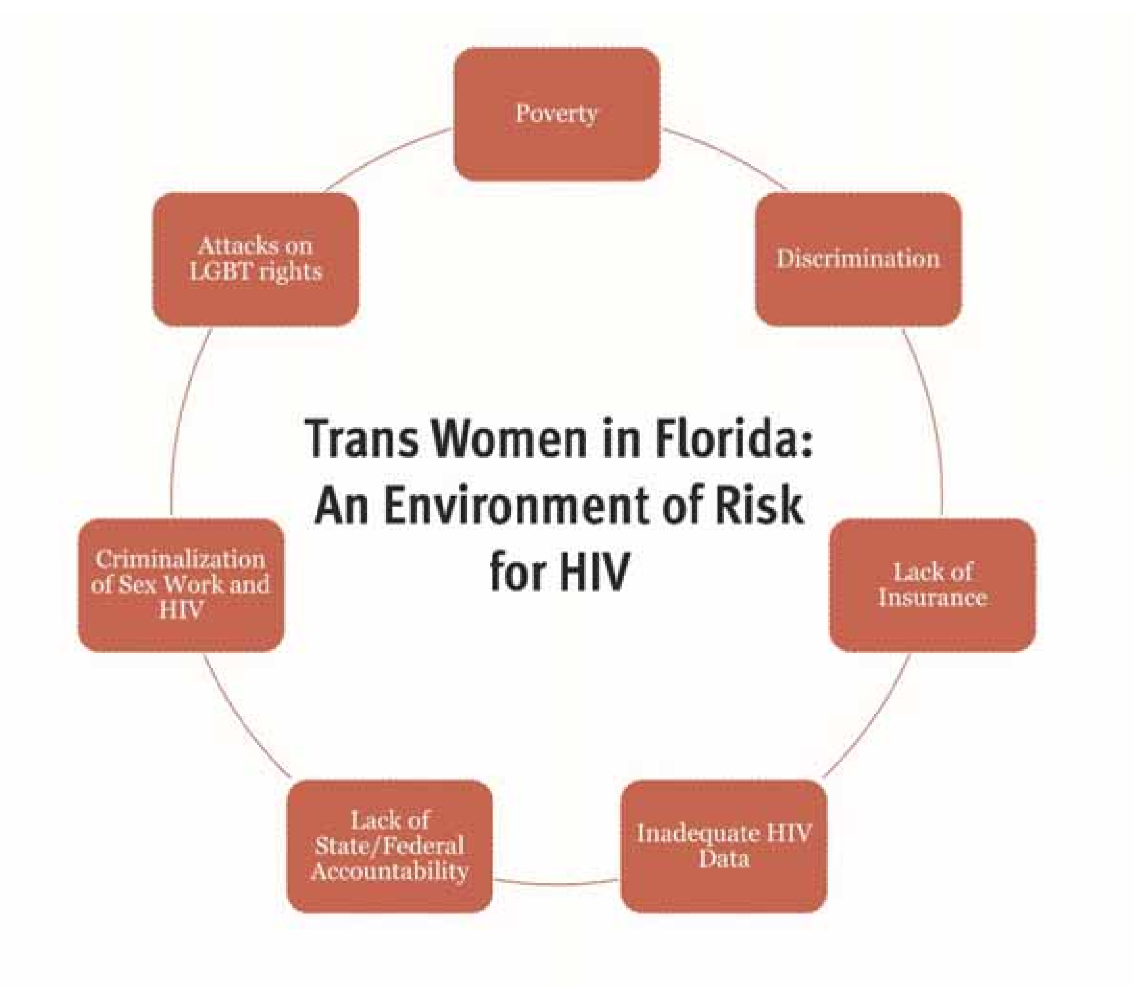
For this report, Human Rights Watch administered 125 questionnaires to women of trans experience in Miami-Dade and Broward counties, gathering demographic information as well as information related to access to health care, including HIV prevention and treatment. The surveys and additional interviews with trans women, their advocates, HIV providers, and others indicated that many trans women in south Florida, particularly Latina and African-American women, live in an environment of high HIV risk as a result of multiple factors, with poverty and lack of health insurance standing out as primary vulnerabilities. Lack of income was associated with high rates of participation in sex work and with high rates of involvement with the criminal justice system – factors that increase HIV risk. These findings are consistent with other surveys of trans women in Florida, such as the one conducted by the 2015 US Transgender Survey, showing high rates of poverty and criminal justice involvement for trans women, particularly women of color.[141]

This severe and compound environment of risk for HIV demands a robust response from both state and federal government. There is ample evidence of how to provide effective health care, including HIV care, for trans women. But in south Florida, trans women face a fragmented landscape for health care that fails to ensure that effective, integrated HIV care is available at a cost that transgender women can afford. With no explicit or coordinated policies to ensure systematic monitoring and evaluation of HIV prevention or care for trans women, accountability is lacking. Policy development is hindered by lack of accurate or complete data regarding HIV among transgender women, a continuing problem that perpetuates a cycle of perceiving this at-risk population as “too small to help” at both the state and federal levels. Criminalization of sex work and HIV promote unemployment, poverty, and stigma that make access to health services more difficult. Few questions remain about what needs to be done, but without commitment by policymakers to do it, trans women will continue to experience grossly disproportionate disparities in access to health and HIV prevention and care.

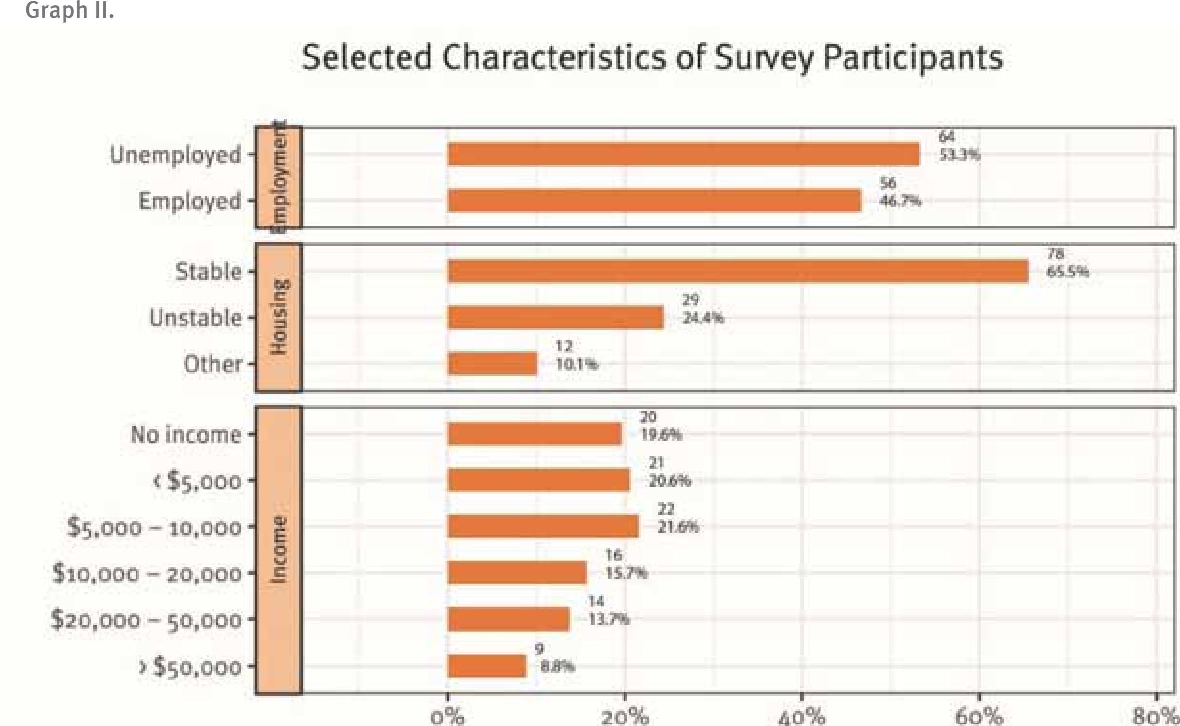
[141] NCTE, National Transgender Survey, 2015.

Trans Women Face Barriers to Health Care in Florida

Trans women in Miami-Dade and Broward counties face multiple challenges that impact access to health care. As part of the research for this report, Human Rights Watch conducted a survey of 125 trans women with the assistance of local organizations and trans health advocates. The results below indicate severe socio-economic deprivation and a fragile existence for the majority of trans women interviewed.



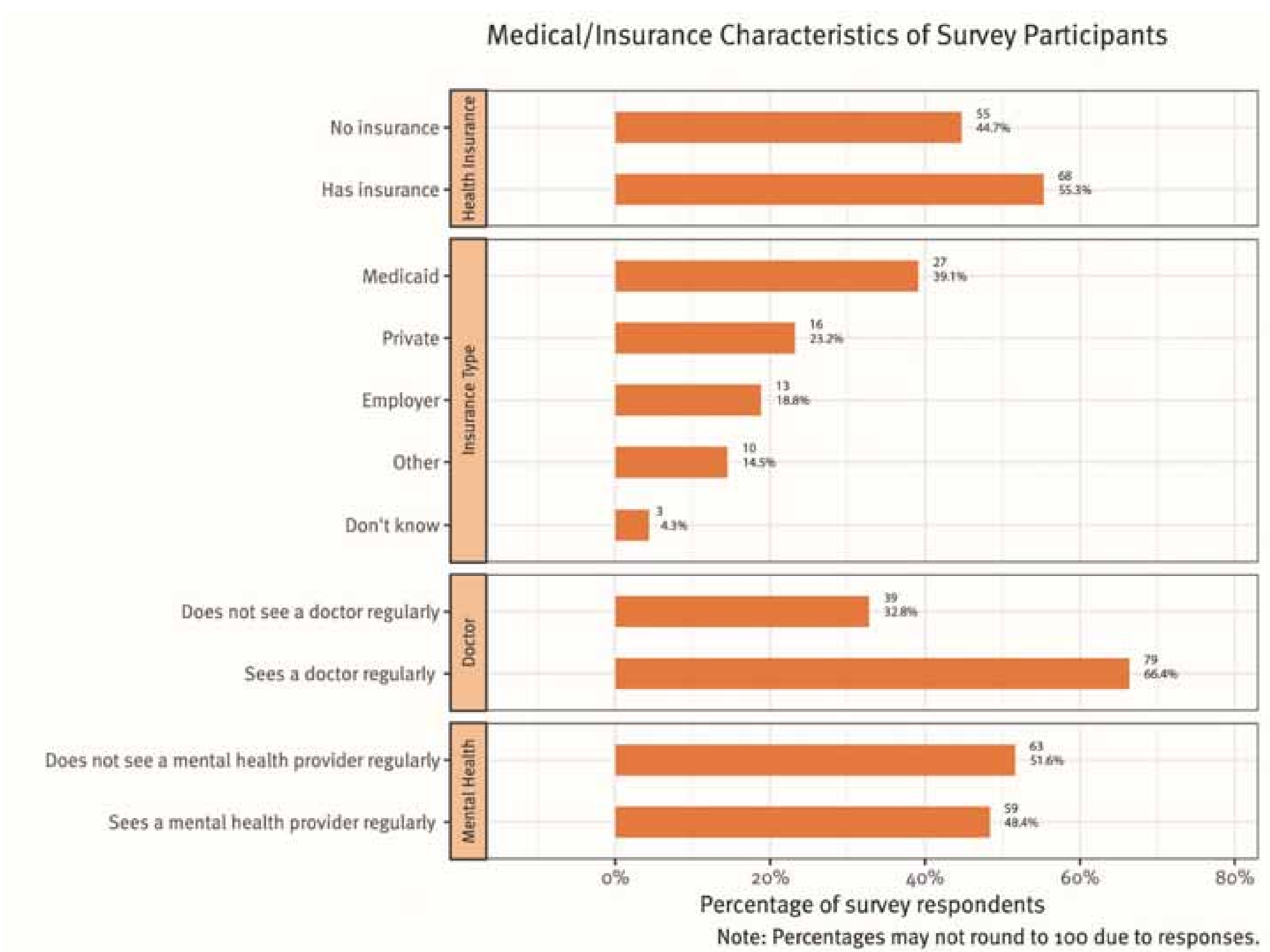
Graph II.



The survey results reveal many trans women experience extreme poverty, with 63 percent of participants reporting income of less than $10,000 per year (20 percent of survey participants had no income; 21 percent reported income under $5,000 per year; 22 percent reported income between $5000 and $10,000 per year). More than half (53 percent) were unemployed. One third reported that their housing situation was "unstable" or "other" than stable (see Graph II).

These were not the most marginalized trans women living in areas with scarce resources. The survey was distributed through organizations providing services to trans women and participants were more likely to be connected to health care than in a more randomized sample. Also, the surveys were distributed in two major metropolitan areas with extensive health and HIV care infrastructure. Yet the results below indicate significant gaps in coverage and access to health insurance or care (see Graph III).

Graph III.



Of trans women surveyed, 45 percent had no health insurance. Of those that had health insurance, 39 percent had Medicaid and 23 percent reported having private insurance. Sixty-six percent see a doctor regularly (defined as twice a year or more) and 48 percent see a mental health provider regularly. Of those who did not see a doctor regularly, 38 percent said they could not afford it.

In detailed survey responses, many women described bad experiences with medical providers and their struggles to access gender-affirming care:

"Every time you walk into the doctor's office, you become a science experiment." – Ellen, age 44.[142]

[142] Human Rights Watch interview with Ellen A., Fort Lauderdale, FL, December 11, 2017.

"When I transitioned, my doctor wouldn't see me after that. I couldn't get in to see them. I had an infection and they wouldn't call in the antibiotics. It was an ordeal. It was scary. I just felt bad about how they treated me." Susan, age 22.[143]

"I used to go to Jackson hospital, but I haven't been there in over a year. They are terrible. Not knowledgeable about trans health. They misgendered me. I don't feel comfortable or trust them." – Barbie, age 65.[144]

Many described cost and lack of insurance as the key factor in lack of health care:

"I made $450 a month and was working for ten years. Was denied Obamacare. Very hard to find insurance in Florida." – Valerie, age 50.[145]

"I have diabetes. Hormones and diabetes medications cost $500 a month, I can't afford that." – Diana, age 54.[146]

Knowledge of where to get an HIV test was high, with 91 percent reporting that they knew where they could get tested. Nearly one quarter (23 percent) of survey participants reported that they were HIV-positive. To place this result in context, many surveys were distributed through agencies that provide referrals for HIV-related services. More than one in three (35 percent) trans women living with HIV had no health insurance. However, 88 percent of women living with HIV reported seeing a doctor regularly, and most were taking HIV medications (92 percent). With 77 percent of women living with HIV reporting that they had achieved an undetectable viral load, these results indicate the importance of the Ryan White safety net in states such as Florida, where many are without insurance and Medicaid has not been expanded.

Many of the women, including those living with HIV, described a difficult process for finding care that centered around safety and trust concerns.

Misty Eyez is a trans woman who works as an educator, trainer and case manager for trans women at Sunserve, an NGO in Broward County. Eyez described the fear of going to the doctor:

[143] Human Rights Watch interview with Susan B., Fort Lauderdale, FL, April 25, 2018.
[144] Human Rights Watch survey response, Miami, March 27, 2018.
[145] Human Rights Watch interview with Valerie N., Miami, Florida, March 30, 2018.
[146] Human Rights Watch interview with Diana A., Fort Lauderdale, April 25, 2018.

> Many trans women are not comfortable leaving their house during the day. Therefore, going to the doctor can be an ordeal. For many reasons, some feel they have to put themselves totally together with the dress, the wig, the makeup in order to go out of the house, and then will they be safe in public, on the street, or on the bus? And how will they be treated when they get there? It is very lonely and isolating.[147]

Lack of Gender-Affirming Care Impedes HIV Response

For trans women, including those living with HIV, gender-affirming health care is not optional. Not all trans women want hormone replacement therapy (HRT), but for many it is central to their wellbeing and their number one health care priority. As Morgan Mayfaire, a trans man and co-director of TransSOCIAL, an advocacy organization for trans people living with HIV in Broward and Miami-Dade counties, told Human Rights Watch: "In this community, HRT is all. You will walk through a moat full of alligators to get your hormones."[148]

This is true even for women living with HIV, which is one reason that HIV and trans health experts consider integration of HRT and HIV care to be critically important. The WHO, the Center for Excellence in Transgender Health at the University of California at San Francisco, the Fenway Institute, and others clearly identify integration of HRT and HIV care to be a best practice for HIV care for trans individuals.[149] The trans leaders convened by AIDS United emphasized the importance of a "one-stop shop" providing HRT and HIV treatment:

> Due to financial hardship, housing instability, trauma due to a very real fear of violence in their lives, and distrust of medical personnel, trans people often fall out of care. If trans people are to successfully engage in and remain retained in care, clinical settings must design care that accounts for this reality. [As a best practice] Providers should consider establishing trans medical homes that address all health needs in a "one-stop shop" to

[147] Human Rights Watch telephone interview with Misty Eyez, Sunserve, Fort Lauderdale, FL, July 24, 2018.
[148] Human Rights Watch interview with Morgan Mayfaire, co-director of Transsocial, Fort Lauderdale, FL, November 17, 2017.
[149] The Fenway Institute, "Retaining Transgender Women in HIV Care," http://fenwayhealth.org/wp-content/uploads/TFIR46_RetainingTransgenderWomenInHIVCare_BestPractices_webready.pdf (accessed August 31, 2018).

> retain and engage people in a consistent level of preventive and primary care.[150]

According to Dr. Madeline Deutsch, an expert in transgender health at the University of California at San Francisco, integration of HRT with HIV treatment should be considered not only a best practice, but the standard of care for trans people living with HIV:

> Hormone therapy can increase engagement in care and increase adherence to anti-retroviral medication. It may not yet be considered a standard of care, but it should be. Not providing hormone therapy with HIV care is akin to providing HIV care in a Latina neighborhood without any Spanish speakers available.[151]

In south Florida, finding health care in a gender-affirming environment is difficult, and for trans people living with HIV the options are limited. Human Rights Watch interviewed trans women and their advocates, Ryan White providers, public health officials, and organizations in each county whose primary mission includes directing trans people either recently diagnosed with, or living with, HIV to appropriate medical services. These latter resources, many of which are small non-profit agencies, make it their priority to stay abreast of which clinics offer gender-affirming care, including HRT, to trans HIV patients so they can make effective referrals for care. It is a fluid situation that often depends on the presence of an individual trans-friendly or trans doctor, case manager, or another key employee. Based upon these sources, three to five clinics in each county were consistently identified as providing gender-affirming integrated HIV care to transgender people.

HIV care is widely available in Miami-Dade and Broward counties. An extensive, federally funded network of private, public and community-based providers offer prevention, medical care, case management and support services. The Health Resources Services Administration (HRSA) administers the Ryan White program funding in the US. HRSA designates priority funding for primary medical services under Part A of the program to metropolitan areas throughout the country. Due to the severity of their local HIV epidemics, Broward and Miami-Dade counties are two of six Florida metropolitan areas

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[150] AIDS United, "Stepping Up: Best Practices In Providing HIV Medical Care, Support Services and Funding To Trans Communities," file:///C:/Users/Megan%20McLemore/Downloads/Stepping_Up__A_Consensus_Statement_by_Trans_Leaders%20(2).pdf (accessed August 22, 2018).

[151] Human Rights Watch telephone interview with Madeline Deutsch, MD, Assistant Clinical Professor, UCSF, San Francisco, CA, May 17, 2018.

that receive Ryan White funds for primary medical services under Part A of the Ryan White program. In fiscal year 2017-18, Miami received more than $26 million in Part A funding for treatment and care and Fort Lauderdale received more than $15 million. This does not include separate funding received by both counties for Part B services which include the AIDS Drug Assistance Program (ADAP) for HIV-related medications.[152]

In Broward County, there are 13 providers of primary medical care for HIV that are entirely or partially funded by Ryan White. In Miami-Dade County, there are 24 providers of primary medical care for HIV entirely or partially funded by Ryan White. These range in type from private non-profit organizations such as the AIDS Healthcare Foundation to the University of Miami Comprehensive AIDS Program at the Miller School of Medicine. In both counties, clinics are available in all regions of the county, though most services are concentrated in the cities of Fort Lauderdale and Miami.[153]

However, finding gender-affirming health services is a challenge. Arianna Lint is a Latina trans woman and director of Arianna's Center, a non-profit organization whose mission is to provide support services, outreach, and advocacy for Latina trans women in both Miami-Dade and Broward counties. Arianna is a woman living with HIV and, as part of the national Positively Trans initiative sponsored by the Transgender Law Center, about one third of Arianna's 350 clients are HIV-positive trans women. Arianna explains that in south Florida, finding a clinic where Spanish language services are available is not a problem, but HRT availability is limited, making referrals difficult for many of her clients.

> For the girls who are HIV-positive I help them in every way – I counsel them about HIV, I get them connected to medical care that they can afford, and I help them stay on their HIV medications. I know which clinics in the area are trans-friendly, and they can either start or get onto hormones if they want them. Unfortunately, there are very few clinics that provide both hormones and HIV care, but I know which ones they are, so that is where I send women when they call me for help.[154]

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[152] Health Resources and Services Administration, "FY 2017 Ryan White HIV/AIDS Program Part A Final Awards," https://hab.hrsa.gov/awards/fy-2017-ryan-white-hivaids-program-part-a-final-awards (accessed August 31, 2018) and FDOH Responses.

[153] Florida Department of Health, "State of Florida Integrated HIV Prevention and Care Plan 2017-21," and Miami-Dade HIV/AIDS Partnership materials, on file with Human Rights Watch.

[154] Human Rights Watch interview with Arianna Lint, Executive Director of Arianna's Center, Wilton Manors, FL, July 13, 2017.

As co-director of TransSOCIAL, a non-profit organization that provides a wide array of support, Morgan Mayfaire refers hundreds of trans people to services in both Broward and Miami-Dade counties each year. TransSOCIAL also provides cultural competence trainings to businesses, health centers, and HIV providers in an effort to expand safe and affirming resources for the trans community. Mayfaire is also a member of the state HIV Comprehensive Planning Network (FCPN), and he told Human Rights Watch:

> There is a severe lack of HIV providers who are willing to prescribe hormones or offer a trans-friendly environment. We refer to a handful of clinics and that covers both Miami-Dade and Broward counties. It's a big problem because there are many more HIV providers than HRT providers, but most HIV providers do not want to prescribe hormones, or people have had bad experiences going to that location. We spend a lot of time working on trying to make HRT and ART available in the same place.[155]

Dr. Sheryl Zayas is the Medical Director of Care Resource Community Health Center in Fort Lauderdale, a full-service health center that is partially funded by Ryan White to provide HIV care in the community. Dr. Zayas estimates that between 10 and 15 percent of her several hundred patients are trans women, many of them HIV-positive. Dr. Zayas describes Care Resource as a gender-affirming environment, an opinion that was confirmed by trans survey participants and those who refer trans patients for HIV care. At Care Resource Fort Lauderdale, services are offered on a sliding scale for income, staff are trained regularly on trans-sensitive issues, low thresholds are set for documentation and it need not be conforming to one's gender identity, and a trans woman is employed in an outreach program to inform trans women about HIV services at the clinic. Dr. Zayas told Human Rights Watch that she considers offering hormone replacement therapy to be "essential" to keeping people in care:

> This is a community under stress. Homelessness, lack of jobs, lots of having to do sex work to survive. All of my trans clients don't want hormones, but most do, and I have a better chance to keep them in health care if I can prescribe it.[156]

[155] Human Rights Watch interview with Morgan Mayfaire, co-director of TransSOCIAL, Fort Lauderdale, FL, November 17, 2017.
[156] Human Rights Watch interview with Sheryl Zayas, MD, Fort Lauderdale, FL, February 7, 2018.

However, not all of the Care Resource locations offer this level of service to trans patients. At one clinic, for example, Dr. Zayas said, "We have one provider who treats HIV patients but doesn't want to do HRT. I don't know why. It might be for religious reasons."[157]

Dr. Zayas believes training of medical professionals can go a long way toward reducing reluctance to provide hormone therapy. She is not an endocrinologist, but finds it sufficient to follow the WPATH guidelines for transgender primary care and the standards for hormone treatment established by the Endocrine Society Clinical Guidelines. She participates in medical training symposia that address transgender health issues and clinical practice.

Dr. Maureen Greenwood's practice at the AIDS Healthcare Foundation clinic in Oakland Park, Broward County, focuses on HIV. Dr. Greenwood has approximately 200 transgender patients. Dr. Greenwood, a Doctor of Nursing Practice, said she follows the WPATH guidelines for transgender clinical care and consults their staff endocrinologist in more complex cases, but that that situation is rare. Dr. Greenwood also stated that training for medical practitioners in transgender health issues is essential to increasing the availability of services.[158]

Some medical providers may not be aware that standards and best practices for transgender health have evolved, moving away from specialist care for hormone therapy and eliminating the need for a mental health referral to initiate hormone replacement therapy. Historically, a mental health provider had to approve an individual for HRT before a primary care physician could prescribe the medication. Though this approach is still accepted by WPATH as valid, an "informed consent" model is now widely implemented that lowers the threshold and focuses on the elements of informed consent that are ethically required for administration of all other medications: an individual's understanding of the risks, benefits and consequences of taking, and of not taking, gender-affirming medications. This model is endorsed by WPATH, CETH, and other experts as appropriate for medical providers to implement on their own.[159] Under current standards, doctors, nurse practitioners, physicians' assistants, and other providers qualified to assess and diagnose gender dysphoria and assess informed consent can

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[157] Ibid.

[158] Human Rights Watch interview with Maureen Greenwood, DNP, Oakland Park, FL, November 10, 2017.

[159] World Professional Association for Transgender Health, Standards of Care, https://www.wpath.org/media/cms/Documents/Web%20Transfer/SOC/Standards%20of%20Care%20V7%20-%202011%20WPATH.pdf (accessed August 17, 2018.);); University of California at San Francisco, Center for Excellence in Transgender Health (CETH), "Overview of Gender Affirming Treatments and Procedures," http://transhealth.ucsf.edu/trans?page=guidelines-overview (accessed August 17, 2018).

prescribe hormone replacement therapy for gender transition. As stated in an article by Dr. Madeline Deutsch of CETH:

> Prescribing gender-affirming hormones is well within the scope of a range of medical providers… Most medications used in gender-affirming hormone therapy are commonly used substances with which most prescribers are already familiar due to their use in the management of menopause, contraception, hirsutism, male pattern baldness, prostatism, or abnormal uterine bleeding.[160]

Florida State Response

The Florida state HIV Plan for 2017-21 identifies transgender people, particularly women of color, as a "high priority" population, and the state has taken a variety of steps to address HIV among transgender women. Between 2013 and 2017, statewide programs provided HIV testing for more than 2,500 transgender individuals, identifying 85 trans persons as living with HIV. Since 2012, $8 million in federally funded HIV grants have been distributed to community-based organizations statewide for prevention activities focused on all priority populations, including transgender women. Because prevention efforts now include ensuring that people living with HIV are in treatment, these programs offer traditional prevention activities such as education and condoms as well as linkage to treatment services for people living with HIV. During 2016 and 2017, prevention services were provided to more than 1,000 transgender women in the state through these programs.[161]

In Broward and Miami-Dade counties, federal and state funds support at least seven agencies that provide HIV prevention and supportive activities and events for transgender communities.[162] Since 2016, the state has used federal and state funds to conduct eight trainings to improve LGBT cultural competency for both DOH staff and community providers in various cities in Florida, including two in Miami. To the credit of state HIV officials, HRW survey results show that most trans women participants living with HIV were receiving HIV care. This result likely reflects the methodology of the survey, which was administered largely through organizations that provide services to trans women, including referrals to HIV treatment and support.

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[160] CETH, "Initiating Hormone Therapy," http://transhealth.ucsf.edu/trans?page=guidelines-initiating-hormone-therapy (accessed August 31, 2018).

[161] FDOH Responses.

[162] Ibid.

Retention in Ryan White care, however, is a significant issue in Florida, and the state has very incomplete information regarding how many trans women living with HIV are actually in care, why they are not receiving care, or why they fail to remain in care. The problem is not a fiscal one; federal funding for HIV care has remained stable, and unlike many other states in the Deep South, state funding also contributes to HIV prevention, care, and support services.[163] The Department of Health told Human Rights Watch that there is no shortage of funds for transgender related services.[164] Rather, the problem is a policy void. There is no mention of gender-affirming HIV care in the State HIV Plan and there is no systematic approach – no policy, no guidelines, no monitoring, no evaluation – of whether the multiple medical care providers in Miami-Dade and Broward counties are providing gender-affirming care or making hormone replacement therapy available.

State HIV officials told Human Rights Watch:

> The Ryan White program does not specifically fund transgender-specific services. However, both Part A and Part B programs fund agencies that provide transgender-friendly services... Several clinics in Broward County provide gender-affirming care… There are a few in Miami-Dade as well.[165]

According to state HIV officials, "transgender individuals are always welcome at any Ryan-White supported medical provider."[166] But in reality, there are no mechanisms in place to ensure that that is true, and evidence from the ground suggests otherwise. Multiple survey participants described bad experiences at local Ryan White clinics, and trans health advocates described their unwillingness to refer clients to most of the Ryan White clinics in Miami-Dade and Broward counties. Arianna Lint stated:

> Most of the Ryan White clinics I would not refer [clients] to – women tell me about rude staff and doctors who won't give hormones or don't understand their bodies. Many bad stories. One clinic told me 'transgenders are not a priority.'[167]

[163] Ibid.
[164] Ibid.
[165] FDOH Responses.
[166] FDOH Responses.
[167] A Human Rights Watch interview with Arianna Lint, Executive Director of Arianna's Center, Wilton Manors, FL, July 13, 2017.

Morgan Mayfaire told Human Rights Watch, "We recently called a Ryan White clinic in Fort Lauderdale to ask if they offer gender-affirming care. They hung up on us. [168] Ashley Mayfaire of TransSocial said, "Another Ryan White clinic we called recently told us they don't have a doctor at that location that treats trans patients."[169]

Joey Wynn is Community Relations Director at Empower-U, a federally qualified health center in north Miami. Empower-U is one of the few clinics in Miami that provide gender-affirming care, including hormone replacement therapy, to transgender clients with HIV. According to Wynn, "We serve many transgender clients with HIV and we use Ryan White funds to partially support our HIV services. But state involvement in the quality of care for our trans clients is minimal – it is not something they are following closely."[170]

Three to five clinics offering HIV and HRT services meets the needs of some trans women in Miami and Fort Lauderdale. But the fact that these represent a fraction of the federally and state funded HIV clinics is cause for concern. Consistent with principles of non-discrimination, all Ryan White clinics should accept trans patients.[171] Moreover, more trans-competent providers are needed. Many trans women not connected to referral services may not find these clinics or may face transportation and other barriers to accessing care at these locations. When service is disrupted, as is not uncommon when doctors leave or stop taking new patients, delays and waiting lists can leave women without care. Ashley Mayfaire stated, "Just in the last few months we have had doctors leave two of our clinics that we most often refer people to – we are not sure if or when these will be replaced."[172] Pressure on these few locations is increased by the shortage of gender-affirming health care services elsewhere in the state, which brings trans people from throughout Florida to Miami-Dade and Broward counties for care.[173] "We get calls all the time from all over the state – these clinics are a 'mecca' for trans people who can't find care where they live."[174]

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[168] Human Rights Watch telephone interview with Morgan Mayfaire, Fort Lauderdale, FL, August 13, 2018.

[169] Human Rights Watch telephone interview with Ashley Mayfaire, Fort Lauderdale, FL, October 3, 2018.

[170] HRW email communication with Joey Wynn, August 17, 2018.

[171] Section 1557 of the Affordable Care Act prohibits discrimination on the basis of race, color, national origin, sex, age or disability in programs and activities funded by the US Department of Health and Human Services; HHS.gov, "Section 1557 of the Patient Protection and Affordable Care Act," https://www.hhs.gov/civil-rights/for-individuals/section-1557/index.html (accessed October 3, 2018).

[172] Human Rights Watch telephone interview with Ashley Mayfaire, Fort Lauderdale, FL, October 3, 2018.

[173] Ibid.

[174] Ibid.

According to state HIV officials, much of the problem is a failure of federal Ryan White policy to prioritize transgender care:

> It has been difficult to fund services for the trans community, because many of the services that are needed are not allowable (e.g. surgery) under the Ryan White legislation. Some areas of the state have included HRT (hormone replacement therapy) in their formularies. But other body transformation services (implants, lip enhancements, etc.) cannot be supported by Ryan White funds. Serving the transgender community has been a challenge in many areas and is one of the top issues identified for training and technical assistance for providers throughout the state. This is an issue that the patient care program continues to struggle with, and continuously works to improve on.[175]

State officials are correct in pointing to deficiencies in Ryan White coverage for transgender health issues, as discussed in detail below. But gender-affirming care comprises more than funding for surgeries. Many of its components – staff awareness of trans issues, knowledgeable providers, trans employees and involvement, and other factors that create a safe space – could, and should, be a focus of state HIV policy, planning, and evaluation. As they noted, provider training is of the utmost importance, but eight trainings statewide in 2.5 years does not signal a commitment to ensuring that all trans women are "welcome" at Ryan White facilities and services.

State leadership could also make a huge difference to trans women living with HIV by ensuring that hormone replacement therapy is available through the Ryan White ADAP program.

Cost and Lack of Insurance Coverage for Hormone Replacement Therapy (HRT)

In the insurance-based health care system in the United States, lack of insurance coverage is a major barrier to accessing care. As reflected in the Human Rights Watch survey, many trans people lack insurance altogether. For those who do have insurance, the issue of coverage for transgender people's health care is complex and characterized by harmful gaps in coverage. Claims for care are often denied by both private and public insurers, whether for services and medications related to gender affirmation or for primary care such

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[175] FDOH Responses.

as pap smears, prostate tests, and other procedures not related to transgender identity.[176] Providers bill for services using codes for diagnosis and procedure, and claims denial or delay often originates due to perceived gender incongruity between gender and diagnosis or procedure codes.

For example, pap smears for a patient whose gender is reported as male in the medical record may be automatically denied by the insurer or sent back for clarification.[177] To address chronic denials of care on the basis of gender, legal protections have been established in recent years at the federal level for transgender patients. Most important of these is section 1557 of the Affordable Care Act that prohibits discrimination in both federally funded and private insurance coverage based on factors that include "sex," a category interpreted by the Obama administration to include gender identity.[178] Federal regulations for the Medicare program also explicitly address the issue of gender incongruity denials and provide a special billing code intended to prevent the practice and an appeal process if a claim is erroneously denied.[179] Enforcement and implementation of these protections, however, was incomplete and discrimination in coverage remained widespread, a situation expected to worsen under the Trump administration's plan to abandon gender identity entirely as a protected category under 1557.

In contrast to Medicare, no such protections exist for the Medicaid program, a gap that significantly impacts many trans people living with HIV. Federal Medicaid regulations are silent when it comes to transgender health issues and coverage, leaving coverage determinations for transgender patients to the states and to a "case-by-case basis."[180] Although 18 states and the District of Colombia specifically prohibit discrimination against transgender patients in their Medicaid plans, Florida is not one of them – state Medicaid regulations are silent on the issue. There is no explicit state Medicaid policy that excludes or includes trans health care. This leaves coverage of transition-related care, from HRT to

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[176] National Center for Transgender Equality, "The Stigma and Bias Making Health Insurance Terrible for Trans People," August 13, 2018, https://transequality.org/blog/the-stigma-and-bias-making-health-insurance-terrible-for-trans-people (accessed September 4, 2018); AmfAR Issue Brief, "Trans Populations and HIV: Time to End the Neglect," http://www.amfar.org/uploadedFiles/_amfarorg/Articles/On_The_Hill/2014/IB%20Trans%20Population%20040114%20final.pdf (accessed August 22, 2018); Department of Health and Human Services, healthcare.gov, "Transgender Health Care," https://www.healthcare.gov/transgender-health-care/ (accessed August 31, 2018).

[177] Jordan Aiken, "Promoting an Integrated Approach to Ensuring Access to Gender Incongruent Health Care," *Berkeley Journal of Gender, Law and Justice,* 31(1) 2016, 1-59.

[178] 45 CFR 92, May 18, 2016.

[179] Proctor, K., et al., "Identifying the Transgender Population in the Medicare Program," *Transgender Health,* 1:1, 2016, https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/Identifying-the-Transgender-Population-in-the-Medicare-Program.pdf (accessed September 4, 2018).

[180] Dean Spade, "Medicaid Policy and Gender-Confirming Health Care for Trans People: An Interview with Advocates," *Seattle Journal for Social Justice,* 2:8, 2010.

body transformation surgeries, to be decided by the state Medicaid office on a case by case basis. This lack of policy guidance creates inconsistencies and confusion among both patients and providers regarding coding, billing, and coverage. Advocates have pressed state Medicaid officials and the state Insurance Commissioner for policy guidance but to date have not been successful.[181]

Even when a trans woman finds a doctor to prescribe hormone replacement therapy, cost can be a significant barrier.[182] In the Human Rights Watch survey, 45 percent of those without a doctor identified cost as a barrier to health care and many commented on their inability to afford HRT. As one survey participant commented, "I have no access to hormones, insurance doesn't cover them."[183] Another said, "I am taking pills (hormones) informally – I can't afford them from the doctor and they aren't covered by insurance."[184] Indeed, many trans women turn to the street for hormones due to cost barriers, a practice that carries health risks including lack of dosage monitoring, unknown substances, and the possibility of shared needles for injected hormones.[185]

In their survey responses, some trans women expressed despair about the obstacles faced in obtaining hormone therapy:

> I am afraid because cost is so high; all the girls say it is so expensive. When am I going to be able to see my real self? To be my real self? Very fearful that I will never be able to be my real self because I can't afford it.[186]

Trans patients whose doctors will prescribe hormones often struggle to pay for them. In addition to medication cost, hormone levels must be regularly monitored, and the lab work

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[181] Movement Advancement Project, "Healthcare Laws and Policies," http://www.lgbtmap.org/equality-maps/healthcare_laws_and_policies/medicaid (accessed September 4, 2018); Human Rights Watch email communication with Jen Laws, health policy consultant, Fort Lauderdale, FL, September 10, 2018.

[182] Medications and dosages vary for each patient, but the retail cost of the medications identified as most common for hormone replacement therapy in the report National Association of State and Territorial AIDS Directors, "Issue Brief: ADAP Considerations for Transgender Health," https://www.nastad.org/sites/default/files/Crossroads-Trans-Health.pdf (accessed August 22, 2018), range from 60 to 140 dollars per unit on retail pharmaceutical sales websites such as wwwGoodrx.com and wwwwellrx.com.

[183] Human Rights Watch survey response, Fort Lauderdale, December 11, 2017.

[184] Human Rights Watch survey response, Miami, October 17, 2017.

[185] Denson, D., et al., « Health Care Use and HIV-Related Behaviors of Black and Latina Transgender Women in 3 Metropolitan Areas : Results from the Transgender HIV Behavioral Survey, » *Journal of Acquired Immune Deficiency Syndrome*, 1(75) 2017, Supp. 3, s. 268-275; Sevelius, J., "Gender Affirmation: A Framework for Conceptualizing Risk Behavior Among Transgender Women of Color," *Sex Roles*, 68: July 2013, pp. 675-689.

[186] HRW survey response, Wilton Manors, FL, December 17, 2018.

can cost as much as $250.[187] Even at clinics where hormones were prescribed for trans patients and services were offered on a sliding scale to those who had no insurance, providers described issues with cost for hormone treatment.

Amethyst St. John, director of Behavioral Health at the Empower-U clinic in Miami, said that 90 percent of their transgender patients have the goal of starting hormone replacement therapy. However, according to St. John, lack of insurance coverage for the treatment forces out-of-pocket payments, which few patients can afford. "Without the proper finances in place, or an insurance plan that will adequately cover the cost of this therapy, clients are stalled for months or years waiting to begin hormones."[188]

Dr. Michelle Powell at the AIDS Healthcare Foundation clinic at Mercy Hospital in Miami-Dade County stated, "I will prescribe hormones, but cost is a problem. Medicaid only covers hormones for cisgender people. Ryan White doesn't cover it."[189]

Dr. Maureen Greenwood at the AIDS Healthcare Foundation in the Oakland Park clinic in Broward County said that some hormones are covered by Medicaid and other insurance providers for cisgender patients. "But the same claim will be denied for trans patients, and most of my patients pay for their hormones out of pocket as a result. Once insurance companies find out it is for a transgender person, they won't cover it."[190]

For trans women living with HIV, access to HRT through the Ryan White program would address a primary health care need as well as improve HIV outcomes for a population at high risk. However, the Ryan White program fails to ensure coverage for hormone replacement therapy medications under its AIDS Drug Assistance Program (ADAP). The program, funded under Part B of the Ryan White legislation, is a lifeline for the more than 200,000 Ryan White clients nationwide, including 20,000 in Florida, whose medications are covered by ADAP, either directly or through assistance with insurance premiums or medication costs. Importantly, ADAP covers more than just anti-retroviral medications for people living with HIV. ADAP regulations establish minimum criteria that require state formularies to 1) include at least one medication from each class of anti-retroviral medication, 2) be FDA-approved, 3) be consistent with HHS Adult HIV/AIDS Treatment

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[187] FDOH Responses.

[188] HRW email communication with Amethyst St. John, director of behavioral health, Empower-U, August 17, 2018.

[189] Human Rights Watch interview with Michelle Powell, MD, Coral Gables, FL, November 6, 2017.

[190] Human Rights Watch telephone interview with Maureen Greenwood, DNP, Oakland Park, FL, November 10, 2017.

Guidelines, and 4) be available on an equitable basis to all ADAP clients within the jurisdiction.[191]

Consistent with this criteria, ADAP formularies in all 50 states cover some number of medications in addition to anti-retroviral medications, including drugs for co-occurring infections, anxiety and depression, hepatitis C, and other conditions for patients living with HIV. As stated by the National Association of State and Territorial AIDS Directors (NASTAD), an organization that issues a major annual analysis and evaluation of ADAP programs nationwide, "ADAP's inclusion of treatment medications for co-occurring needs demonstrates a commitment to addressing the full physical and mental health of the clients they serve."[192]

Ryan White program data indicates that approximately 1 percent of ADAP clients are identified as transgender, yet coverage of hormone replacement therapy for trans patients is limited.[193] In an issue brief addressing ADAP policies regarding transgender patients, NASTAD highlighted the importance of adding gender-affirming hormone medications to state ADAP formularies:

> Medication adherence among transgender people is heavily dependent on the availability of gender-affirming health services and continued hormone therapy. Although the extent to which members of the transgender community may avail themselves of various gender-affirming health services changes by the individual's experience, it is integral for ADAPs to assess plans to include coverage of care and treatment for the needs of transgender people.[194]

According to NASTAD, 29 states provide some hormone medications on their formulary, but only 21 states designate those medications for use in gender transitioning, an important distinction in several respects. Florida has a state drug formulary and formularies that apply in its Part A jurisdictions (for urban areas with high HIV prevalence,

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[191] National Association of State and Territorial AIDS Directors, "Issue Brief: ADAP Considerations for Transgender Health," https://www.nastad.org/sites/default/files/Crossroads-Trans-Health.pdf (accessed August 22, 2018).

[192] Ibid.

[193] HRSA, Ryan White HIV/AIDS Program Client Level Data Report 2016, https://hab.hrsa.gov/sites/default/files/hab/data/datareports/RWHAP-annual-client-level-data-report-2016.pdf (accessed August 22, 2018).

[194] National Association of State and Territorial AIDS Directors, "Issue Brief: ADAP Considerations for Transgender Health," https://www.nastad.org/sites/default/files/Crossroads-Trans-Health.pdf (accessed August 22, 2018).

including Miami-Dade and Broward counties). The state and the Part A formularies list some hormone medications, but many of the medications used for gender transition are missing.[195] None of the formularies indicate that these medications are designated for gender transition treatment rather than to address wasting, weight loss, and other conditions in cisgender people resulting from HIV or AIDS. This is an omission that limits awareness on the part of patients and providers that these medications could be covered by ADAP and results in unnecessary denials from insurance companies.[196]

When asked about the failure to include HRT on ADAP formularies, federal officials referred Human Rights Watch to the state ADAP program.[197] The federal regulations do leave to the states discretion to add medications for co-occurring needs – but as NASTAD noted in its brief, HRSA has taken steps to encourage states to add certain medications such as hepatitis C treatment medications, and should do the same for hormone replacement therapies.[198] State officials also disclaimed responsibility, stating that they do not have jurisdiction over Ryan White Part A medication formularies as these formularies are administered by local county government.[199] This is another area where state leadership could establish a clear policy that would improve coverage and awareness of a vital component of HIV care for trans women in Florida.

Trans Women Face Barriers to Key HIV Prevention Medication

Pre-exposure prophylaxis (PrEP) is a combination of two medicines (tenofovir and emtricitabine) in one pill that, if taken every day, has demonstrated significant results in HIV prevention for people who are HIV-negative. This key biomedical intervention has been shown to reduce the risk of getting HIV from sex by as much as 90 percent. If combined with other prevention methods such as condoms, the risk of acquiring HIV can be even lower.[200] Federal agencies tasked with reducing new HIV infections have made increased awareness of and access to PrEP a top priority. The CDC, HRSA, SAMHSA, and other agencies have called for a 500 percent increase in access to PrEP by 2020. A framework

[195] National Association of State and Territorial AIDS Directors, "Issue Brief: ADAP Considerations for Transgender Health," https://www.nastad.org/sites/default/files/Crossroads-Trans-Health.pdf (accessed August 22, 2018); Human Rights Watch email communication with Madeline Deutsch, MD, May 28, 2017.

[196] Human Rights Watch telephone interview with Madeline Deutsch, MD, San Francisco, CA, May 17, 2018; Human Rights Watch email communication with Brittany Pund, NASTAD, May 31, 2018.

[197] Human Rights Watch email communication with Jennifer Moore, HRSA, Washington DC, June 28, 2018.

[198] National Association of State and Territorial AIDS Directors, "Issue Brief: ADAP Considerations for Transgender Health," https://www.nastad.org/sites/default/files/Crossroads-Trans-Health.pdf (accessed August 22, 2018).

[199] FDOH Responses.

[200] US Department of Health and Human Services, HIV.gov, "Pre-exposure Prophylaxis," https://www.hiv.gov/hiv-basics/hiv-prevention/using-hiv-medication-to-reduce-risk/pre-exposure-prophylaxis (accessed September 4, 2018).

document outlines a broad array of federal initiatives intended to raise awareness, provide technical assistance and training for medical personnel and fund community-based and public health departments to provide PrEP to groups at high risk of HIV.[201]

Trans women are one of the groups at highest risk for HIV in the US. Yet attention to transgender people in both research and distribution of PrEP has been limited and taken a back seat to a focus on men who have sex with men (MSM). The first clinical trial of PrEP, published in 2010, included both MSM and trans women and was the only study with confirmed enrollment of trans women; other clinical trials for MSM are open to trans women but enrollment levels are unclear.[202] Overall, the study showed 44 percent decrease in risk of HIV acquisition, but no decrease among trans women.[203] The failure of the first PrEP study to show a decrease in risk for trans women has been attributed primarily to lack of adherence to the daily medication regimen; negative interaction of PrEP with hormone medications was not observed but requires further study.[204]

Federally funded projects that distribute PrEP through community organizations and public health entities also show very low participation of trans women.[205] The first CDC guidelines for prescription of PrEP by medical providers, issued in 2014, did not mention transgender women at all; the updated guidelines, issued in 2017, note lack of research into efficacy of PrEP for trans women but recommend that they be included in consideration for PrEP as a group at high risk of HIV from sexual transmission.[206] In 2015, CDC published a report finding that PrEP would be an indicated prevention for 1.2 million people at high risk for HIV, but this report addressed only MSM, cisgender heterosexual women and people who inject drugs, failing to make any mention of transgender people.[207]

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[201] US Department of Health and Human Services, "HIV PrEP Framework Federal Activities," https://files.hiv.gov/s3fs-public/PrEP-framework.pdf (accessed September 5, 2018).

[202] Sevelius, J., et al., "The Future of PrEP Among Transgender Women: The Critical Role of Gender Affirmation in Research and Clinical Practices," *Journal of the International AIDS Society*, 197 (6) 2016.

[203] Deutsch, MB et al., "HIV Pre-exposure Prophylaxis in Transgender Women: A Sub-Group Analysis of the iPrEx Trial," *Lancet HIV,* 2(12) 2015, e512-9.

[204] Sevelius, J., et al., "The Future of PrEP Among Transgender Women: The Critical Role of Gender Affirmation in Research and Clinical Practices," *Journal of the International AIDS Society*, 197 (6) 2016.

[205] Ibid.

[206] US Public Health Service, Preexposure Prophylaxis for the Prevention of HIV Infection in the United States 2014: A Clinical Practice Guideline, https://www.cdc.gov/hiv/pdf/guidelines/PrEPguidelines2014.pdf (accessed September 5, 2018); US Public Health Service, Preexposure Prophylaxis for the Prevention of HIV Infection in the United States 2017: A Clinical Practice Guideline, https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2017.pdf (accessed September 5, 2018).

[207] CDC, Weekly Morbidity and Mortality Report, "Vital Signs: Estimated Percentages and Numbers of Adults with Indications for Preexposure Prophylaxis to Prevent HIV Acquisition- United States, 2015," November 27, 2015. https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6446a4.htm (accessed September 5, 2018).

PrEP has tremendous potential to make a difference in lowering new HIV infections for trans women. In a 2016 study in San Francisco, knowledge of PrEP was low but once introduced to it, interest among trans women was strong.[208] But trans health experts emphasize that PrEP implementation guidelines must consider and address trans women's unique barriers and facilitators to uptake and adherence. On the ground, integration of PrEP distribution with gender-affirming health care is fundamental to successful uptake of PrEP among trans women. One trans health expert put it bluntly:

> Gender-affirming providers and clinic environments are essential components of any sexual health programme that aims to serve trans women, as they will largely avoid settings that may result in stigmatizing encounters and threats to their identities.[209]

Race is another barrier to PrEP access and represents another burden for trans women of color seeking to access PrEP.

Federal efforts to increase access to PrEP have been incomplete and problematic even for the groups it prioritizes, with evidence of wide racial disparities in coverage for MSM, heterosexual women and people who inject drugs. According to the CDC, of the estimated 1.2 million people who are in need of PrEP, 69 percent are people of color; 44 percent are Black and 25 percent, Hispanic. However, only one percent of Black people who need it are on PrEP, creating what CDC has called "an urgent" need to increase PrEP coverage for this population, noting that most Black people who are in need of PrEP, but not taking it, live in the US South.[210]

HRW survey results in south Florida indicate that awareness of PrEP was high among participants – 82 percent of survey participants indicated that they were familiar with PrEP. But few women were taking PrEP: of those who were HIV-negative, only ten percent were on PrEP, with 62 percent of participants indicating they "didn't need it" and 19 percent (nearly one of four) stating they "did not know enough about it" to take it. Other reasons given for not taking PrEP included cost issues, too much stigma, and mistrust, with one woman

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[208] Sevelius, J., et al., "I Am Not a Man: Trans-specific Barriers and Facilitators to PrEP Acceptability Among Transgender Women," *Global Public Health*, 11 (7-8) 2016, 1060-75.

[209] Sevelius, J., et al., "The Future of PrEP Among Transgender Women: The Critical Role of Gender Affirmation in Research and Clinical Practices," *Journal of the International AIDS Society*, 197 (6) 2016.

[210] Conference on Retroviruses and Opportunistic Infections 2018, Updates on PrEP, http://www.natap.org/2018/CROI/croi_188.htm (accessed September 5, 2018). These studies utilized the term Black in discussion racial categories.

stating, "I don't want to be part of an experiment."[211] Need for PrEP, however, was demonstrated; of survey participants who were HIV negative and not taking PrEP, 38 percent said they have exchanged sex for money, drugs, or life necessities in the last year.

In 2016, Florida began a campaign to increase access to PrEP as part of a plan to reduce new HIV infections. The State Surgeon General issued a mandate that by the end of 2018, PrEP should be available at no cost in each of the 67 county health departments. As part of this campaign the state made efforts to increase education and infrastructure to distribute PrEP, compiled a resource guide and directory for sites that offer PrEP statewide, made PrEP available through the central pharmacy system that serves state Medicaid and Medicare patients, and launched targeted social media campaigns aimed at increasing PrEP awareness among minority populations.[212] A series of intensive PrEP training courses were presented in partnership with the University of California at San Francisco (UCSF) and other organizations throughout 2018 with the goal of reaching every county health department as well as providers and interested community organizations in that area.[213] According to Dr. Jonathan Fuchs of USCF, Florida's effort to make PrEP available in all county health departments is broader and more ambitious than in any other state, and the commitment from Florida Department of Health has been exemplary. Fuchs described the training curriculum as including substantive components on the experience of transgender women and the issues they may face in relation to PrEP.[214]

The campaign, supported primarily with state funds, has already achieved significant results. As of May 2018, 37 of 67 county health departments, including Miami-Dade and Broward counties, were implementing a PrEP distribution program. Between July 2017 and April 2018, the number of PrEP clients served by county health departments has increased from 18 to 632.[215]

The state provided no data on how many trans women were enrolled in these programs, however. Both Miami-Dade and Broward county health departments have created PrEP programs as part of this statewide campaign, but transgender participation in both of these programs remains low.[216] In Miami-Dade County, Dr. Susanne Doblecki-Lewis is one of the medical advisors to the county PrEP program. Dr. Doblecki-Lewis said that the PrEP

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[211] Human Rights Watch interview with Ellen D., Wilton Manors, FL, December 11, 2017.

[212] FDOH Responses.

[213] Ibid.

[214] Human Rights Watch telephone interview with Jonathan Fuchs, MD-MPH, San Francisco, CA, July 25, 2018.

[215] FDOH Responses.

[216] FDOH Responses; Human Rights Watch interview with Susanne Doblecki-Lewis, MD, Miami, FL, February 7, 2018; Human Rights Watch telephone interview with Regina Gerbier, Fort Lauderdale, FL, August 2, 2018.

clinic at the department of health does not have many trans women clients. She attributed this to many factors, including the cost of PrEP and mistrust of a health department setting. "Health departments may not provide the most comfortable environment for trans women."[217]

The Miami-Dade program has made efforts to increase the participation of trans women, specifically by engaging a local and trusted community organization that provides a variety of services to trans women to encourage referrals to the county program. According to state HIV officials, the involvement of Survivor's Pathway, which is located near to the department of health PrEP clinic, has increased trans women's engagement, though no data was provided regarding trans participation in the program.[218]

In Broward County, the department of health PrEP program hired Regina Gerbier, a trans woman, to act as Coordinator of Transgender Programs for the HIV Prevention unit. According to Ross, trans women's participation in the PrEP program remains low, again as a result of numerous factors including reluctance to engage with a county health department, low knowledge of PrEP, lack of "readiness" for PrEP and cost barriers. According to Gerbier:

> PrEP is not a pill, it is a program. It requires someone to see a doctor every three months to get labwork. This is a commitment, and it is expensive if you don't have insurance.[219]

Cost is a major barrier to PrEP roll out nationwide, as a one month course of PrEP can cost up to $2000 per month for the uninsured.[220] The Ryan White and ADAP programs do not cover it as they serve people already living with HIV. Primary sources of funding for the medication are limited to donations from the manufacturer and as in the case of Florida, states themselves. Gilead Pharmaceuticals, the manufacturer of Truvada, will subsidize PrEP coverage for six months for those who meet low income requirements, but one must re-apply every six months. "Even for trans women who do want to take PrEP, paying for it is still a problem. I spend a lot of my time trying to help women find a place they can get it paid for," said Gerbier.[221]

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[217] Human Rights Watch interview with Susanne Doblecki-Lewis MD, Miami, FL, February 7, 2018.
[218] FDOH Responses.
[219] Human Rights Watch telephone interview with Regina Gerbier, Fort Lauderdale, FL, April 25, 2018.
[220] George Citroner, "Cost of HIV Prevention Drug Discouraging People from Doing PrEP Therapy," Healthline, July 11, 2018, (accessed October 3, 2018).
[221] Ibid.

Insurance coverage, including Medicaid, has been found to significantly increase PrEP participation and adherence.[222] Medicaid covers PrEP, but in states like Florida that have not expanded Medicaid, access remains limited for low income people. Dr. Doblecki-Lewis has conducted numerous clinical trials involving PrEP accessibility and found lack of insurance coverage in Florida contributes to lower PrEP adherence compared to that in other locations. Dr. Doblecki-Lewis stated, "In Florida, Medicaid expansion would make a huge difference to PrEP access-given their socio-economic status, it would be very important for trans women."[223] For trans women, availability of Medicaid would alleviate some of the cost concerns as well as provide options for finding PrEP outside of county health departments, sites where they may not feel safe or comfortable.

In Broward County, PrEP availability for trans women has begun to improve, according to Misty Eyez who provides many referrals for trans women to HIV prevention and care services through Sunserve. In the spring and summer of 2018, two health clinics began to offer PrEP to people without insurance, and most importantly, they also offer hormone replacement therapy at no or low cost to PrEP patients who are transitioning. Eyez stated, "This is the model that works for trans women. If they can get their hormones at the same time, they are much more likely to go. However, some of these clinics already have waiting lists, creating long waits for an appointment.[224]

In June 2018, Broward County Health Department took steps to address cost issues by establishing a PrEP partnership with the AIDS Healthcare Foundation (AHF) in Fort Lauderdale. AHF will provide patients with an immediate supply of PrEP medication as well as cover the cost for doctor visits and labwork. The ability of Broward County to refer clients to a no-cost clinic has significantly increased participation in the PrEP program – between June and August 2018 more than 300 patients enrolled in the program, more than during the entire previous year before the no-cost option became available. Participation by trans women, however, remains low – only a handful of these new AHF patients are trans women.[225] AHF does not provide hormone replacement therapy as part of the PrEP program, and Gerbier heard feedback that some trans women had bad experiences there in the past. Gerbier hopes to address these issues in the coming months, including by

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[222] Patel, R., et al., "Impact of Insurance Coverage on Utilization of Pre-Exposure Prophylaxis for HIV Prevention", PLOS One, May 30, 2017, http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0178737 (accessed September 7, 2018); CDC, Weekly Morbidity and Mortality Report, November 27, 2015, "Vital Signs: Increased Medicaid Prescriptions for Pre-Exposure Prophylaxis Against HIV Infection- New York 2012-2015," https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6446a5.htm?s_cid=mm6446a5_w (accessed September 7, 2018).

[223] Human Rights Watch interview with Susanne Doblecki-Lewis MD, Miami, FL, February 7, 2018.

[224] Human Rights Watch telephone interview with Misty Eyez, Fort Lauderdale, FL, July 25, 2018.

[225] Human Rights Watch telephone interview with Regina Gerbier, Fort Lauderdale, FL, August 2, 2018.

launching a social media campaign to make sure than trans women know about the new program and provide reassurance that it is trans-friendly.[226]

Latina Trans Women and HIV

Latina trans women share many of the social determinants of health with Black trans women that place both groups at higher risk for HIV than their white counterparts, including higher rates of poverty, lack of insurance, pervasive intersectional discrimination, unemployment and involvement in the criminal justice system.[227] However, Latina trans women often face unique circumstances that impact access to health care and increase HIV risk. Chief among these are language barriers, lack of awareness of social services and, for undocumented immigrants, avoidance of health care services due to fear of deportation.[228] Each of these factors impact HIV risk for Latina trans women in Florida, a highly diverse state where three-quarters of immigrants originate from Mexico, Central America and the Caribbean.[229]

HIV disparities are significant among Latinx people; despite comprising 18 percent of the US population, Latinx people represent one quarter of those living with HIV.[230] New HIV infections continue to increase among young Latino men who have sex with men, a category that often incorrectly includes trans women. Latinx people are more likely to delay HIV testing, to receive an AIDS-related diagnosis once tested, and to die within one year of HIV diagnosis than non-Latinx African-Americans or white populations.[231]

In the Human Rights Watch survey, Latina trans women comprised 41 percent of participants. Survey results indicated that Latina trans women surveyed were more

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[226] Ibid.

[227] Denson, D., et al., "Health Care Use and HIV-Related Behaviors of Black and Latina Transgender Women in 3 Metropolitan Areas : Results from the Transgender HIV Behavioral Survey," *Journal of Acquired Immune Deficiency Syndrome*, 1(75) 2017, Supp. 3, s. 268-275.

[228] MM Morales-Aleman and MY Sutton, "Hispanics/Latinos and the HIV Continuum of Care in the Southern USA: A Qualitative Review of the Literature, 2002-2013," *AIDS Care*, 26(12) 2014, pp. 1592-604.

[229] Lopez-Quintero C., et al., "HIV Testing Practices Among Latina Women at Risk of Getting Infected: A Five Year Follow Up of a Community Sample in South Florida," *AIDS Care*, 28(2) 2016 137-146; Migration Policy Institute, "Florida: Demographics and Social," https://www.migrationpolicy.org/data/state-profiles/state/demographics/FL (accessed September 13, 2018); Florida Department of Health, "State of Florida Integrated HIV Prevention and Care Plan 2017-21."

[230] Latinx is a term intended to encompass people of Latin origin across the spectrum of gender identities. CDC, "HIV and Hispanics," https://www.cdc.gov/hiv/group/racialethnic/hispaniclatinos/index.html (accessed September 7, 2018).

[231] Lopez-Quintero C., et al., "HIV Testing Practices Among Latina Women at Risk of Getting Infected: A Five Year Follow Up of a Community Sample in South Florida," *AIDS Care*, 28(2) 2016 137-146.

likely to be HIV-positive than non-Latina respondents, but if HIV-negative, were more likely to be on PrEP. They were insured at the same rate—45 percent—as non-Latina participants, but were more likely to be unemployed, more likely to have engaged in sex work, and more likely to have been arrested.

Francesco Duberli is Executive Director of Survivors' Pathway in Miami, an organization providing social, psychological, legal and other support services to the LGBT and Latinx communities. According to Duberli, "Trans Latina women are under many pressures and for most of them HIV is not their primary concern even though they are at risk. Immigration issues, poverty, domestic violence, and human trafficking are all common stressors for our clients."[232]

Survivors' Pathway in Miami-Dade County and Arianna's Center in Broward County work closely with the Florida Department of Health to provide HIV testing and linkage to PrEP, programs that are helping to address HIV risk in the Latinx trans community and should be expanded.

Lack of Data Impedes Government Response

For trans women living with HIV, the legal and policy environment is worsening, but has long been characterized by government neglect. The clearest example of this is the failure for decades of federal and state governments to collect accurate data related to HIV infection among the transgender population. Accurate data collection on HIV among specific populations is vitally important to developing effective government funding and support for prevention, treatment and services related to HIV. As stated by one evaluator of the federal HIV data collection system, this information is used for "allocation of funding, program evaluation, and as a driver for public health action."[233]

Since 1981, the federal Centers for Disease Control (CDC) has collected data on a multitude of aspects of the HIV epidemic including incidence (new infections occurring), prevalence (how many people are living with HIV), modes of transmission, deaths from AIDS and other categories. There are numerous sources for this information: the National HIV Surveillance System (NHSS) is the primary source, supplemented by other programs such as the Medical Monitoring Project (funded in approximately 30 states to collect data on people

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[232] Human Rights Watch interview with Francesco Duberli, Miami, FL, July 11, 2017.

[233] Karch, D., et al., "Evaluation of the National Human Immunodeficiency Virus Surveillance System for the 2011 Diagnosis Year," *Journal of Public Health Management and Practice*, 20(6) 2014, pp.598-607.

living with HIV who are in care) and the Behavioral HIV Surveillance System that gathers information on specific populations at risk for HIV such as people who inject drugs and men having sex with men.[234]

All states and territories require HIV diagnoses to be reported to the local health departments and this information is then provided to the state.[235] States receive HIV-related information from a variety of sources – clinical reports, lab tests, death certificates, and other documents. This information is transferred into a standardized database called eHARS (electronic HIV/AIDS reporting system), available to all states for the purpose of reporting this information to the CDC.[236]

For many decades, transgender people were invisible to the national and local HIV surveillance system; to the extent that data was collected for transgender women, they were incorrectly grouped into the category of "men who have sex with men." It was not until 2009 that states had the option to submit "current gender identity" as well as "male" and "female" into eHARS. In 2011, the CDC reporting forms used to transfer information into eHARS were revised and eHARS fields were updated to reflect current gender identity as well as sex assigned at birth. In 2012, the CDC issued its first guidance document to states regarding this two-step process for more accurate collection of data regarding transgender persons and this guidance was updated in 2015.[237] The guidance emphasized the importance of utilizing numerous sources for identification of transgender people among those reported to be living with HIV; for example, state surveillance staff should attempt to flag discrepancies between the sex assigned at birth on a birth certificate and the information recorded on the standardized reporting form in order to make an accurate input of gender identity into eHARS.[238]

However, state implementation of these optional guidelines varies widely; 26 states provide no publicly available surveillance data relating to HIV among transgender people. Numbers that do exist are likely to be grossly underestimated. A 2015 analysis of national surveillance HIV data for transgender persons during the years 2009-2014 found that, "Diagnosed HIV among transgender populations may be vastly underestimated or

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[234] Human Rights Watch telephone interview with Angela Hernandez, CDC, Chief of HIV Incidence and Case Surveillance Branch, Atlanta, GA, December 7, 2017.

[235] CDC, Weekly Morbidity and Mortality Report, July 21, 1989, https://www.cdc.gov/mmwr/preview/mmwrhtml/00001425.htm (accessed September 7, 2018).

[236] Karch, D., et al., "Evaluation of the National Human Immunodeficiency Virus Surveillance System for the 2011 Diagnosis Year," *Journal of Public Health Management and Practice*, 20(6) 2014, pp.598-607.

[237] CDC, "Guidance for HIV Surveillance Programs: Working with Transgender Specific Data" Version 2.0, 2015.

[238] Ibid.

misclassified due to data collection challenges for jurisdictions, including correctly identifying current gender identity from documentation in medical records and other data sources."[239]

The absence of data related to HIV among transgender people is a nationwide problem, not limited to the state of Florida. The CDC has stated that, "Because there is no reliable system for collecting and sharing sex and gender identity information in health records, our nation currently lacks reliable HIV surveillance data for transgender populations."[240] Largely ignored as an issue for decades, the National HIV/AIDS Strategy Updated for 2020 acknowledges that transgender HIV data is so scarce that the federal government has no way to systematically evaluate the collection process or the data itself, and recommends that such an "indicator" be developed.[241] Collecting data and developing such an indicator are essential first steps, but without more urgent and coordinated attention from federal policymakers it is a goal that will remain out of reach, leaving transgender women at a huge disadvantage in funding, programming and support for HIV prevention and care.[242]

Incomplete Data Collection in Florida

A key factor hindering Florida from implementing an effective HIV policy for trans women is lack of accurate and complete data. Without knowing how many trans women are living with HIV, where they are located and to what extent current programs are effectively serving trans women and identifying unmet need, Florida trans women will continue to navigate a fragmented and inadequate health care system for both HIV prevention and treatment.

Florida officials have emphasized that accurate data and surveillance information is key to the state's HIV response:

> The Department of Health, Bureau of Communicable Diseases, HIV/AIDS Section collects, analyzes and disseminates surveillance data on HIV infection. These surveillance data are one of the primary sources of information on HIV and AIDS in Florida. For instance, HIV and AIDS

[239] Clark, H., et al., "Diagnosed HIV Infection in Transgender Adults and Adolescents: Results from the National HIV Surveillance System 2009-2014," *AIDS and Behavior*, 21 (9), September 2017, pp. 2774-83.

[240] CDC Issue Brief, "HIV and Transgender Communities," https://www.cdc.gov/hiv/pdf/policies/cdc-hiv-transgender-brief.pdf (accessed September 7, 2018).

[241] US Office of National HIV/AIDS Strategy, "National HIV/AIDS Strategy for the United States, Updated to 2020," https://files.hiv.gov/s3fs-public/nhas-update.pdf (accessed August 22, 2018).

[242] Ibid.

> surveillance data are used by the Department's public health partners in local health departments, federal agencies, non-profit organizations, academic institutions, and the general public to help focus prevention efforts, plan services, allocate resources, and monitor trends in HIV infection.[243]

According to the Williams Institute, an estimated 100,000 transgender people reside in the state of Florida, largely located in Broward, Miami-Dade, Orange, Pinellas and Hillsborough counties. The Williams Institute estimate indicates that 50 percent of trans people in Florida are white; 26 percent are Hispanic or Latino; 19 percent are Black, non-Hispanic and four percent fall into other racial or ethnic categories.[244] Yet transgender people are largely invisible in Florida state HIV surveillance data. In the most recent report publicly available, "The State of the HIV Epidemic in Florida 2017," genders are limited to "male" and "female" for every component of the epidemic that is addressed in the report.[245]

The 2017 surveillance data does include one slide referencing transgender persons and HIV (see Table I)[246]:

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[243] Florida Department of Health, "State of Florida Integrated HIV Prevention and Care Plan 2017-21."

[244] UCLA School of Law, Williams Institute, "How Many Adults Identify as Transgender in the United States?" https://williamsinstitute.law.ucla.edu/wp-content/uploads/How-Many-Adults-Identify-as-Transgender-in-the-United-States.pdf (accessed September 7, 2018).

[245] Florida Department of Health, HIV/AIDS Section, "State of the HIV Epidemic in Florida 2017," on file with Human Rights Watch.

[246] Ibid, slide 53. Human Rights Watch does not consider people aged 13-17 to be adults, but they are so counted in national and state HIV surveillance data.

Table I. Transgender Adults (Age 13+) Living with HIV, Year-end 2017, Florida

Race/Ethnicity	Transgender Men (Number)	Transgender Men (Percent)	Transgender Women (Number)	Transgender Women (Percent)
White	4	40%	54	18%
Black	4	40%	150	50%
Hispanic	2	20%	86	29%
Other	0	0%	10	3%
Age Group				
13 – 19	0	0%	2	1%
20 – 29	6	60%	73	24%
30 – 39	1	10%	111	37%
40 – 49	1	10%	54	18%
50 +	2	20%	60	20%
Mode of Exposure				
Sexual Transmission	9	90%	267	89%
IDU	0	0%	0	0%
Sexual Transmission/IDU	--	--	33	11%
Other Risk	1	10%	0	0%
TOTAL	10	100%	300	100%

Limitations: Transgender data were not aggressively collected or recorded until 2013 therefore numbers may be underrepresented.

According to this slide, there were 310 transgender people living with HIV in the state of Florida in 2017. The text at the bottom acknowledges the limitations of the information presented, both in gender identification and modes of transmission. State HIV officials told Human Rights Watch that their data on HIV among transgender persons is likely to be underestimated.[247] Also, this number is significantly lower than that shown in the Ryan White program report issued by HRSA showing 355 transgender clients enrolled in the Florida Ryan White program in 2016.[248]

The state data sets can only be as accurate as the information relied upon. As noted above, the CDC's primary form for reporting HIV cases, the Adult Case Reporting Form (ACRF) has included a two-step gender identification question since 2013. But according to state officials, most information received is from providers and laboratories who may not provide accurate information on current gender identity.[249]

[247] FDOH Responses.

[248] Health Resources and Services Administration, "Ryan White HIV/AIDS Program Annual Client-Level Data Report 2016," https://hab.hrsa.gov/sites/default/files/hab/data/datareports/RWHAP-annual-client-level-data-report-2016.pdf (accessed September 7, 2018).

[249] FDOH Responses.

The state does monthly reviews of data in the eHARS system to identify discrepancies in gender reporting such as birth certificates that do not match the gender in medical records. But if medical providers, HIV testing and counseling sites, and other sources do not report accurately, gaps in eHARS will remain. Also, the state does not yet match the eHARS data with that from other databases such as the Ryan White system that uses a two-step gender process for patients, or ADAP records, other state electronic health records and other sources. According to state officials, these cross-database matches are planned but the timeline is unclear.[250]

In the meantime, the state's information regarding HIV among trans people is incomplete and not reliable. For example, the state's transgender data slide fails to accurately record how people acquired HIV. For 87 percent of male to female transgender individuals, the mode of exposure listed is "men having sex with men," and the slide indicates that mode of exposure is categorized by sex assigned at birth. In order to distinguish modes of exposure for trans women from men who have sex with men, the CDC Guidance document for working with transgender data states that "transmission categories correspond to a person's sex assigned at birth and therefore may not accurately describe the mode of transmission for a transgender person with diagnosed HIV infection." The Guidance recommends that states consider using alternative categories such as "sexual transmission" instead of "male to male sexual contact" or "heterosexual contact."[251] Ryan White providers are utilizing this category; the 2016 Ryan White report indicates "sexual contact" as the mode of transmission for 97 percent of transgender Ryan White clients in Florida, but the state has not yet matched its eHARS database to the Ryan White data to capture this information.[252]

Perhaps most important is state surveillance data indicating health outcomes for trans people with HIV. Nationally and statewide, public health decisions are made based upon HIV surveillance data known as the "continuum of care" — a chart that shows how many people diagnosed with HIV are in medical care, stay in medical care, and become virally suppressed. Continuum of care data are typically shown in the aggregate as well as broken down by race, gender, age and mode of transmission. The most recent continuum of care for the state of Florida shows that statewide, 93 percent of people diagnosed with HIV were in care at one time, 68 percent have been retained in care, and 62 percent are virally

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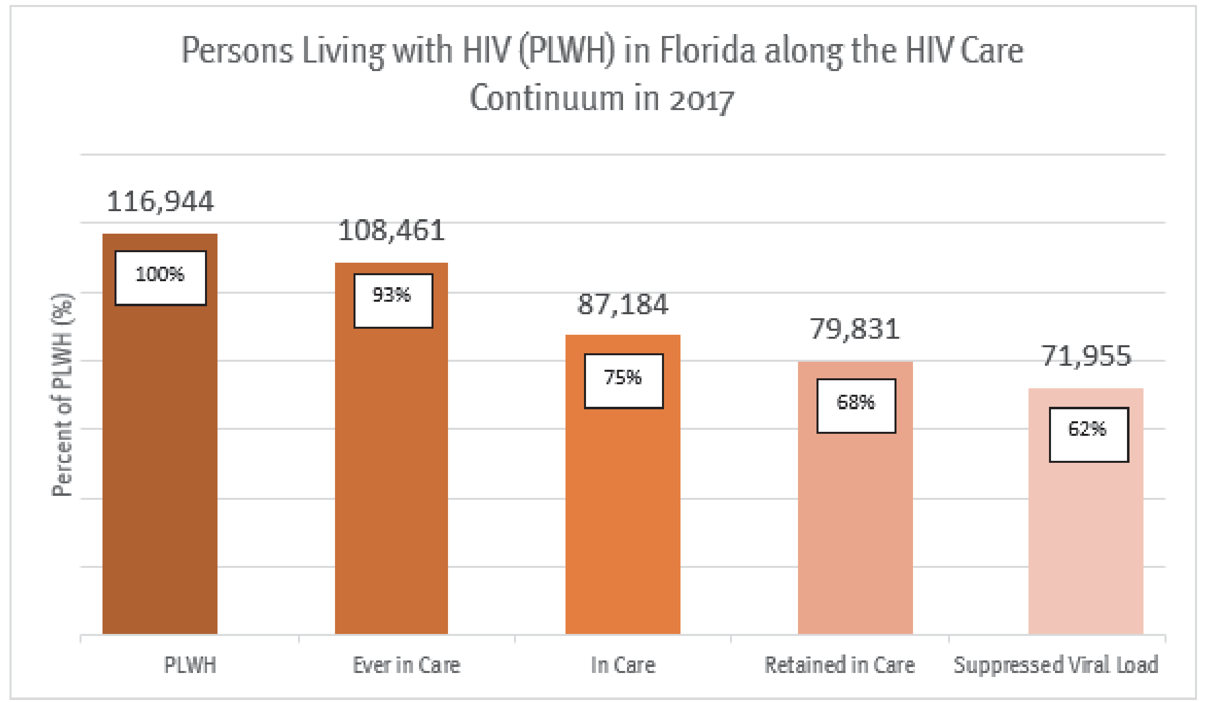
[250] Ibid.

[251] CDC, "Guidance for HIV Surveillance Programs: Working with Transgender Specific Data," Version 2.0, 2015.

[252] Health Resources and Services Administration, "Ryan White HIV/AIDS Program Annual Client-Level Data Report 2016," https://hab.hrsa.gov/sites/default/files/hab/data/datareports/RWHAP-annual-client-level-data-report-2016.pdf (accessed September 7, 2018).

Graph IV.



suppressed (see Graph IV).[253] In 2016, of people living with HIV who are out of care, 73 percent were identified as male, and 27 percent as female; 40 percent were Black, 26 percent were White, and 23 percent were Hispanic.[254]

Continuum of care data for trans women is important as they are a population that is likely to be lost to follow up. Given their difficulty in accessing health care, their frequent failure to return to care after a bad health care experience, and lower rates of adherence to HIV medications than other groups, trans women are at high risk of falling out of HIV care and not achieving viral suppression.[255] Outcomes are likely to be particularly poor for African-American trans women; in Florida, African-Americans are less likely than either whites or

[253] Florida Department of Health, HIV/AIDS Section, "State of the HIV Epidemic in Florida 2017," on file with Human Rights Watch. This document indicates that "in care" is defined as a person living with HIV who had lab work, medical visit or a prescription since diagnosis; "retained in care" is defined as two instances of lab work, a medical visit or a prescription at least 3 months apart in the previous 15-month period.

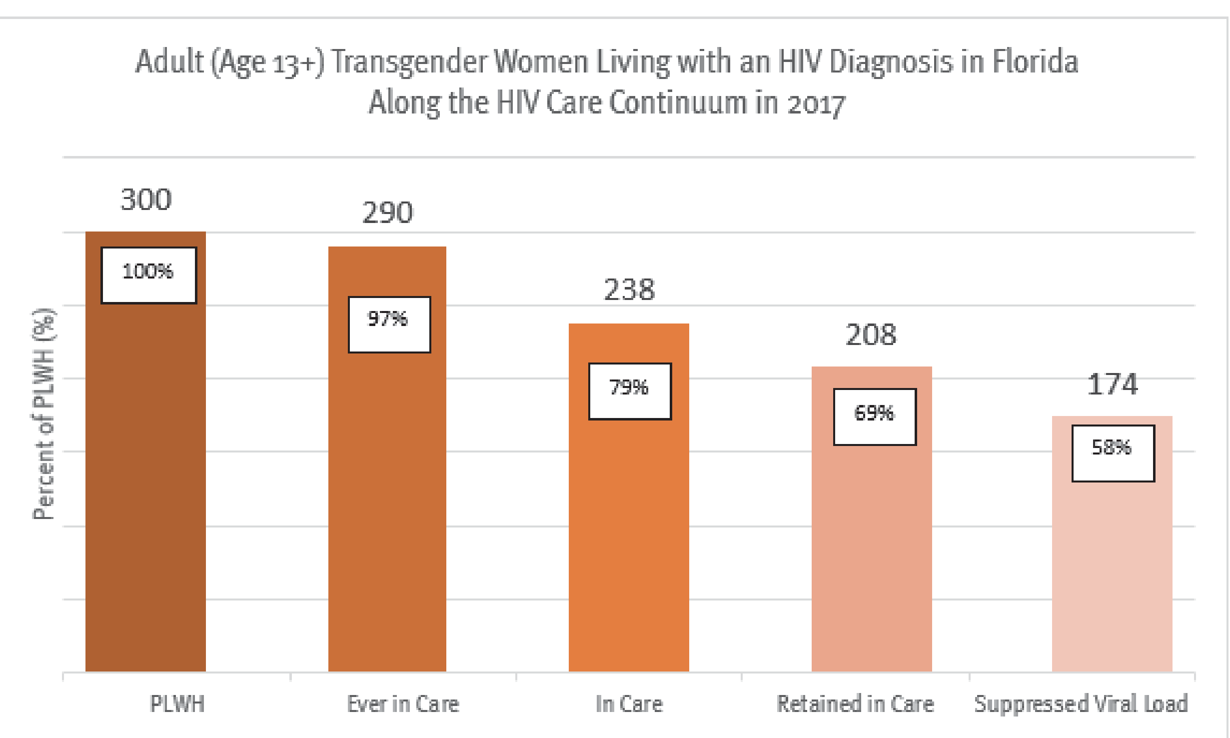
[254] Florida Department of Health, "Persons Living with HIV Out of Care in Florida, 2018" on file with Human Rights Watch.

[255] Sevelius, J., et al., "Antiretroviral Therapy Adherence Among Transgender Women Living With HIV," *Journal of Association of Nurses in AIDS Care*, 21(3) May-June 2010, 256-64.

Hispanics to be linked to care, to stay in care, and to achieve viral suppression.[256] Lack of accurate transgender data hinders the state's ability to address these issues among trans women of color.

In 2017, the state reported that of the 300 transgender women living with HIV in the state of Florida, 79 percent were in care at one time, 69 percent were retained in care and 58 percent had achieved viral suppression or an "undetectable" viral load.[257] In 2016, the most recent data available show that in Miami-Dade County, there are 53 trans women identified as living with HIV; 70 percent are said to be in care, and 66 percent have achieved viral suppression. In Broward County, 43 trans women are identified as living with HIV; 72 percent are retained in care however, viral suppression is only 47% (see Graphs V[258], VI[259], VII[260]).

Graph V.



Transgender women are defined as those whose birth sex is male but who live and identify as female.

[256] Florida Department of Health, HIV/AIDS Section, "State of the HIV Epidemic in Florida 2017," on file with Human Rights Watch.

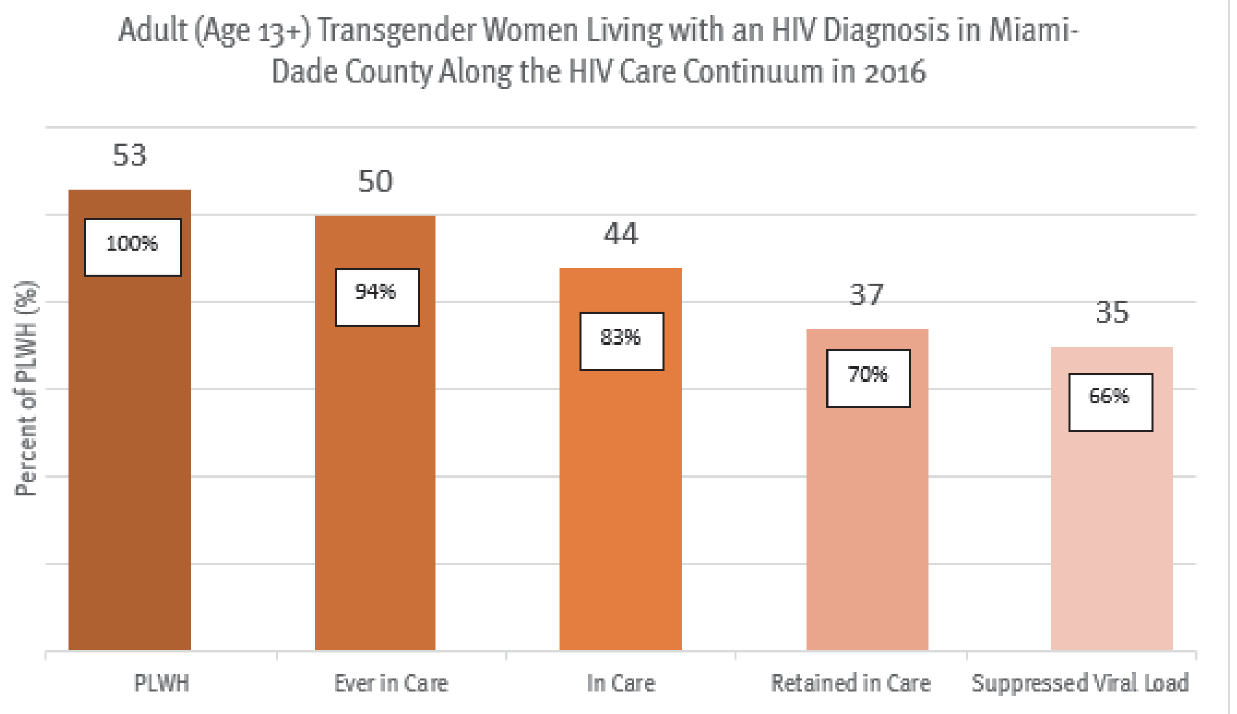
[257] Ibid.

[258] FDOH Responses.

[259] FDOH Responses.

[260] FDOH Responses.

Graph VI.



Transgender women are defined as those whose birth sex is male but who live and identify as female.

Given the limitations on data collection for trans individuals in Florida, the numbers of trans women living with HIV are likely to be significantly underestimated. This data shows that high numbers of trans women are initially engaging in care, but significantly fewer women remaining in treatment and achieving viral suppression. This reflects the larger problem of retention in care that is occurring at the state and national levels for people living with HIV. However, Florida may be missing opportunities to obtain valuable information to supplement their surveillance data to learn more about why trans women may be lost to care.

For example, Florida has a specific program dedicated to identifying people who have been diagnosed with HIV but fallen out of care. The "Data to Care" Program is a federally funded initiative for states to use multiple data sources to identify, contact and support persons with an HIV diagnosis who are not in care. In 2017, 20 percent of people identified in Florida through this program were connected to medical care. The state tracked the percentage of males and females in the program and showed that those most likely to drop out of care are Black men, but there is no data on transgender clients.[261] State HIV officials

[261] FDOH Responses.

Graph VII. Transgender HIV Data Provided to Human Rights Watch from Florida Department of Health

Adult (Age 13+) Transgender Women Living with an HIV Diagnosis in Broward County Along the HIV Care Continuum in 2016

	PLWH	Ever in Care	In Care	Retained in Care	Suppressed Viral Load
Number	43	39	35	31	20
Percent of PLWH (%)	100%	91%	81%	72%	47%

Transgender women are defined as those whose birth sex is male but who live and identify as female.

told Human Rights Watch that any transgender persons identified as out of care or never linked to care would be "added automatically to our Data To Care lists for linkage/ re-engagement" and that "as we work to improve and automate the D2C process, we constantly evaluate priority populations including Transgender persons who need linkage/re-engagement services."[262] Yet the state provided no information about how many transgender people had been identified as out of care as part of the Data To Care program or the results of any evaluations conducted.

Another missed opportunity occurred in a retention in care study in Miami. In 2017, the Miami-Dade County Department of Health, concerned about high rates of people dropping out of Ryan White programs, undertook a study to examine retention issues. However, according to the state, "a separate retention analysis for transgender clients was not undertaken due to too few clients being represented in the sample. Analysis found lower retention rates among Blacks/African-Americans."[263] Despite evidence indicating that trans women of color are at high risk of dropping out of care, trans individuals were excluded from this study. This illustrates the circular and problematic "too small to be

[262] FDOH Responses.
[263] FDOH Responses.

included" argument that impedes many efforts to address a grossly disproportionate HIV burden among a population whose numbers are acknowledged to be underestimated.

In Broward County, the Department of Health called the lack of information on HIV among the county's trans population "horrible – we have very few pieces of the puzzle," and explained that lack of data leads to lack of targeted programs, a vicious cycle that impedes their ability to address the needs of a vulnerable population.[264] Broward County officials said they had conducted trainings for two-step gender identification for HIV testing and care providers funded by Ryan White or by the state or county health departments, but those not funded were considered to be out of their control.[265] They expressed a strong desire to improve the situation, describing plans to partner with Florida International University to conduct community-led research into how to improve HIV data collection in an effective, culturally competent manner.[266]

Trans and HIV advocates in Florida frustrated with the lack of progress on data collection at the federal and state levels are taking steps to address it. Jen Laws, a health policy consultant and member of the state HIV Comprehensive Planning Network (FCPN) told Human Rights Watch, "We are tired of excuses, and the data the state is presenting is obviously flawed and incomplete. But the lives of trans people are at stake."[267] Laws and other trans advocates are moving ahead on their own – at a statewide planning meeting in April 2018 several trans members of FCHN presented data estimating more accurate numbers for trans people living with HIV in the state of Florida. This data was developed using a synthesis of available information on national and state estimates of transgender population, the national transgender survey, Florida population-level data on race and ethnicity, and epidemiological and HIV surveillance data from the state of Florida. Based upon these sources, Laws estimates that between 1,404 and 2,808 transgender people are living with HIV in Florida, five to ten times more than the 291 reported by the state of Florida Department of Health (see Graph VIII).[268]

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[264] Human Rights Watch interview with Janelle Tavares, Broward County Department of Health, Fort Lauderdale, FL, April 26, 2018.

[265] Ibid.

[266] Ibid.

[267] Human Rights Watch interview with Jen Laws, health policy consultant, Fort Lauderdale, FL, April 24, 2018.

[268] Ibid; according to Laws, these revised numbers are still likely to underestimate the extent of the HIV epidemic among trans people in Florida due to chronic undercounting of this population as well as steadily increasing self-identification by people in the US as LGBT, see Gallup, "In US, Estimate of LGBT Population Rises to 4.5%," https://news.gallup.com/poll/234863/estimate-lgbt-population-rises.aspx (accessed September 7, 2018).

Graph VIII.

FDOH vs. Williams Institute/USTS HIV Prevalence Estimates

FDOH reported transgender individuals in care:

Florida rate of HIV among transgender individuals, assuming Williams Institute/USTS population data:

FDOH	LOW	MEDIAN	HIGH
(291)	(1,404)	(2,106)	(2,808)
0.6%	1.4%	2.1%	2.8%

SOURCES:
Williams Institute (2014 Collection, 2016 Report):
General Reports: https://williamsinstitute.law.ucla.edu/research/cesus-lgbt-demographics-studies/estimates-of-transgender-populations-in-states-with-legislation-impacting-transgender-people/
FL Reports: https://williamsinstitute.law.ucla.edu/uncategorized/florida/
FDOH Data (2016 Year-End Reporting): http://www.floridahealth.gov/diseases-and-conditions/aids/surveillance/_documents/hiv-aids-slide-sets/State_of_Epidemic-2016.pptx
United States Trans Survey (USTS) Reports (2015 Collection, 2016 Reports):
Florida Specific Statistics: http://www.transequality.org/sites/default/files/docs/usts/USTSFLStateReport%281017%29.pdf
National Statistics: http://www.transequality.org/sites/default/files/docs/usts/USTS%Full%20Report%20%FINAL%201.6.17.pdf

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The Florida Department of Health has expressed concern about the accuracy of these much higher estimates; the complete text of their response to these estimates is included in this report as Appendix A. Health officials and advocates agree, however, that current data attempts to quantify HIV among transgender people in Florida are incomplete, likely to be inaccurate and need to be improved.

HIV data collection is challenging, requiring synthesis of information received from hundreds, and in states as large as Florida, thousands, of independent and varied sources. Reporting systems are not uniform, and the state is taking some steps to address it. But the stark reality is that for a group known to be one of the most heavily burdened with HIV, neither the federal government nor the state of Florida has accurate, complete data on how many trans people have HIV, how they got it, how many are in medical care for it, and the effectiveness of such treatment. Thirty-plus years into the epidemic, lack of information continues to jeopardize the health, and lives, of a group known to be at high risk of HIV.

Criminal Justice Involvement Increases HIV Risk

Trans women experience high rates of incarceration, with one in five trans women reporting having been in jail or prison.[269] The rate of incarceration for African-American trans women is three times higher than for white trans women – some studies indicate that half of African-American trans women report a history of incarceration.[270] This experience was reflected in the surveys conducted by Human Rights Watch; 40 percent of trans women surveyed reported having been arrested at least once. Seven women reported being arrested five to ten times, and one woman reported more than 20 arrests. Nearly half (49 percent) of survey respondents said they had exchanged sex for money, drugs, or life necessities in the last year. Of these, 38 percent said they had been arrested for sex work. The survey indicated racial disparities, with white women reporting higher income, significantly less engagement in sex work and fewer arrests than their African-American or Latina counterparts.

The evidence continues to increase that involvement in the criminal justice system at every stage carries negative health consequences, particularly for LGBT individuals. Even short

[269] Reisner, S., et al., "Racial/Ethnic Disparities in History of Incarceration, Experiences of Victimization, and Associated Health Indicators Among Transgender Women in the US," *Women and Health*, 54(8) 2014, pp. 750-67; Sevelius and Jenness, *Challenges and Opportunities for gender-affirming healthcare for transgender women in prison,* Journal of Prisoner Health, (2017) 13, pp. 32-40.

[270] Ibid; Lambda Legal, "Transgender Incarcerated People in Crisis," https://www.lambdalegal.org/sites/default/files/2015_transgender-incarcerated-people-in-crisis-fs-v5-singlepages.pdf (accessed September 7, 2018).

jail stays have been linked to negative health outcomes. Harassment and abuse at arrest and during pre-trial detention, lack of access to medical care while incarcerated, and the impact of a criminal record on employment and housing stability contribute to health disparities for members of minority and LGBT communities.[271] Incarceration also has been found to increase poverty, a major barrier to access to health care for trans women.[272]

Human Rights Watch has documented police harassment of trans women and profiling them as sex workers in major US cities, as well as police harassment for carrying condoms, which can be considered evidence to support prostitution charges.[273] In the Human Rights Watch survey conducted for this report, one third of those engaging in sex work reported harassment by police for carrying condoms and 43 percent reported harassment by police for other reasons. One woman described a recent experience in Miami when she was attempting to take an Uber and the police surrounded her, examined her purse, and said she was "prostituting." They called her a "puta" and said they would arrest her if they saw here around there again.[274]

Violence from clients increases HIV risk for sex workers, but fear of the police often leaves them without assistance. Of the women who exchanged sex for money, drugs or life necessities, half had been threatened or assaulted by clients, but only 15 percent called the police. One woman reported having been drugged and raped by a client in Miami, but never went to the hospital or called the police, saying she "did not feel safe" and expected to be harassed.[275]

Incarceration creates numerous barriers to HIV prevention and care – condoms are not available in the majority of prisons and jails in the United States; as Human Rights Watch

[271] Bacak, V., et al., "Incarceration as a Health Determinant for Sexual Orientation and Gender Minority Persons," *American Journal of Public Health*, 108 (August 2018) pp. 994-999.

[272] Adam Looney, "5 Facts About Prisoners and Work, Before and After Incarceration," Brookings Institution, March 14, 2018, https://www.brookings.edu/blog/up-front/2018/03/14/5-facts-about-prisoners-and-work-before-and-after-incarceration/ (accessed September 10, 2018); Pew Charitable Trusts, "Collateral Costs: Incarceration's Effects on Economic Mobility, 2010 http://www.pewtrusts.org/~/media/legacy/uploadedfiles/pcs_assets/2010/collateralcosts1pdf.pdf (accessed September 10, 2018).

[273] Human Rights Watch, "Sex Workers at Risk: Condoms as Evidence of Prostitution in Four US Cities," July 2012, https://www.hrw.org/report/2012/07/19/sex-workers-risk/condoms-evidence-prostitution-four-us-cities; Human Rights Watch, "Paying the Price: Failure to Deliver HIV Services in Louisiana Parish Jails," March 2016 https://www.hrw.org/report/2016/03/29/paying-price/failure-deliver-hiv-services-louisiana-parish-jails

[274] Human Rights Watch survey response, Miami, FL, October 6, 2017.

[275] Human Rights Watch survey response, Wilton Manors, FL, April 25, 2018.

has documented, access to HIV medications and treatment is often inadequate or in many jails, non-existent and linkage to medical care upon re-entry is uneven at best.[276]

In addition to incarceration itself as an HIV risk factor, transgender women experience alarming rates of sexual assault in prison. According to federal data for 2015, more than one-third of trans women reported assault by other prisoners or staff.[277] African-American and Latina trans women are more likely to be victims of assault in jail or prison than their white counterparts.[278] Most prisoners were HIV-positive prior to their incarceration. However, lack of HIV prevention measures and failure to provide safe environments for trans prisoners – such as the widespread practice of placing trans women in male prison facilities – increases HIV risk in correctional settings.[279] Of the women surveyed by Human Rights Watch who had been jailed in Florida in the last year, 10 of 15 reported having been placed in a male facility; 6 of 10 reported abuse from jail staff and five reported abuse from other prisoners.

The Prison Rape Elimination Act (PREA) is a federal law, passed in 2003, that established standards for US prisons and jails for protection of prisoners from assault while incarcerated.[280] In 2012, the Department of Justice issued detailed guidelines for determining a gender-appropriate and safe housing assignment for trans and gender non-conforming prisoners, but these guidelines are non-binding and not implemented in many of the nation's prisons and jails.[281] The Trump administration has changed those guidelines to weaken consideration of gender identity in making housing determinations, an act challenged by advocates as undermining the purpose of the PREA legislation itself.[282] Both Miami-Dade and Broward County Jails have adopted PREA-mandated procedures for placement of trans prisoners, but survey responses and interviews with trans women indicate that concerns about safety remain. One woman wrote about her

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[276] Human Rights Watch, "Paying the Price: Failure to Deliver HIV Services in Louisiana Parish Jails," March 2016 https://www.hrw.org/report/2016/03/29/paying-price/failure-deliver-hiv-services-louisiana-parish-jails

[277] US Bureau of Justice Statistics, "PREA Data Collection Activities 2015" https://www.bjs.gov/content/pub/pdf/pdca15.pdf (accessed September 7, 2018).

[278] Sevelius and Jenness, "Challenges and Opportunities for Gender-affirming Healthcare for Transgender Women in Prison," *Journal of Prisoner Health*, (2017) 13, pp. 32-40.

[279] Prison HIV Lancet Cities; Lambda Legal, "Transgender Incarcerated People in Crisis", https://www.lambdalegal.org/sites/default/files/2015_transgender-incarcerated-people-in-crisis-fs-v5-singlepages.pdf (accessed August 22, 2018).

[280] Prison Rape Elimination Act of 2003, PL-108-79.

[281] National PREA Resource Center, "Does a Housing Policy That Houses Transgender or Intersex Inmates Based Exclusively on External Genital Anatomy Violate 115.42 c and (e)?" https://www.prearesourcecenter.org/node/3927 (accessed September 7, 2018).

[282] Human Rights Watch, "US Bureau of Prisons Policy Change Endangers Transgender Prisoners," May 14, 2018 https://www.hrw.org/news/2018/05/14/us-bureau-prisons-policy-change-endangers-transgender-prisoners

experience in two Miami jail facilities, "When I was arrested, they put me alone. Even times I was placed alone I was still harassed by inmates and staff.[283]

In Broward County Jail, most LGBT prisoners are placed in a separate "pod" where meals, activities, and recreation occur without encountering the general population. According to jail officials, the jail is organized into "pods" for all prisoners and there are no restrictions or limitations that result from placement in the what they call the "fragile" pod.[284] One trans woman, however, told Human Rights Watch that her experience in Broward County Jail in February and March of 2018 was "a nightmare." According to Savannah Cash, it began at intake when they would not recognize her California drivers' license that indicated her full and legal transition to female. Because they had booked her years before into the jail as a man, they insisted on calling her by her "dead name" the entire 40-plus days she was there.

In the "fragile" pod, Cash says she was harassed by staff and other prisoners, placed in solitary confinement – a punitive method with potentially harmful consequences for mental and physical health – as a result of conflicts with one staff member who threatened her.[285] According to Cash the staff member called her "sir" continually and said to her 'who do you think you are, you are a fucking man.' Cash also experienced delays in receiving her previously prescribed hormone replacement therapy for much of the time she was incarcerated.[286] Her attorney told Human Rights Watch that during a legal visit, he observed staff "cat-calling her and wolf whistling" while she walked to meet him in the visitation room.[287] Since release, Cash is working with her lawyer on possible legal action and Broward Sheriff's Office said they were unable to comment on the case.[288]

An arrest history or criminal record also carries negative consequences for trans women's employment prospects. For a community experiencing pervasive discrimination and with many living in extreme poverty, this can be devastating. There are no federal laws explicitly protecting LGBT people from employment discrimination, and the Trump administration has generally been unwilling to read such protections into existing laws. In 2017, the

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[283] Human Rights Watch survey response, Miami, FL, October 15, 2017.

[284] Human Rights Watch interview with Major Angela Neely, Assistant Director; Yusi Arencibia, Health Care Manager; Deputy Jorge Velez, PREA Training Officer; Broward County Sheriff's Office, Department of Detention, Fort Lauderdale, FL, April 25, 2018.

[285] Human Rights Watch, "Solitary Confinement," https://www.hrw.org/tag/solitary-confinement

[286] Human Rights Watch telephone interview with Savannah Cash, New York, NY, June 19, 2018.

[287] Human Rights Watch telephone interview with Adam Goldberg, Broward County Public Defender, Fort Lauderdale, FL, June 12, 2018.

[288] Human Rights Watch email communication with Angela Neely, Assistant Director, Broward County Sheriff's Office, Department of Detention, Fort Lauderdale, FL, July 6, 2018.

Department of Justice adopted the position that Title VII's prohibition on sex discrimination does not include sexual orientation or gender identity.[289]

Florida has no state legislation explicitly protecting against employment discrimination on the basis of sexual orientation or gender identity. The National Transgender Discrimination Survey indicated "alarming" rates of employment discrimination in Florida, where 81 percent of respondents reported having experienced harassment or mistreatment on a job, 46 percent reported not being hired, and 36 percent reported losing a job due to their trans status.[290] A 2017 report by the Williams Institute at UCLA School of Law found pervasive stigma and discrimination against LGBT individuals in Florida including employment discrimination.[291] Both Broward County and the City of Miami have local ordinances prohibiting discrimination on the basis of sexual orientation and gender identity.[292] However, many trans women told Human Rights Watch of their experiences with employment discrimination in south Florida. One woman lost her job at a Broward County academic institution within days of announcing her gender transition. Another woman was demoted at a computer company in Broward County and isolated from her work colleagues: "Imagine 1,000 people in a cafeteria and no one will sit by you," she said. "Employment discrimination is trauma."[293] Another said, "I am looking for a job but hear 'the position has been filled.' Also, they ask on the application 'have you ever been known by any other name.'"[294]

In this difficult employment environment, a criminal record can be the end of job prospects altogether and it begins, and perpetuates, a cycle of engaging in sex work for many trans women in order to survive. Participants in the Human Rights Watch survey who had been arrested had lower incomes than those who had not. In Florida, prostitution is prohibited under a range of both misdemeanor and felony charges addressing solicitation as well as human trafficking.[295] Florida also imposes enhanced penalties for engaging in prostitution

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[289] Human Rights Watch, "US Reverses Position on Transgender Discrimination," October 5, 2017, https://www.hrw.org/news/2017/10/05/us-justice-department-reverses-position-transgender-discrimination; Lambda Legal, "Zarda v. Altitude Express," https://www.lambdalegal.org/in-court/cases/zarda-v-altitude-express (accessed September 7, 2018).

[290] National Center for Transgender Equality, "National Transgender Discrimination Survey, Florida Results," https://transequality.org/sites/default/files/docs/resources/ntds_state_fl.pdf (accessed September 10, 2018).

[291] Williams Institute, UCLA School of Law, "The Impact of Stigma and Discrimination Against LGBT People in Florida," https://williamsinstitute.law.ucla.edu/wp-content/uploads/Florida-Impact-Discrimination-Oct-2017.pdf (accessed September 7, 2018).

[292] City of Miami Charter, Part 1, section 52; Broward County Code section 16.5-33.

[293] Human Rights Watch interview with Ellen D., Fort Lauderdale, FL, December 11, 2017.

[294] Human Rights Watch interview with Gabriella A., Fort Lauderdale, FL, April 25, 2018.

[295] Florida Statutes, sections 796 and 787.

while knowingly HIV-positive.[296] Public health and HIV experts have found these and other laws criminalizing HIV exposure as unnecessary, stigmatizing and counterproductive in that they may discourage HIV testing and disclosure.[297]

Many of these laws, including those in the state of Florida, require no actual transmission of HIV, fail to account for current medical treatment that can eliminate any potential for transmission, and have been shown to be disproportionately enforced against people of color and sex workers.[298] Arianna Lint works with many trans women who engage in sex work and told Human Rights Watch, “The girls are aware of the laws about HIV and prostitution – they don’t want to get tested, and they don’t even want to get medications sometimes because they are afraid of felony charges.”[299]

In Florida, a criminal record also makes obtaining gender-affirming documentation from the state more difficult. For trans people, state-issued documentation that reflects their gender identity is fundamental to overcoming the obstacles they face in almost every area of life. A drivers’ license that shows a different gender than they are presenting can trigger negative encounters, keep one from getting a job, and lead to violence. In the national survey, one of three trans people reported experiencing physical or sexual assault, being asked to leave, or being denied benefits after showing a non-conforming identity card.[300]

In Florida, the law permitting name changes requires both a background check with fingerprints and disclosure of any conviction that has resulted in a suspension of civil rights.[301] Neither provision automatically disqualifies someone with a criminal record, but the statute grants wide discretion to the judge in case of a criminal record and trans women and their advocates described how having arrests or convictions for misdemeanors resulted in denials of name changes. Alisha Hurwood is an attorney at Broward County Legal Aid who assists trans people with changing their names and gender markers on state

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[296] Florida Statutes, section 796.08 (5).

[297] Lehman, JS et al., “Prevalence and Public Health Implications of State Laws that Criminalize Potential HIV Exposure in the United States,” *AIDS Behavior*, 18 (6) 2014; CDC, “HIV-Specific Criminal Laws,” https://www.cdc.gov/hiv/policies/law/states/exposure.html (accessed September 7, 2018).

[298] Williams Institute, UCLA School of Law, “HIV Criminalization and Sex Work in California,” October 2017, https://williamsinstitute.law.ucla.edu/wp-content/uploads/HIV-Criminalization-Sex-Work-Oct-2017.pdf (accessed September 7, 2018); Williams Institute, UCLA School of Law, “HIV Criminalization in Florida,” October 2018, https://williamsinstitute.law.ucla.edu/wp-content/uploads/HIV-Criminalization-Florida-Oct-2018.pdf (accessed October 3, 2018).

[299] Human Rights Watch interview with Arianna Lint, Wilton Manors, FL, July 13, 2017.

[300] National Women’s Law Center, “Transgender People are Facing Incredibly High Rates of Poverty,” https://nwlc.org/blog/income-security-is-elusive-for-many-transgender-people-according-to-u-s-transgender-survey/ (accessed September 7, 2018).

[301] Fla Statute 68.07 2(a) and 2 (l).

and federal documentation. "It is not a ground for automatic disqualification, but it makes it more complicated and gives judges an easy method to deny name change despite no reasonable grounds for denial."[302] The background check and fingerprinting also costs $65 and obtaining certified dispositions of past criminal cases can cost hundreds of dollars. Clients who are represented by counsel can get assistance in applying for indigent petitions to waive these fees, but many trans women do not have lawyers or advocates to assist them. As the first crucial step in obtaining a drivers' license and social security card with a marker that matches their gender identity, these can be daunting barriers in the gender transition process.

HIV officials both state and federal acknowledge sex work as a factor contributing to HIV risk for trans women. Inclusion of trans women in PrEP rollout efforts are based largely on recognition of high rates of engagement in sex work. But there is little reference in HIV planning or strategy documents to the role of the criminal justice system in increasing HIV risk for any of the populations that are at highest risk both for incarceration and for HIV – people of color, youth, LGBT persons, and people who use drugs. To the extent that criminal justice issues are addressed, they largely focus on ensuring linkage to HIV care at re-entry from jail or prison.[303] But this limited approach neglects the increased risk of HIV and other negative health outcomes that result from entering jail or prison in the first place.

Criminalization of adult, consensual sexual relations is incompatible with human rights protection for personal liberty and autonomy.[304] Human Rights Watch takes the position that this also holds true with regard to the commercial exchange of sexual services. In addition, Human Rights Watch has extensively documented the harmful consequences of criminalization, both globally and in the US.[305] Human Rights Watch also opposes criminal laws such as the Federal Online Sex Trafficking Act of 2018 that conflate human trafficking

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[302] Human Rights Watch telephone interview with Alisha Hurwood, Fort Lauderdale, FL, August 3, 2018.

[303] US Office of National HIV/AIDS Strategy, "National HIV/AIDS Strategy for the United States, Updated to 2020", https://files.hiv.gov/s3fs-public/nhas-update.pdf (accessed August 22, 2018).

[304] Rachel Marshall, "Sex Workers and Human Rights: A Critical Analysis of Laws Regarding Sex Work," *William and Mary Journal of Women and the Law,* 23(1), 2016.

[305] Human Rights Watch, *Swept Away: Abuses Against Sex Workers in China*, May 2013, https://www.hrw.org/news/2013/05/14/china-end-violence-against-sex-workers ; Human Rights Watch, *Sex Workers at Risk: Condoms as Evidence of Prostitution in Four US Cities*, July 2012, https://www.hrw.org/report/2012/07/19/sex-workers-risk/condoms-evidence-prostitution-four-us-cities ; Human Rights Watch, *In Harms Way: State Response to Sex Workers, Drug Users and HIV in New Orleans,* December 2013, https://www.hrw.org/report/2013/12/11/harms-way/state-response-sex-workers-drug-users-and-hiv-new-orleans ; Human Rights Watch, "Hopes of Decriminalizing Sex Work in South Africa," June 21, 2018 https://www.hrw.org/news/2018/06/21/hopes-decriminalizing-sex-work-south-africa.

– a serious violation of human rights – with adult, consensual sexual relations.[306] Failure to make this critical distinction interferes with the right of sex workers to work safely and to advocate for their rights. Decriminalization of adult, consensual sex work, as well as repeal of criminal laws that enhance penalties for HIV exposure, would be important steps toward reducing the many HIV risks for trans women that result from incarceration. There is ample evidence to support public health arguments for criminal justice reform, both nationally and in the state of Florida.[307] In addition, support for Medicaid expansion, a program shown to reduce poverty, could improve economic conditions for trans women and reduce engagement in sex work as a necessity.

[306] Human Rights Watch, https://www.hrw.org/news/2018/06/29/why-weve-filed-lawsuit-against-us-federal-law-targeting-sex-workers

[307] Wideman, C., Yang, E., "Mass Incarceration, Public Health and Widening Inequality in the USA," The Lancet, 389(10077), April 2018, pp. 1464-74; Manuel Villa, "The Mental Health Crisis Facing Women in Prison," The Marshall Project, June 22, 2017; Kaiser Health News, "Prisons Fail to Offer to 144,000 Inmates with Deadly Hepatitis C," July 9, 2018; Brendan Farrigan, "Florida Prisons to Cut Programs Due to Health care Cost Hike," Associated Press, May 2, 2018.

Human Rights Standards

For transgender women, socio-economic conditions combine with harmful or inadequate federal and state policies that undermine their human rights and contribute to an environment in which their risk of HIV infection is higher than among any other group. With a particularly devastating impact on African-American and Latina women, this is a public health crisis that federal and state governments are obligated under international law to address.

Right to Health

All people have the right to health, a principle established by numerous international instruments including the Universal Declaration of Human Rights (UDHR).[308] The UDHR, endorsed by all members of the United Nations, including the United States, and considered to be broadly reflective of customary international law, protects the right to health as part of the right to a "standard of living adequate for the health and well-being of one's self and one's family."[309] The International Covenant for Economic, Cultural and Social Rights (ICESCR) establishes that medical care, necessary social services and housing are integral components of human dignity.[310] The ICESCR treaty has been ratified by 166 countries but not by the United States. The United States has signed, but not ratified, the ICESCR.[311]

In addition, the right to health is inseparable from provisions on the right to life and the right to be free from discrimination, protections included in the International Covenant on Civil and Political Rights (ICCPR), a treaty the United States has signed and ratified.[312] Article 26 of the ICCPR states, "All persons are equal before the law and are entitled without any discrimination to the equal protection of the law. In this respect, the law shall

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[308] Universal Declaration of Human Rights (UDHR), G.A. Res 217, UN GAOR, 3rd Session, UN Doc A/810, (1948) art. 25(1); The International Covenant on Economic, Social and Cultural Rights, adopted December 16, 1966, GA Res. 2200A (XXI), UN GAOR (no. 16) at 49, UN Doc. A/6316 (1966), entered into force January 3, 1976, signed by the US on October 5, 1977.

[309] Universal Declaration of Human Rights, art. 25 (1).

[310] The International Covenant on Economic, Social and Cultural Rights (ICESCR), adopted December 16, 1966, GA Res. 2200A (XXI), UN GAOR (no. 16) at 49, UN Doc. A/6316 (1966), entered into force January 3, 1976, signed by the US on October 5, 1977; Committee on Economic, Social and Cultural Rights, General Comment 14, The Right to the Highest Attainable Standard of Health, UN Doc. E/C.12/2000/4, adopted August 11, 2000.

[311] As a signatory, the US is obliged to refrain from taking steps that undermine the "object and purpose" of the treaty. Vienna Convention on the Law of Treaties, adopted May 23, 1969, entered into force January 27, 1980, article 18.

[312] The International Covenant on Civil and Political Rights (ICCPR), adopted December 16, 1966, GA Res. 2200A (XXI), 21 UN GAOR Supp. (No. 16) at 52, UN Doc A/6316 (1966), 999 UNTS 171, entered into force March 23, 1976, ratified by the US on June 8, 1992.

prohibit any discrimination and guarantee to all persons equal and effective protection against discrimination on any ground such as race, colour, sex, language, religion, political, or other opinion, national or social origin, property, birth or other status."[313] Authoritative treaty bodies as well as UN special rapporteurs and other international legal experts interpreting this provision have determined that it prohibits discrimination on the basis of sexual orientation and gender identity.[314]

The right to health does not guarantee to everyone the right to be healthy. Rather, it obligates governments to enact policies that promote the availability and affordability of basic health care services, without discrimination against those most likely to face obstacles to access – the poor, minorities, LGBT persons, women, prisoners, people with disabilities, and others.[315] The Trump administration has promoted policies that would have the opposite impact, attempting to repeal and undermine the Affordable Care Act without an adequate replacement, reducing the reach of Medicaid programs and turning away from interpretations of existing federal laws and regulations that would protect LGBT individuals from discrimination. As of October 2018, the Trump administration was moving ahead with plans to expand the grounds for religious and moral objections to providing health care services.[316] Without adequate provisions to ensure protection against discrimination, these and other Administration moves are likely to worsen pervasive and well documented discrimination against LGBT people in access to health services.

A key component of promoting affordability and availability of health services for transgender people is ensuring access to transition-related care. Under the Yogyakarta Principles, a set of non-binding standards endorsed by international legal experts from 25 countries that apply existing international human rights law to sexual orientation and gender identity, states are obligated to protect LGBT persons from discrimination in health care settings. This obligation includes "ensuring that gender-affirming health care is

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[313] ICCPR, art. 26.

[314] United Nations, Office of the High Commissioner on Human Rights, "Embrace Diversity and Protect Trans and Gender Diverse Children and Adolescents," https://www.ohchr.org/en/NewsEvents/Pages/DisplayNews.aspx?NewsID=21622&LangID=E (accessed September 7, 2018); UN Human Rights Committee, *Toonen v. Australia*, CCPR/C/50/D 1992 (March 31, 1994).

[315] Committee on Economic, Social and Cultural Rights, General Comment 14, The Right to the Highest Attainable Standard of Health, UN Doc. E/C.12/2000/4, adopted August 11, 2000.

[316] Human Rights Watch, "Human Rights Watch Letter to US Secretary of Health and Human Services Alex Azar," March 27, 2018, https://www.hrw.org/news/2018/03/27/human-rights-watch-letter-us-secretary-health-and-human-services-alex-azar

provided by the public health system or, if not so provided, ensuring that such services are covered under private and public insurance schemes."[317]

Right to Be Free from Racial Discrimination

The federal, state and local governments in the United States are obligated to address all forms of racial discrimination, including the stark disparities that characterize the domestic HIV epidemic. This duty is fundamental to upholding international human rights law, including the ICCPR and the International Convention on the Elimination of All Forms of Racial Discrimination (CERD).[318] CERD, to which the United States is a party, requires governments, when circumstances warrant, to take "special and concrete measures" to ensure the development and protection of racial groups "for the purpose of guaranteeing them the full enjoyment of human rights and fundamental freedoms."[319]

CERD obligates governments to address not only intentional racial discrimination but laws, policies and practices that result in disparate racial impact.[320] The UN Committee on Racial Discrimination, the international expert body responsible for interpreting the ICERD, has expressed its concern that the United States lacks appropriate mechanisms for implementation of the treaty at the state level.[321]

Right to an Adequate Standard of Living

The Universal Declaration of Human Rights states:

> Everyone has the right to a standard of living adequate for the health and well-being of one's self and one's family, including food, clothing, housing and medical care and necessary social services, and the right to security in the case of unemployment, sickness, disability, widowhood, old age or other lack of livelihood due to circumstances beyond his control.[322]

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[317] The Yogyakarta Principles on the Application of International Human Rights Law in relation to Sexual Orientation and Gender Identity, March 2007, http://yogyakartaprinciples.org/relating-to-the-right-to-the-highest-attainable-standard-of-health-principle-17/ (accessed September 7, 2018).

[318] International Convention on the Elimination of All Forms of Racial Discrimination (ICERD), adopted December 21, 1965, GA Res. 2106, (XX), annex, 20 UN GAOR Supp. (No. 14), at 47, UN Doc A/6014 (1966), 660 UNTS 195, entered into force January 4, 1969, ratified by the United States November 20, 19994, art. 5.

[319] ICERD, art. 2(2).

[320] ICERD, art. 1(1).

[321] Committee on the Elimination of Racial Discrimination, Concluding Observations of the Committee on the Elimination of Racial Discrimination in the United States, Geneva, May 8, 2008, UN Doc. CERD/C/USA/CO 6, paras 16, 32.

[322] UDHR, art. 25.

Disproportionately, trans women struggle to secure access to many of these basic necessities. Living in extreme poverty keeps many trans women on the margins of society and vulnerable to violence, stigma and discrimination. Circumstances beyond their control – including numerous federal and state policies – contribute to this condition, including lack of legal protection against discrimination in employment, health care and public accommodation. Health care policies that reduce access to care for low income people and criminal laws that make it more difficult to find a job expose trans women to the harms of arrest and incarceration and reduce their ability to seek HIV prevention and care.

The state of Florida's continued rejection of expanded Medicaid coverage is a key policy decision that helps to entrench these grim realities. In his report on the United States, the UN Special Rapporteur on Extreme Poverty and Human Rights documented the "shocking" extent of extreme poverty in the US and criticized federal and state health care policy to undermine and restrict the Affordable Care Act. [323]

[323] UN Human Rights Council, "Report of the Special Rapporteur on Extreme Poverty and Human Rights," May 4, 2018, A/HRC/38/33/Add.1, https://documents-dds-ny.un.org/doc/UNDOC/GEN/G18/125/30/PDF/G1812530.pdf?OpenElement (accessed September 7, 2018).

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Appendix A – Florida Department of Health Response to Alternative HIV Prevalence Estimate (Graph IV)

We appreciate that the data limitations towards transgender persons are being discussed and being brought to the forefront, these discussions are also occurring internally as well as HIV surveillance using multiple sources outside of traditional surveillance to identify transgender persons living with HIV in Florida. We however, would like to point out a few limitations of the data estimates provided by Johnson and Mayfair.

Between 2009–2014, 2,351 transgender people had received a diagnosis of HIV in the United States (U.S.)[1], in 2016, 291 transgender persons were living with a diagnosis of HIV in Florida[2]. We recognize that these data may underreport the diagnoses of HIV among transgender people due to how HIV surveillance is conducted and the sources they report cases from (e.g. laboratory results that do not have current gender identity listed, or from provider reports which may or may not report current gender identity in medical record).

The total population of transgender persons in the U.S. are not well known due to the lack of official records (Department of Motor vehicles, etc.) collecting only sex at birth and not current gender identity, and any estimates are produced through meta-analysis of surveys and articles which may not be generalizable to the U.S. or Florida. Current estimates used by CDC estimate approximately 1 million transgender persons are living in the U.S.[1,3] or 0.39% of the U.S. population. The study that Johnson and Mayfair referenced for their estimate of transgender person living with HIV in Florida, suggested an estimated number of 0.60% of the U.S. population identifies as transgender (1.4 million people), with an estimate of 100,300 transgender persons living in Florida[4]. This study used data reported from 19 states who asked if a person identified as transgender on the Behavioral Risk Factor Surveillance System (BRFSS) survey and extrapolated results to estimate population for the U.S. and individual states. Florida did not participate in this BRFSS transgender optional module question, furthermore these studies only estimate the transgender population and not persons who identify as transgender who live with a diagnosis of HIV. Current estimates used by the CDC report that 22–28% of transgender individuals (approximately 220,000–280,000) are living with HIV in the U.S.[1,5]

As we do not know the exact methodology that was used by Johnson and Mayfair to calculate their estimated prevalence of transgender persons living with HIV in Florida, we can't comment on their estimate. We do not understand how they got a prevalence of 0.6% prevalence for transgender persons living with HIV in Florida.

[1] https://www.cdc.gov/hiv/pdf/group/gender/transgender/cdc-hiv-transgender-factsheet.pdf

[2] http://www.floridahealth.gov/diseases-and-conditions/aids/surveillance/epi-slide-sets.html

[3] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5227946/

[4] http://williamsinstitute.law.ucla.edu/wp-content/uploads/How-Many-Adults-Identify-as-Transgender-in-the-United-States.pdf

[5] https://www.sciencedirect.com/science/article/pii/S1473309912703158?via%3Dihub

LIVING AT RISK

Transgender Women, HIV, and Human Rights in South Florida

The 1.4 million transgender and gender-non-conforming people in the United States generally face multiple barriers, from family rejection to non-acceptance and abuse at school, and pervasive discrimination in employment, housing, and health care. Nationally, rates of HIV infection are declining, but among transgender women, rates of new HIV infection have remained at crisis levels for more than a decade, particularly among women of color. This public health emergency demands a robust response – one that the state of Florida, and the federal government, are failing to deliver.

Living at Risk: Transgender Women, HIV and Human Rights in South Florida documents the harmful impact of federal and state policies on transgender women in two counties – Miami-Dade and Broward – with the highest rates of new HIV infection in the country. Based on hundreds of interviews with transgender women, their advocates, medical providers, public officials, and law enforcement, this report describes the failure of Florida to provide basic HIV prevention and treatment services to many transgender women, leaving them without affordable health care and contributing to the uncontrolled epidemic in the state. Neglected by HIV policymakers and undercounted in government HIV data, transgender women are left with limited options for HIV prevention and care.

Until federal and state policymakers ensure that transgender women have access to affordable health care that respects their identity and rights, HIV will continue to endanger the lives of the transgender community.

Rajee Narinesingh, a transgender human rights advocate, in Miami, Florida, October 2018.

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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

WHITMAN-WALKER CLINIC, INC., *et al.*,

Plaintiffs,

v.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, *et al.*,

Defendants.

Case No. 1:20-cv-1630

DECLARATION OF DARREL CUMMINGS, CHIEF OF STAFF, LOS ANGELES LGBT CENTER

I, Darrel Cummings, hereby state as follows:

1. I am the Chief of Staff of the Los Angeles LGBT Center ("the Center"), a not-for-profit 501(c)(3) organization based in Los Angeles, California, that provides a variety of services to members of the lesbian, gay, bisexual, and transgender ("LGBT") communities. I have served in this capacity since 2003, and also previously served as Chief of Staff from 1993 through 1999. More broadly, I have been an advocate on LGBTQ issues since 1979.

2. I am submitting this Declaration in support of Plaintiffs' Motion for a Preliminary Injunction to prevent the revised regulation under Section 1557 of the Affordable Care Act, published by the Department of Health and Human Services on June 19, 2020 (the "Revised Rule"), from taking effect.

3. The Center was founded in 1969 and offers programs, services, and global advocacy that span four broad categories: health, social services and housing, culture and education, and leadership and advocacy. The mission of the Center is to fight bigotry and build a world where LGBTQ people thrive as healthy, equal, and complete members of society. Today the Center's

more than 650 employees provide services for more LGBTQ people than any other organization in the world, with about 500,000 client visits per year.

4. As the largest provider of services to LGBTQ people in the world, many of the Center's patients tell us that they come to the Center seeking culturally competent health care due to being denied care or being discriminated against based on their real or perceived sexual orientation, gender identity, transgender status, and HIV status. The Center's client population is disproportionately low-income and experiences high rates of chronic physical and mental conditions, homelessness, unstable housing, trauma and discrimination, and stigmatization in health care services. Many of these clients come to the Center from different areas of California, other states, and even other nations to seek services in a safe and affirming environment.

5. Many of the Center's clients live in states that do not have explicit nondiscrimination protections in health care on the basis of gender identity, transgender status, or sexual orientation. These clients travel long distances to the Center because they have even greater fear of discrimination by health care providers in their states. With the Trump Administration's constant attacks on the LGBTQ community, the Center has seen and will continue to see an increase in clients traveling from out of state, especially clients who reside in rural areas where there may not be *any* LGBT-affirming health care providers to treat them in their most desperate times of need. This has been especially true during the current COVID-19 pandemic.

6. The Center provides a wide spectrum of health care services, including, but not limited to, HIV treatment, testing, and prevention care, as well as treatment for gender dysphoria and mental health care. The Center has medical providers who specialize in the care of transgender patients and who provide a full range of primary care services in addition to hormone therapy, pre- and post-surgical care, and trans-sensitive pap smears, pelvic exams, and prostate exams. The

Center's broad array of health care services are all under one roof, from counseling and therapy to pharmaceutical and nutrition needs.

7. The Center is one of the nation's largest and most experienced providers of LGBTQ health and mental health care. As a federally qualified health center, the Center is required to serve anyone on a nondiscriminatory basis who walks into its doors. We accept a variety of health insurance plans, including Medi-Cal (California's Medicaid program), Medicare, and most private insurance plans. We also provide services to uninsured individuals. We work with these individuals to help them access insurance through Covered California (California's Affordable Care Act "exchange"), and/or navigate other medical- and drug-assistance programs. Where insurance is not available, our services are offered on a sliding-scale basis, based on ability to pay. We pride ourselves on providing leading-edge health care, regardless of individuals' ability to pay. Given our commitment to serve all clients regardless of their ability to pay, the Revised Rule's removal of insurance coverage and nondiscrimination requirements will cause the Center to be flooded with more clients and create significant financial strains on the Center.

8. The Center has remained open for services throughout the COVID-19 health crisis, which already stretched the Center's resources thin. Releasing this discriminatory Revised Rule during a time of pandemic is particularly egregious. The Revised Rule will deter patients from seeking testing and treatment for COVID-19, which will endanger the lives our patients' lives and will cause serious harm to the public at large. Testing and contact tracing are key to effectively respond to this and other health pandemics. Yet, when patients fear discrimination, testing and contact tracing cannot be implemented effectively.

9. Amidst existing stress from the COVID-19 pandemic, our clients and staff have become increasingly panicked and stressed about the Revised Rule. As a result, the Center needs

to devote significant resources to reaffirming its commitment to the LGBTQ community, educating about the effects of the Revised Rule. The Center also needs to devote significant resources to addressing our clients' increased need for medical services and for affirming medical referrals given their fears of the discrimination by other health care providers that the Revised Rule invites. There is no more important time than now for our clients to know that we are open for services and they will continue to receive affirming, nondiscriminatory care at the Center. Our community needs to know that they have a safe and affirming place to receive care, especially emergency care. However, the Center cannot—despite our best efforts—meet effectively the needs of all the LGBTQ people that will be harmed by the Revised Rule, in California and other states.

10. The Center receives various forms of Health and Human Services funding, including Public Health Service Act funding. Approximately 80 percent of the Center's funding originates from the federal government, including, but not limited to, funding under the Ryan White Comprehensive AIDS Resources Emergency Act of 1990, direct funding from the Centers for Disease Control and Prevention, discounts under the 340B Drug Discount Program, and Medicaid and Medicare reimbursements. The Center also receives federal funding for research programs, and is currently a participant in multiple federally-funded studies, including through National Heart, Lung, and Blood Institute; National Institute of Allergy and Infectious Diseases; National Institute of Child Health and Human Development; the National Institutes of Health; National Institute of Drug Abuse; and the Patient-Centered Outcomes Research Institute. The Center is, therefore, a covered entity under the Revised Rule and is subject to its provisions.

11. The Revised Rule eliminates the definition of "on the basis of sex" and the specific prohibitions on discrimination on the basis of gender identity, transgender status, and failure to

conform to sex stereotypes. The Revised Rule also eliminates specific provisions related to discrimination against transgender individuals, as well as the provision relating to the discrimination on the basis of association. The elimination of these provisions will result in direct harms to the LGBTQ patients that the Center serves.

12. The Revised Rule caused immediate panic from the Center's clients and staff about what the Revised Rule means and how it will affect the Center's clients' ability to obtain health care services. The Center's clients are and will continue to be confused and misled by the Revised Rule, which will further deter them from seeking care. The Center also refers its clients to other health care providers for many specialty health care services it does not provide. As a result of the Revised Rule, our clients who seek care by other health care providers outside of the Center, particularly those from other states but also those within California, will reasonably fear discrimination and be afraid to assert their rights if they are discriminated against. The Revised Rule creates confusion over what rights patients have and how patients may assert such rights. This is especially true given the Revised Rule's removal of a unitary legal standard that creates an additional barrier for clients to seek justice for the harms they experience, let alone finding a successful remedy for the harms.

13. In addition to the Revised Rule's elimination of the unitary standard, its removal of notice and tagline requirements will also make it much more difficult for transgender and gender nonconforming patients with Limited English Proficiency (LEP) to understand what rights they have, how to advocate for such rights, what language services are still available to them, how they can access such services and how to handle discrimination and other complaints. The Revised Rule appears to have been drafted to be purposefully sow chaos and confusion about what Section

1557 requires. That chaos and confusion is heightened for LEP patients who cannot reasonably be expected to understand what rights they still have if this discriminatory rule is implemented.

14. As a result of confusion and panic created by the Revised Rule, the Center has already and will continue to expend additional resources educating its clients and staff about their rights and reassuring them that the Center will continue providing nondiscriminatory services to all clients.

15. The Revised Rule will also worsen health disparities between the LGBTQ community and other communities. With existing health and health care disparities in the LGBTQ community – particularly the shortage of LGBTQ/HIV culturally competent providers – the Revised Rule's invitation to health care providers to discriminate will further exacerbate existing barriers to health care and result in negative community health outcomes.

16. The Center's providers have observed patients arriving at the Center with acute medical conditions that could have been avoided but-for the patients' reluctance to seek routine and necessary medical care for fear of discrimination and being turned away. A shocking number of LGBTQ patients fear going to a health care provider due to negative past experiences directly related to their sexual orientation, gender identity, or transgender status. The Revised Rule will exacerbate those numbers as a result of increased discrimination and denials of health care treatment. For example, we have had clients arrive at the Center with Stage 4 ovarian cancer because they were afraid to seek routine pap smears. The Revised Rule creates additional barriers to accessing affirming health care, increases patients' reluctance to seek care for both minor and serious conditions, and decreases trust between patients and their providers out of fear of judgment, discrimination, and denials of treatment. An increase in community members experiencing the

trauma of discriminatory or unwelcoming health care experiences will worsen community health outcomes among the population that the Center serves.

17. For similar reasons, LGBTQ people are less likely to have a primary care provider whom they consider their personal doctor. That means that in times of need, LGBTQ people are more likely to randomly select a health care provider with whom they do not have a relationship, and they are at increased risk of finding a provider who is not LGBTQ-affirming. With an increase in discrimination as a result of the Revised Rule, LGBTQ people will be far less likely to receive the health care treatment that they need because, after being discriminated against, they are unlikely to seek other care out of fear of repeated rejections.

18. The Revised Rule sends a message to the Center's LGBTQ clients that they do not have a right to equal access to health care and empowers health care providers to discriminate against them, which has caused and will continue to cause panic and fear within the Center's client community and staff. This fear will deter clients from seeking medically-necessary health care services out of fear of discrimination and will cause delays in treatment. This delay has serious medical ramifications for clients and public health at large. It also results in increased costs to the Center and the health care system at large.

19. Transgender and gender nonconforming clients are particularly likely to delay care as a result of the Revised Rule given the Rule's broad invitation to discriminate on the basis of any religious or moral beliefs in combination with the Rule's narrowing of insurance coverage options for transgender patients. The Revised Rule creates confusion over what treatments patients' insurance will cover and how they may access medically-necessary care. Discrimination by other outside health care providers will result in transgender patients delaying medical care, especially for medically-necessary treatment for gender dysphoria.

20. As a result of the discrimination and denials of care and coverage it will cause, the Revised Rule will increase demand for the Center's services and will cause financial strains on the Center. For some patients that the Center serves, especially those who live in regions with limited options for LGBTQ-affirming health care services, finding LGBTQ-inclusive health care options is already a struggle. Additionally, for some medical specialties, there are only a handful of health care providers in a patient's region who have the specialty necessary to treat the patient, so discrimination by even one provider could make it practically impossible for an LGBTQ patient to receive the specific health care service sought. This is even more concerning in regions where patients' only options are religiously-affiliated organizations that could claim religious or moral-based objections to providing any and all care to LGBTQ patients as a result of the Revised Rule, in contradiction to medical ethics and standards of care. This is especially true during the COVID-19 pandemic when medical services are more limited.

21. The Revised Rule eliminates explicit nondiscrimination regulatory protections and instead invites increased discrimination against LGBTQ people and people living with HIV at other health care centers, outside of the Center. By eliminating the explicit protections against discrimination based on gender identity, transgender status, and failure to conform with sex stereotypes, the Revised Rule invites an increase in discriminatory experiences for LGBTQ patients seeking health care services, such as those documented below. This results in harm to the patients and community that the Center serves.

22. The Center's health care providers – particularly its counselors, psychiatrists and other behavioral-health staff – have treated many patients who have experienced traumatic stigma and discrimination based on sexual orientation, gender identity, transgender status, HIV status, and/or

other factors. The stories that patients tell the Center's staff about their discriminatory experiences outside of the Center include:

a. One transgender patient was unable to find supportive mental-health housing due to discriminatory experiences based on gender identity, which led to the patient being homeless.

b. Another transgender patient, who developed profuse bleeding after surgery, was denied treatment at an emergency room where they were told by an emergency room doctor: "what do you want me to do about it?" They arrived at the Center in distress three days later, having lost a significant amount of blood.

c. A transgender patient needed to have a pelvic exam. The Center referred him to a specialist who denied services to him because he was transgender.

d. Patients have stated that their physicians told them that they do not need HIV testing because they are not engaging in same-sex sexual relationships. Not only is that conclusion contrary to medical guidelines, but when patients refuted assumptions about their sexual relationships, they were met with disapproval.

e. Patients have expressed concern about traveling outside of Los Angeles for business because if they are ever in need of emergency medical assistance, they will not know where to go to ensure that they will receive nondiscriminatory, proper health care services.

f. One patient recalled that when her late partner was in the hospital, she was there most of the time to care for her. There was a nurse who treated them

kindly and appropriately until the nurse heard them refer to each other by "Honey." The look on the nurse's face changed and she treated the couple "like trash" after that. The patient remarked that allowing health care employees (everyone from those working in food service and housekeeping to physicians and nurses) to express judgment or disapproval based on their religious or moral views when providing care to patients results in placing LGBTQ patients in a "lesser-than" category of patients.

g. Patients residing at assisted-living facilities have described discrimination and denials of care when their sexual orientation, gender identity, and HIV status were revealed. Patients who are transgender have described having to hide their gender identity and transgender status once they are no longer able to care for themselves and are required to find assisted-living arrangements.

h. Patients have described being intentionally referred to by names and pronouns other than their preferred names while seeking health care services elsewhere. There is no valid medical reason to not refer to a patient by their name and pronouns, consistent with their gender identity.

i. A patient described being given his positive HIV results by way of his provider placing a lab printout on the counter then leaving for 10 minutes and letting the patient read it. The patient was not given any further information, and was instead told to go to our Center.

j. Patients have reported that their primary care physicians do not feel comfortable prescribing HIV preventatives, such as Truvada for Pre-

Exposure Prophylaxis (PrEP), even when such medications are appropriate and should be provided according to current medical guidelines and standards of care. Patients also have reported that their physicians shame them for requesting PrEP medications and then deny them the medication, which is how they find their way to the Center. For example, when one patient asked his provider about Truvada, his physician questioned him as to why he needed it and proceeded to tell the patient that he would not need the medication if he were more careful. Another patient was denied PrEP altogether and lectured that he did not need PrEP unless he was having sex with sex workers.

k. Patients also have expressed reluctance to use their insurance for PrEP because they are afraid of having the drug documented on their insurance record. These patients fear that a history of using a medically necessary HIV preventative could be used against them in the future by making them targets for discrimination based on sexual orientation, gender identity and/or transgender status, and HIV status, given the current political climate and discrimination in the health care context.

l. A significant number of patients come to the Center's Sexual Health and Education Program for testing and sexual education rather than their primary care physicians because they do not feel comfortable talking about their sexual histories and choices out of fear of being treated negatively, judgmentally, and with bias and discrimination.

m. Multiple patients have stated that they come to the Center to be tested for sexually transmitted infections because the Center does rectal and throat swabs instead of only urine tests. Not all health care providers do all three forms of testing even though three-site testing provides the most accurate results for testing and treating sexually transmitted infections. This is especially true for gay men. Someone could test negative for a sexually transmitted infection with a urine test, for example, but test positive with a rectal swab. Patients report that when they specifically asked their outside provider to do rectal swabs, they were judged. When patients are judged by their physicians and/or cannot be out to their physicians about their sexual orientation and/or gender identity out of fear of discrimination, LGBTQ patients cannot receive the health care services that they need, including prophylactic treatments, and may experience delays in medically necessary treatments, resulting in more acute, life-threatening conditions.

23. Many of the Center's patients and LGBTQ people in general have reported that they are not out to their other medical providers about their sexual orientation and/or gender identity out of fear of discrimination and denial of health care. The Revised Rule's attempt to exclude sexual orientation, gender identity, and transgender status from the nondiscrimination protections under Section 1557 and its invitation to health care providers to discriminate on the basis of religious or moral beliefs will harm the Center's patients and puts the health of LGBTQ patients at risk.

24. The Revised Rule encourages LGBTQ patients to attempt to hide their LGBTQ identities when seeking health care services, especially from religiously-affiliated health care

organizations, in order to avoid discrimination. When patients are unwilling to disclose their sexual orientation and/or gender identity to health care providers out of fear of discrimination and being refused treatment, their mental and physical health is critically compromised.

25. The Revised Rule also adversely impacts the Center by necessitating the diversion and reallocation of resources to address the increase in the numbers of referrals requested by the Center's clients who seek LGBTQ-affirming services that the Center does not have sufficient resources to provide as a result of the Revised Rule. The Center will also have more difficulty finding LGBTQ-affirming health care providers, especially those with niche specialties, given that the Rule emboldens health care providers to refuse to treat LGBTQ patients.

26. As a result of the Revised Rule, the Center may need to hire additional staff to address the community's need for referrals to welcoming providers. A substantial part of the Center's staff and resources has already been spent engaging in advocacy, policy analysis, and services to address the ill-effects of the Revised Rule. The Center will also have to divert resources away from other programming to conduct informational sessions about the Revised Rule to answer patients' and staff members' questions about how the Rule will affect them and the services that the Center provides, as well as actually meet the increased demand for its services and the need to better vet referrals.

27. The increase in referral requests requires the Center to allocate additional staff time to pre-screen service referrals to ensure that staff are sending patients to LGBTQ-affirming providers and not to providers who themselves or whose staff would cause additional harm to the Center's patients. With the Revised Rule emboldening increased discrimination against LGBTQ patients, the Center will have to do additional checks on potential referrals to confirm with the providers that they will continue abiding by their obligation to provide nondiscriminatory care to all patients.

Additionally, the Rule's removal of accommodation requirements for LEP patients will make it increasingly difficult for the Center to find appropriate referrals for our LEP clients. Without requiring accommodations for our LEP clients, our clients are at an increased risk of receiving inferior care and improper testing and delayed diagnoses when they seek health care services from outside providers.

28. When a patient cannot communicate with and trust their health care provider, the provider has incomplete information to be able to properly diagnose, test and treat patients. This is especially true for patients who are unable to or fear disclosing their sexual orientation or gender identity to their providers out of fear of discrimination or denials of treatment. The Center will have to expend more resources on its health promotion campaigns to ensure that LGBTQ patients access necessary preventative screenings and testing (including for cancer, HIV and other STIs) given that the Revised Rule will change the health care landscape for the LGBTQ patient population.

29. Under the Revised Rule, covered entities will not be considered as discriminating on the basis of sex if they refuse to use a transgender patient's pronouns consistent with their gender identity; refuse them access to sex-specific facilities that are consistent with their gender identity and instead forces them into facilities/shared rooms based on the sex they were incorrectly assigned at birth; and identifies them by the sex they were incorrectly assigned at birth such as on patient identification bracelets and any signage outside the patient's room. These discriminatory actions, which as documented above, have been experienced by the Center's clients at other health care facilities, are inconsistent with the 2016 Final Rule and Section 1557 of the Affordable Care Act. They are also detrimental to transgender patients' health and wellbeing, and can lead to significant distress and hypertension. Moreover, HHS in the preamble to the Revised Rule warns

covered entities such as the Center that treating transgender patients consistent with their gender identity as it relates to sex-specific facilities may subject them to liability and enforcement by HHS. However, the Center treats each patient in accordance with their gender identity, consistent with the 2016 Final Rule and established case law. If the Center were to be sanctioned and lose federal funding as a result of the Revised Rule's enforcement, the impact would include massive service reduction if not closure.

30. The 2016 Final Rule protects against "categorical coverage exclusion[s] or limitation[s] for all health services related to gender transition" and denials, limitations, or restrictions "for specific health services related to gender transition if such denial, limitation, or restriction results in discrimination against a transgender individual," 81 Fed. Reg. at 31,472 (formerly codified as 45 C.F.R. § 92.207(b)). Affirming providers like the Center and their patients have been able to use the 2016 Final Rule to reinforce the obligations of Medicaid administrators, insurers, and employee health plan sponsors to provide services to LGBTQ people devoid of discrimination, including the need to cover procedures when supported by evidence of medical necessity. The Revised Rule, which eliminates these protections that we at the Center rely upon to advocate on behalf of our patients, invites health plans to discriminate through the exclusion of gender-affirming procedures, especially those used to treat transgender patients suffering from gender dysphoria, and through the reinstitution of insurance practices regarding the "tiering" of certain drugs that are of crucial for LGBTQ patients living with HIV and/or other medical conditions or disabilities that require expensive treatments.

31. The Revised Rule also exempts numerous forms of health insurance from Section 1557, subjecting LGBTQ patients who rely on those forms of insurance to discrimination based on sex, gender identity, transgender status, sexual orientation, race, national origin, age, or

disability. Additionally, the Revised Rule excludes HHS health-related programs and activities from Section 1557, unless a program was established under Title I of the ACA. This affects many programs, including those under the Centers for Medicare and Medicaid Services. The narrowing of covered entities under Section 1557 will increase discrimination against LGBTQ patients while at the same time limiting remedies available to address such discrimination.

32. In sum, the Revised Rule will exacerbate the acute health disparities LGBTQ people already face and send the message that discrimination on the basis of gender identity, transgender status, sexual orientation, and failure to conform with sex stereotypes is permissible under federal law, which will increase the number of the Center's LGBTQ patients who will be denied care outside the Center.

33. The Revised Rule makes it difficult, if not impossible, for the Center to continue providing the same level of social, mental, and physical health care to its patients. The Center's mission includes addressing the need for equity in health care for all of the Center's patients and the LGBTQ community generally. This mission will be frustrated by the Revised Rule as there will be a decline in overall LGBTQ-patient health and public health at large. By eliminating the regulatory protections and clear guidance provided in the 2016 Final Rule, the Revised Rule presents a grave threat to the health and wellbeing of the patient population that we serve, most specifically LGBTQ patients and patients with LEP. The Revised Rule also frustrates our ability to provide referrals to our patients and imposes increased costs on the Center.

[*Signature on next page.*]

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Dated this 6th day of July, 2020.

____
Darrell Cummings

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

WHITMAN-WALKER CLINIC, INC., *et al.*, *Plaintiffs,* v. U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, *et al.*, *Defendants*.	Case No. 1:20-cv-1630

DECLARATION OF DR. ROBERT BOLAN, MD
CHIEF MEDICAL OFFICER, LOS ANGELES LGBT CENTER

I, Robert Bolan, declare as follows:

1. I am the Chief Medical Officer and Director of Clinical Research for the Los Angeles LGBT Center (the "Center" or "LA LGBT Center").

2. I oversee all medical care related services at the LA LGBT Center, as well as maintain a panel of patients for whom I provide direct care. In addition, I oversee the LA LGBT Center's Research Department, am the principal investigator for multiple HIV treatment and prevention trials, and have written and presented extensively on various matters related to the care and treatment of people living with or at risk of acquiring HIV and other sexually transmitted infections (STIs).

3. I am also Clinical Associate Professor of Family Medicine at the University of Southern California (USC) – Keck School of Medicine, and an Adjunct Clinical Professor of Pharmacy Practice at the Western University of Health Sciences. I received my medical degree from the University of Michigan Medical School, interned at St. Mary's Hospital Medical Center, and completed my residency at St. Michael Family Practice Residency. I was the Director of HIV Services in the Department of Family Medicine at the USC Keck School of

Medicine, and I have been honored with the Leadership Award from the San Francisco AIDS Foundation. I maintain active board certification with the American Board of Family Physicians and specialty certification with the American Academy of HIV Medicine. A copy of my curriculum vitae is attached as **Exhibit A**.

4. I am submitting this declaration in support of Plaintiffs' Motion for Preliminary Injunction to prevent the revised regulation under Section 1557 of the Affordable Care Act ("ACA"), published by the U.S. Department of Health and Human Services ("HHS") on June 19, 2020 (the "Revised Rule"), from taking effect. The Revised Rule eliminates explicit regulatory protections for LGBT people in health care that were included in the 2016 Final Rule, which was promulgated under Section 1557 in May 2016.

5. As the Chief Medical Officer, I oversee the delivery of health care for approximately 32,000 patients who come to the LA LGBT Center and have a panel of approximately 250 patients for whom I personally provide medical care. Over 90% of my patients identify as LGBTQ. My patient population is also disproportionately low-income and experiences high rates of chronic conditions, homelessness, unstable housing, trauma history, and discrimination and stigmatization in health care services. Many of these patients come to me from different areas of California, other states, and even other nations to seek services in a safe and affirming environment.

6. Our health care services span the full spectrum of primary health care services, including, but not limited to, HIV treatment and testing, treatment and prevention of sexually transmitted infections, as well as treatment for gender dysphoria, mental-health disorders, and substance-use disorders.

7. Many if not most of the individuals in our very diverse patient population face considerable stigma and discrimination – as people living with HIV, as sexual or gender minority people, and/or as people of color. In addition, there is a very high incidence of other social determinants of poor health outcomes among the patient population that we serve. These include homelessness, food insecurity, lack of access to transportation, and lack of employment opportunities.

8. There is every reason to believe that the Revised Rule will encourage health care providers to claim a right to discriminate, refuse care or opt out of serving patients with particular needs, which will result in more discrimination against LGBT patients and patients living with HIV at other clinics, doctors' offices, hospitals, pharmacies, and other health care facilities outside of the LA LGBT Center. I, and the other providers whom I supervise at the Center, treat patients who have experienced traumatic stigma and discrimination – based on their sexual orientation, gender identity, transgender status, HIV status, and/or other factors – even before the Revised Rule was proposed or finalized. Based on the stories that my patients have shared with me, this discrimination, mistreatment, and denial of health care services has on many occasions been motivated by the moral or religious beliefs of other health care providers and staff outside of the Center.

9. In the more than twenty years that I have been at the Center, I have listened to the stories of countless individuals who have suffered overtly homophobic remarks from health care providers and who were either refused care or given clearly inadequate and inappropriate care because of their sexual orientation or gender identity. One of the most egregious examples was a transgender woman who needed extensive surgery to repair diffuse damage done by silicone injections into her breasts several years earlier. In 2009, she was turned away from an academic

plastic surgery center in Los Angeles after the surgeon said her problem was caused by her own poor decision-making and she would therefore not be considered for treatment.

10. Incidents like this reveal that many health care providers and other staff harbor explicit or implicit biases against LGBTQ people. Because of legal requirements, health care facility nondiscrimination policies, and professional norms, many of them have kept their personal biases and feelings in check. By empowering health care staff to think that they have the legal right to act on their personal beliefs, even at the expense of patient needs, the Revised Rule will result in many more incidents of discrimination and greater harm to LGBTQ individuals struggling with mental-health or substance-use issues, including the patients whom I treat and whose treatment I supervise.

11. Such experiences are not only insulting and demoralizing for the patient, but can jeopardize the patient's health, especially, for example, when a screening or treatment is denied or postponed, or the patient is discouraged from seeking medical care out of fear of repeated discrimination. Many, if not most, of my transgender patients and the LA LGBT Center's transgender patients express strong distrust of the health care system generally and are reluctant to seek care outside the Center unless they are in a crisis or suffer from severe physical or mental stress. This is because they want to avoid discrimination or belittlement. Such incentives to avoid regular check-ups and other medical care can result in disease processes that are more advanced at diagnosis, less responsive to treatment, or even no longer curable in the case of some cancers.

12. In the case of the transgender woman I described above, her general medical condition gradually deteriorated over the several years it took for me to finally identify a surgeon who would take her case. She was suffering from systemic metabolic complications from the

chronic inflammation and skin breakdown caused by the hardened subcutaneous silicone injections. I feared for her survival. Fortunately, the surgeon who cared for her did so with kindness, respect, and compassion, and the patient has had an excellent result. The affirming surgeon saved her life. Nevertheless, the ultimate tragedy in my patient's case was that after the humiliating and callous abuse to which she was subjected by the academic center's specialists, she was completely unwilling to even consider seeing another surgeon for the next six-and-a-half years. Her suffering during that time was completely avoidable had she been treated with basic human respect from the beginning.

13. With existing health and health care disparities affecting the LGBTQ community – particularly the shortage of LGBTQ/HIV culturally competent providers – confusion and chaos resulting from the Revised Rule will further exacerbate existing barriers to health care and result in negative community health outcomes. The Revised Rule will remove any expectation that a provider will approach LGBTQ patients with compassion and respect for their dignity. Good medical care is based on trust as well as frank and full communication between the patient and their provider. Such communication will not happen if the patient is made to feel like a supplicant. It is the providers' responsibility to non-judgmentally elicit the patient's relevant health history, sexual history, substance-use history, lifestyle, and gender identity in order to provide appropriate care for the patients' health, both physical and mental. Incomplete communication, or miscommunication, can have dangerous consequences.

14. For instance, a patient who conceals or fails to disclose a same-sex sexual history may not be screened for HIV or other infections or cancers; and a patient who fails to fully disclose their gender identity and sex assigned at birth may not undergo medically-indicated tests or screenings (*e.g.*, some transgender men may require tests for cervical or breast cancer, and

some transgender women may require tests for testicular or prostate cancer). Patients need to be encouraged to fully disclose all information relevant to their health care and potential treatment, and they are unlikely to do so unless they are assured that the information they provide will be treated confidentially and with respect. The Revised Rule endangers the provider-patient relationship, and is likely to harm many patients' health, by discouraging patients from full disclosure, and by encouraging providers to discriminate and avoid topics that may offend their personal moral or religious beliefs in their encounters with patients.

15. Patients often receive delayed care or misdiagnoses when patients are reluctant to reveal their LGBTQ identity to health care providers out of fear of discrimination or disapproval. Another example of this involved a patient who suffered from a respiratory cough and increasing shortness of breath, which developed over several weeks. The patient was reluctant to go to the emergency room because of distrust of health care providers. After two weeks of suffering from severe symptoms at home, he was persuaded by his boyfriend to go the ER. When he arrived at the ER, the providers were so focused on COVID-19 that they failed to even consider the possibility of HIV-related illness. Had they asked about his health history, sexual history, or sexual orientation, they would have suspected HIV as a cause for his symptoms. Instead, the patient received an incorrect diagnosis and treatment. After two weeks of further decline, he presented at another LGBTQ-affirming clinic where they saw that he had a classic presentation of HIV-related pneumonia. Tragically, even though he was rushed immediately to another hospital where proper treatment was started, it was too late and he died shortly after admission. The nature of a health crisis like COVID-19 is that it inherently creates additional barriers to care for patients. The Revised Rule increases those barriers to treatment.

16. Not only is the Revised Rule discriminatory and harmful to my patients and to public health, but the timing of publication of the Revised Rule makes it especially egregious. We cannot afford additional discrimination in health care when patients are in their most desperate times of need for proper and nondiscriminatory health care. We need people to trust their health care providers, especially when their lives and the lives of those around them are at stake. In order to beat this virus, public health requires that all patients seek medical treatment and testing without hesitation or delay should they experience symptoms of COVID-19. By inviting discrimination against LGBTQ patients, the Revised Rule does the exact opposite, harming both patients and the general public.

17. The Revised Rule will cause LGBTQ patients and patients living with HIV to lose trust in their health care providers. The Rule will cause LGBTQ patients to attempt to hide their LGBTQ identities to an even greater degree when seeking health care services, especially from religiously-affiliated health care organizations, in order to avoid discrimination. The Revised Rule endangers the provider-patient relationship and is likely to harm many patients' health by discouraging patients from full disclosure about their gender identity, sexual orientation, or related medical histories. Patients will avoid raising any topics, questions, facts that they fear could possibly offend their health care providers' personal beliefs, resulting in harm to patients.

18. The Revised Rule is also likely to cause an increase in demand for my health care services. I have seen a spike in behavioral and mental-health issues resulting from discrimination and denials of health care services, and I will undoubtedly see an uptick in requests for my services and the services of the providers that I oversee at the LA LGBT Center because patients will come to us seeking affirming health care out of fear of discrimination elsewhere or because they were already discriminated against elsewhere. The Revised Rule

invites discriminatory behavior that is in direct conflict with the oath I swore as a doctor and many of the federal, state, and insurance rules, regulations, and statutes that I and other health care providers are required to follow.

19. Additionally, the Rule's removal of language access protections for Limited English Proficiency (LEP) patients will make it increasingly difficult for the LA LGBT Center and its health care providers, including me, to find appropriate referrals for our LEP clients. Without requiring accommodations for our limited English proficiency clients, our clients are at an increased risk of receiving inferior care and improper testing and delayed diagnoses when they seek health care services from outside providers. In addition, as discussed above, LGBTQ people already fear discrimination from their medical providers and have immense distrust of the health system. That distrust increases for LEP patients who are not provided with necessary translation services to communicate with their health care providers. Without necessary translations services, LEP patients tend to remain silent during consultations because they either cannot articulate the problems that they are experiencing, cannot comprehend what is being asked of them, or fear being open and honest with their providers about their difficulty understanding the providers' English. Patients may be reticent or worried about asking for a translation or articulating that they do not understand because they may want to present as and feel self-sufficient. One's ability to communicate subtly and precisely is hampered by the Revised Rule's removal of LEP accommodations. Health care is highly personal and has emotional impacts. This is heightened for LEP patients who as a result of the Revised Rule will be left navigating the system and care without the assistance of a translator.

20. The removal of LEP accommodations also will likely result in family members and friends of patients accompanying the LEP patients to their appointments. Many people think that

a family member or friend translating for a patient is sufficient, but that could not be further from the truth. There are a whole host of problems with having friends or family accompany a patient into the examining room, including, but not limited to, confidentiality issues, concerns about potential domestic violence, and concerns that patients, especially youth, may not be out about their LGBTQ identities to their family and friends. Relying on family or friends for translations is particularly dangerous for non-affirming families of transgender patients who would then create a barrier to health care. The end result is misdiagnoses, improper testing, and delay in treatments. In order to provide proper care to patients, there must be open lines of communication between physicians and their patients. The Revised Rule cuts off the line of communication and trust between providers and their patients.

21. These issues are amplified by COVID-19. It is hard enough for LEP patients or LGBTQ patients who fear discrimination in health care to communicate with their providers in person, let alone via telehealth. Each time a patient has their first telehealth visit, there is a learning curve. It is much more difficult for people to feel comfortable sharing information over the phone or video as opposed to in person consultations. The Revised Rule exacerbates these issues by inviting discrimination against LGBTQ patients and decreasing resources for LEP patients. The result is inferior medical care to patients and additional costs to the system, especially during a public health crisis like COVID-19.

22. The Revised Rule also adversely impacts the Center and its individual health care providers by necessitating the diversion and reallocation of resources to address the increase in the numbers of referral requests resulting from the Revised Rule. As a result of the Revised Rule's invitation to discriminate against LGBTQ patients, the LA LGBT Center is and will continue to be flooded with referral requests for LGBTQ-affirming services that the Center does not have

sufficient resources to provide. The Center will also have more difficulty finding LGBTQ-affirming health care providers, especially those with niche specialties, given that the Revised Rule emboldens health care providers to discriminate against and refuse services to LGBTQ patients in complete contradiction to medical and ethical standards of care.

23. For example, just a few weeks ago we received a call from a transgender patient whom we referred to an outside surgeon for an ear/nose/throat (ENT) issue because we do not provide those services at the Center. The patient later notified us that the physician conducted a breast exam on the transgender woman when the patient was very clear that she was only there for ENT-related issues. There was no reason for the physician to remove the patient's shirt and check her breasts. Such inappropriate professional behavior will increase because the Revised Rule sends a message to the medical field that LGBTQ people are unworthy of protections and quality care in accordance with medical and ethical standards of care. For that reason, we will have to divert our time and resources to vetting potential referrals to ensure that we are not sending our patients to outside health care providers that will discriminate or behave inappropriately and do more harm to our patients.

24. The Revised Rule is inherently demeaning and codifies our government's belief that the health care needs of LGBTQ people are unimportant. This proposed rule is shameful. As LA LGBT Center's Chief Medical Officer and Director of Clinical Research, my responsibility includes enforcing our nondiscrimination mandate with respect to all of our providers and staff. The Revised Rule is in direct contradiction with our obligations as physicians and health care providers. We have an obligation to treat all patients in a manner consistent with their best interests to achieve the best possible health results for our patients. The Revised Rule invites health care

providers to do the exact opposite. The increased discrimination resulting from the Revised Rule will harm our patients' health and public health at large.

[*Signature on next page.*]

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Dated this 6th day of July, 2020.

DocuSigned by:
Dr. Robert Bolan
5C5159E12C514C6...
Robert Bolan, MD

5

EXHIBIT A

Curriculum Vitae of Robert K. Bolan, MD

1/13/2020
CURRICULUM VITAE

A. PERSONAL INFORMATION

Name	**Robert Key Bolan, M.D., AAHIVS**
Business Address	Los Angeles LGBT Center 1625 N. Schrader Blvd. Los Angeles, CA 90028
Business Phone	(323) 993-7577

B. EDUCATION

College or University	University of Detroit Detroit, Michigan B.S. Biology 1968 With Honors
Medical School	University of Michigan Medical School Ann Arbor, Michigan M.D. 1972
Internship	St. Mary's Hospital Medical Center Madison, Wisconsin 1972-1973
Residency	St. Michael Family Practice Residency Milwaukee, Wisconsin 1975-1977
Honors and Awards	Leadership Award, San Francisco A2IDS Foundation May 1992
Licensure	California G39301
Board Certification	American Board of Family Physicians 1978, 1983, 1990, 1997, 2005, 2012
Specialty Certification	American Academy of HIV Medicine (AAHIVS)

C. PROFESSIONAL BACKGROUND

TEACHING RESPONSIBILITIES and ACADEMIC APPOINTMENTS:
Clinical Associate Professor of Family Medicine
University of Southern California (USC) – Keck School of Medicine
September 1995 – Present

Adjunct Clinical Professor of Pharmacy Practice
Western University of Health Sciences
February 2008 - Present

Assistant Clinical Professor

University of California San Francisco
Department of Family and Community Medicine
June 1981 - December 1996

Course Organizer and Clinical Faculty
"Clinical Approach to Gay and Lesbian Health Care"
An elective two hour credit course offered by the
University of California, San Francisco Medical School
June 1979 - April 1982

ADMINISTRATIVE RESPONSIBILITIES:
Acting (administrative) Director of Health & Mental Health Services
LA Gay & Lesbian Center
1625 N. Schrader Blvd.
Los Angeles, CA 90028
July 2001 – September 2002

Chief Medical Officer and Director of Clinical Research
Los Angeles LGBT Center
1625 N. Schrader Blvd.
Los Angeles, CA 90028
May 1996-Present

Director of HIV Services
USC School of Medicine
Department of Family Medicine
September 1995-December 2004

Acting Chair
Department of Family Practice
California Pacific Medical Center, San Francisco
January 1991-November1992

Medical Director
Gay Health Clinic
Presbyterian Medical Center, San Francisco
March 1982 – June 1983

Attending Physician
Presbyterian Medical Center Clinic, San Francisco
October 1979- August 1980

HOSPITAL AFFILIATIONS
Queen of Angeles/Hollywood Presbyterian Hospital, Los Angeles
January 1999- 2006

Cedars-Sinai Medical Center, Los Angeles
July 1999-Present

USC University Hospital, Los Angeles
September 1995- 2004

North Hollywood Medical Center, North Hollywood
May 1996-August 1998

California Pacific Medical Center, San Francisco
1979-1996

OTHER ACTIVITIES
Family Practice
Pacific Family Practice Medical Group
San Francisco, California
1979-September 1995

Family Practice
Hartland Clinic, S.C.
Hartland, Wisconsin
August 1977-July 1979

Emergency Medicine
Madison General Hospital
Madison, Wisconsin
June 1974-June 1975

Three-week intensive post-graduate course in Emergency Medicine
Philadelphia, Pennsylvania
April 1974

General Practice
Dells Clinic
Wisconsin Dells, Wisconsin
September 1973-June1974

Emergency Medicine
St. Clare Hospital
Baraboo, Wisconsin
June 1973-September1973

D. SOCIETY MEMBERSHIPS

NATIONAL AND INTERNATIONAL
American Academy of Family Physicians

American Academy of HIV Medicine
Member of Board for California/Hawaii Chapter
2004- Present

E. ACTIVIES IN AREA OF INTEREST

Core Curriculum Committee, American Academy of HIV Medicine
2001– 2009

CME Committee, L.A. HIV Inter-City Rounds

2000 - Present

Organizer and Supervisor, HIV Medicine Fellowship, a Post-Residency one-year training program
LA Gay & Lesbian Center, Jeffrey Goodman Special Care Program.
December 1998 – 2005

Chair, Research Committee, Los Angeles LGBT Center
Los Angeles, California
March 1998 – Present

Chair, Peer Review, LA Gay & Lesbian Center
Los Angeles, California
March 1998 - Present

Member, Mayor's AIDS Advisory Task Force
San Francisco, California
January 1985-April 1988

President and Chairman of the Board, San Francisco AIDS Foundation
San Francisco, California
June 1983-January 1986

Member, AIDS Advisory Task Force of the Director
San Francisco Department of Public Health
San Francisco, California
April 1983-January 1986

Member, Board of Directors, San Francisco AIDS Foundation
San Francisco, California
June 1983-June 1986

President – Elect, Bay Area Physicians for Human Rights (BAPHR)
July 1983-June 1984

Chair, BAPHR Research Committee
March 1983-1983

Chair, BAPHR Task Force on Kaposi's Sarcoma
June 1981-June 1983

Secretary, BAPHR
San Francisco, California
June 1980-June 1981

Director and Organizer, "Current Aspects of Sexually Transmitted Diseases II", a Symposium,
San Francisco State University
San Francisco, California
June 1980

Medical Director, Gay People's Union Venereal Disease Clinic
Milwaukee, Wisconsin
September 1977-July1979

F. RESEARCH ACTIVITIES

Site Principal Investigator, ATN 147, 148, 149: A Comprehensive Community-Based Strategy to Optimize the HIV Prevention and Treatment Continuum for Youth at HIV Risk, Acutely Infected, and with Established Infection. PI: Mary Jane Rotheram-Borus. Sponsor: ATN/NICHD 2017 - 2021

Site Principal Investigator, Performance Evaluation of the DPP HIV Syphilis Assay in the Intended User Setting. Protocol CP-HIV-SYPH03. Funder: Chembio. 2018 – 2019.

Co-Investigator, Four Corners: TGNC Health Research Advisory Network. Funder: Patient Centered Outcomes Research Institute. PI: Andie Baker, Howard Brown University. 2019 – 2021.

Co-Investigator, Understanding tobacco and cannabis use among LGBT emerging adults. PI: Ian Holloway, UCLA. Funder: Tobacco Related Diseases Research Program. 2018 – 2020.

Site Principal Investigator, Performance of Nucleic Acid Amplification Tests for the Detection of Neisseria gonorrhoeae and Chlamydia trachomatis in Extragenital Sites. Antibacterial Resistance Leadership Group Protocol ARLG_pNAAT-Yr3. PI: Jeffrey Klausner. Sponsor: National Institute of Allergy and Infectious Disease.2016-2018.

Site Principal Investigator, Randomized Trial to Prevent Vascular Events in HIV (REPREIVE) – ACTG Protocol A5332. PI (Grinspoon) AIDS Clinical Trial Group Investigators (Overton/Fichenbaum/Aberg/Zanni) Sponsor: National Heart, Lung, and Blood Institute, National Institute of Allergy and Infectious Diseases, National Institute of Diabetes and Digestive and Kidney Diseases. 2015-2022

Site Investigator, Men Who Have Sex with men & Substance Use Cohort at UCLA, Linking Infections, Noting Effects (mSTUDY). PI: Shoptaw/Gorbach. Sponsor: National Institute on Drug Abuse, National Institutes of Health. 2012-2023

Site Principal Investigator, Gilead 2920112. A Phase 3 Open-Label Safety Study of Elvitegravir/Cobicistat/Emtricitabine/Tenofovir Alafenamide Sintle-Table Regimen in HIV-1 Postitive Patients with Mild to Moderate Renal Impairment. 2013 – 2015.

Site Principal Investigator, Gilead 2920109. A Phase 3, Open-Label Study to Evaluate Switching from a TDF-Containing Regimen to a TAF-Containing Combination Single Tablet Regimen (STR) in Virologically-Suppressed, HIV-1 Positive Subjects. 2012 - 2016

Site Investigator, Protocol DMID 15-0090: Clinical Validation of Molecular Test for Ciprofloxacin-Susceptibility in *Neisseria gonorrhoeae*. PI Jeffrey Klausner Sponsor: Division of Microbiology and Infectious Diseases, National Institute of Allergy and Infectious Diseases, National Institutes of Health.. 2015-2019.

Site Investigator, CCTG 603: Randomized Controlled Trial of iTAB plus Motivational Interviewing for PrEP Adherence in Transgender Individuals: A Multicenter Trial of the California Collaborative Treatment Group. Funded by California HIV Research Program. 2015-2020.

A Phase 2b Randomized, Double-Blind, Double-Dummy Trial of 100 or 200 mg Once-Daily Doses of Cenicriviroc (CVC, TBR-652) or Once-Daily EFV, Each With Open-Label FTC/TDF, in HIV-1-Infected, Antiretroviral Treatment-Naïve, Adult Patients With Only CCR5-Tropic Virus. Funded by Tobira. 2011 – 2012.

Site Investigator, Los Angeles County PATH: PrEP and TLC+ for HIV Prevention. A California HIV Research Program (CHRP) Epidemic Interventions Demonstration Research Award. 4/2012 – 3/2016

Sub-investigator, Gilead 263-0110. A phase 3b randomized, open label study to evaluate the safety and efficacy of a single tablet regimen of emtricitabine/rilpivirine/tenofovir disoproxil fumarate compared with a single tablet regimen of efavirenz/emtricitabine/tenofovir disoproxil fumurate in HIV-1 infected, ARV-naïve adults. 2010 – present.

Sub-investigator, Gilead 264-0106. A phase 3 randomized, open label study to evaluate switching from regimens consisting of a ritonavir boosted protease inhibitor and two nucleoside reverse transcriptase inhibitors to emtricitabine/rilpivirine/tenofovir disoproxil fumurate fixed dose regimen in virologically suppressed HIV-1 infected patients. 2010 – present.

Co-Principal Investigator, Doxycycline Prophylaxis or Incentive Payments to Reduce Incident Syphilis among HIV-infected MSM who Continue to Engage in High Risk Sex: A Pilot Study funded by UCLA Center for HIV Identification, Prevention, and Treatment Services (CHIPTS) 2011. 8/1/2011 – present.

Principal Investigator, A Phase 3, Randomized, Double-Blind Study to Evaluate the Safety and Efficacy of GS-9350-boosted Atazanavir Versus Ritonavir-boosted Atazanavir Each Administered with Emtricitabine/Tenofovir Disoproxil Fumarate in HIV-1Infected, Antiretroviral Treatment-Naïve Adults. (GS-US-216-0114). Funded by Gilead, 5/2010 – present.

Principal Investigator, A Phase 3, Randomized, Double-Blind Study to Evaluate the Safety and Efficacy of Elvitegravir/Emtricitabine/Tenofovir Disoproxil Fumarate/GS-9350 Versus Efavirenz/Emtricitabine/Tenofovir Disoproxil Fumarate in HIV-1 Infected, Antiretroviral Treatment-Naïve Adults. (GS-US-236-0102). Funded by Gilead, 6/2010 – present.

Principal Investigator, A Phase 3, Randomized, Double-Blind Study to Evaluate the Safety and Efficacy of Elvitegravir/Emtricitabine/Tenofovir Disoproxil Fumarate/GS-9350 Versus Ritonavir-Boosted Atazanavir Plus Emtricitabine/Tenofovir Disoproxil Fumarate in HIV-1 Infected, Antiretroviral Treatment-Naïve Adults (GS-US-236-0103). Funded by Gilead, 4/2010 – present.

Site Investigator, Project AWARE: HIV Rapid Testing and Counseling in STD Clinics in the U.S.—an Adaptation of CTN 0032. Funded by NIDA, 12/2009 – 8/2011.

Principal Investigator, Evaluation of the Clinical Performance of the Determine® HIV- 1/2 Ag/Ab Combo Test (Clinical Protocol Number 0924401. Funded by Inverness Medical Innovations, Inc. Scarborough, ME, 9/2010 – 6/2011

Co-Investigator, Metromates: Transmission Behavior in Partnerships of Newly HIV Infected Southern Californians. Funded by NIH. 2008-present.

Principal Investigator, Correlation of Short-term Response of Viral Load to Maraviroc Added to a Failing Regimen, with Tropism Assay (A4001060). Funded by Pfizer, 2008 - present

Principal Investigator, A Multicenter, Double-Blind, Randomized, Placebo-Controlled Study to Evaluate the Safety and Antiretroviral Activity of MK-0518 in Combination With an Optimized Background Therapy (OBT), Versus Optimized Background Therapy Alone, in HIV-Infected Patients With Documented Resistance to at Least 1 Drug in Each of the 3 Classes of Licensed Oral Antiretroviral Therapies (019-00). Funded by Merck. 2006 - present

Principal Investigator, A Randomized, Multicenter, Double Blinded, Phase IV Study Comparing the Safety and Efficacy of Pegasys® 180µg plus Copegus® 1000 or 1200 mg to the Currently Approved Combination of Pegasys® 180µg plus Copegus® 800 mg in Interferon-naïve Patients with Chronic Hepatitis C Genotype 1 virus infection coinfected with human immunodeficiency virus (HIV-1) (PARADIGM). Funded by Roche. 2006 - 2008

Principal Investigator, A Multicenter, Randomized, Double-Blind, Placebo-Controlled Trial of A Novel CCR5 Antagonist, UK427,857, In Combination With Optimized Background Therapy Versus Optimized Background Therapy Alone For The Treatment of Antiretroviral-Experienced HIV-1 Infected Subjects (A4001027). Funded by Pfizer. 2004 – 2007

Co-Investigator, MWCCS (MACS/WIHS Combined Cohort Study) Funded by NIH/NHLBI, 2001 – present

Principal Investigator, Early Access of TMC125 in combination with other antiretrovirals in treatment-

experienced HIV-1 infected subjects with limited treatment options (TMC125-C214). Funded by Tibotec, 2007 - 2008

Principal Investigator, Early access of MK-0518 in Combination with an Optimized Background Antiretroviral Therapy (OBT) in Highly Treatment Experienced HIV-1 Infected Patients with Limited to No Treatment Options (023-00). Funded by Merck, 2007 - 2008

Principal Investigator, A Multi-center, Open-Label, Expanded Access Trial of Maraviroc (A4001050). Funded by Pfizer, 2007 - 2008

Principal Investigator, A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Multi-center Trial of Pregabalin Versus Placebo in the Treatment of Neuropathic Pain Associated with HIV Neuropathy (A0081066). Funded by Pfizer, 2006 - 2008

Principal Investigator, An Open-label, Extension Safety and Efficacy Trial of Pregabalin in Subjects with Neuropathic Pain Associated with HIV Neuropathy (A0081095). Funded by Pfizer, 2006 - 2008

Principal Investigator, A Phase 3, Randomized, Open-label Study of Lopinavir/ritonavir Tablets 800/200 mg Once-daily Versus 400/100 mg Twice-daily when Coadministered with Nucleoside/Nucleotide Reverse Transcriptase Inhibitors in Antiretroviral-experienced, HIV-1 Infected Subjects (M06-802). Funded by Abbott, 2007 - 2008

Principal Investigator, Utilization of HIV Drug Resistance Testing in Treatment Experienced Patients (Utilize Study 1182.116). Funded by Boehringer Ingelheim, 2007

Principal Investigator, A Comparative Randomized, Double-Blind, Double-Dummy, Multicenter Study of the Efficacy and Safety of miconazole Lauriad® 50 mg Administered Once a Day and Mycelex® Troches (clotrimazole 10 mg) Administered Five Times a Day in the Treatment of Oropharyngeal Candidiasis in Immunocompromised Patients (SMiLES BA2004/01/04). Funded by BioAlliance Pharma, 2006 - 2007

Principal Investigator, A Multicenter, Open-Label Study Evaluating the Safety and Efficacy of a New Investigational Protease Inhibitor (PI) With FUZEON® (Enfuvirtide) Plus Optimized Background in HIV-1 Infected Triple-Class Treatment-Experienced, Enfuvirtide-Naïve Patients (BLQ Study, ML 19712). Funded by Roche. 2006 – 2007

Principal Investigator, Early access of TMC114 in combination with low-dose ritonavir (RTV) and other antiretrovirals (ARVs) in highly treatment experienced HIV-1 infected subjects with limited to no treatment options (TMC114-C226). Funded by Tibotec. 2006

Co-Principal Investigator, Open-Label, Multiple-Dose, Drug Interaction Study to Assess the Effect of Nevirapine on the Pharmacokinetics of Atazanavir in HIV-Infected Individuals (ANDI). Funded by Bristol-Myers Squibb. 2006

Principal Investigator, A Phase III randomized, double-blinded, placebo-controlled trial to investigate the efficacy, tolerability and safety of TMC125 as part of an ART including TMC114/RTV and an investigator-selected OBR in HIV-1 infected subjects with limited to no treatment options (TMC125-C206). Funded by Tibotec. 2006 - 2008

Principal Investigator, A 48-Week, Randomized, Open-Label, 2-Arm Study to Compare the Efficacy of Saquinavir/Ritonavir BID Plus Emtricitabine/Tenofovir QD Versus Lopinavir/Ritonavir BID Plus Emtricitabine/Tenofovir QD in Treatment-Naïve HIV-1 Infected Patients (Gemini ML18413). Funded by Roche. 2005 - 2007

Principal Investigator, A Multicenter, Randomized, Double-Blind, Placebo-Controlled Trial of A Novel CCR5 Antagonist, UK427,857, In Combination With Optimized Background Therapy Versus Optimized Background Therapy Alone For The Treatment of Antiretroviral-Experienced, Non CCR5-Tropic HIV-1 Infected Subjects (A4001029). Funded by Pfizer. 2004 – 2008

Co-Principal Investigator, A 48-week prospective study comparing the safety and efficacy of switching from a Combivir (Zidovudine/ZDV + Lamivudine/3TC) based HAART regimen to a Viread (Tenofovir DF/TDF) + Emtriva (Emtricitabine/FTC) based HAART regimen in HIV-infected adults with HIV RNA < 50copies/ml (COMET). Funded by Gilead. 2004 - 2005

Principal Investigator, Tipranavir Open Label Safety Study (Trial # 1182.58). Funded by Boehringer Ingelheim. 2004 - 2005

Principal Investigator, A Large, Simple Trial Comparing Two Strategies for Management of Anti-Retroviral Therapy (SMART). Funded by NIH, DAIDS number CPCRA 065. 2003 - 2008

Principal Investigator, A Phase III, 48-week, open label, randomized, multicenter study of the safety and efficacy of the Abacavir/Lamivudine fixed-dose combination tablet administered QD versus Abacavir + Lamivudine administered BID in combination with a PI or NNRTI in antiretroviral experienced patients (ESS 30008). Funded by GlaxoSmithKline, 2002

Principal Investigator, Post exposure prophylaxis as a biobehavioral HIV intervention (PEP). Funded by City of Los Angeles, 2002 - 2004

Co-Investigator, Short cycle intermittent versus continuous HAART for the treatment of chronic HIV infection (M77). Funded by FAIR Foundation, 2002

Principal Investigator, Genotype assisted initial Nelfinavir study (GAIN). Funded by Agouran, 2001

Co-Investigator, A double blind, phase III extension study of SGN-00101 in the treatment of high grade anal intraepithelial neoplasia (AIN 0002). Funded by StressGen, 2001 - 2002

Co-Investigator, A randomized, placebo-controlled, phase III trial of SGN-00101 in the treatment of high grade anal intraepithelial neoplasia (AIN 0001). Funded by StressGen, 2000 – 2001

Co-Investigator, The impact of a prescriptive barriers-to-adherence questionnaire on HIV patients' adherence to HAART medications. Funded through University of Nevada at Reno, 2000

Co-Principal Investigator, Exploratory investigation of medical literacy: meaning of illness, information-seeking, and medical knowledge among people living with HIV/AIDS. Sponsored by University of Southern California, 2001 - 2002

Co-Investigator, A randomized, open-label, two arm trial to compare the safety and antiviral efficacy of GW 433908/Ritonavir QD to Nelfinavir BID when used in combination with Abacavir and Lamivudine BID for 48 weeks in antiretroviral therapy naïve HIV-1 infected subjects (APV 30002). Funded by GlaxoSmithKline, 2001 - 2002

Co-Investigator, Tenofovir DF (tenofovir disoproxil fumarate) Expanded Access Program. Funded by Gilead, April - October 2001

Principal Investigator, A phase II, open-label randomized study to compare the efficacy and safety of Epivir/Ziagen/Zerit versus Epivir/Ziagen/Sustiva versus Epivir/Ziagen/GW433908/Norvir for 96 weeks in the treatment of HIV-1 infected subjects who are antiretroviral therapy naïve (ESS 40001). Funded by Glaxo Wellcome, 2000 - 2002

Principal Investigator, A phase III randomized placebo controlled and double blinded study of IM862 for patients with muco-cutaneous AIDS associated Kaposi's Sarcoma (AMC 013). Funded by Cytran, 2000 - 2001

Principal Investigator, The prevalence of anemia in HIV infected patients (Anemia). Funded by OrthoBiotech, 2000 - 2001

Co-Investigator, Ziagen optimal regimen and resistance observational study (ESS 40009, ZORRO). Funded by Glaxo Wellcome, 1999 - 2000

Co-Investigator, A 96 week, randomized, open-label, multi-center trial to evaluate the safety and tolerability of the antiretroviral activity of Stavudine (40mg BID) + 3TC (150mg BID) + Nelfinavir (1250mg BID) versus Abacavir (300mg BID) + Combivir (150mg/300mg BID) versus Combivir (150mg/300mg) + Nelfinavir (1250mg BID) in HIV-1 infected female subjects (ESS 40002). Funded by Glaxo Wellcome, 1999 - 2000

Co-Investigator, ABT 378/ritonavir Early Access Program. Funded by Abbott , 1999 - 2000

Principal Investigator, A randomized, controlled, open-label comparison of continuing Indinavir vs switching to Norvir/Indinavir 400mg/400mg BID (NICE). Funded by Abbott, 1999 - 2000

Co-Investigator, Preveon (adefovir dipivoxil) Expanded Access Program. Funded by Gilead, 1998 – 2000

Co-Investigator, Role of the oral environment in HIV transmission and pathogenesis (HOT). Funded by NIH/NIDR through UCSF, 1998-2000

Principal Investigator, Brief safer sex intervention for HIV outpatient clinics (Partnership for Health Study). Funded by NIMH through USC, 1997 – 2001

G. PUBLICATIONS

ABSTRACTS, POSTERS, ORAL PRESENTATIONS

Beymer MR, Weiss RE, Sugar CA, Bourque LB, Gee GC, Morisky DE, et al. Are CDC Guidelines for Pre-Exposure Prophylaxis Specific Enough? Formulation of a Personalized HIV Risk Score for Pre-Exposure Prophylaxis Initiation. *Presented at the International AIDS Society Conference, Durban, South Africa* (2016).

Beymer MR, Bolan RK, Flynn RP. It's Not Just Black and White: Determining Within Group Differences for HIV Infection among African-American Gay and Bisexual Men. *Presented at the American Public Health Association Conference, New Orleans, Louisiana* (2014).

Hernandez W, Beymer MR, Flynn RP, Carpenter W, Bolan RK. Elucidating Reasons for PEP Use among Transgender Women at a Community-Based Clinic in Los Angeles, California. *Presented at the Transgender Health Summit, San Francisco, California* (2015).

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LETTERS TO THE EDITOR

Joseph Davey DL, Beymer MR, Roberts C, et al. Regarding Suthar et al.'s article Programmatic Implications of Acute and Early HIV Infection. J Infec Dis. 2015 Nov1;212(9):1351-60.

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H. SCIENTIFIC MEETINGS AND PRESENTATIONS

PARTIAL AND REPRESENTATIVE ONLY (Guest lecturer, numerous speaking engagements concerning clinical and educational AIDS issues)

Lecture: Anal Dysplasia, Community Forum; December 15, 2005. The Village at Ed Gould Plaza.

LA Department of Health Services STD Grand Rounds: Lymphogranuloma venereum; June 15, 2005.

Grand Rounds: LA HIV Intercity Rounds: HIV and Hepatitis B, May 20, 2005.

Lecture: 10th Conference on Retroviruses and Opportunistic Infections, Community Update; March 3, 2003. The Village at Ed Gould Plaza.

Lecture: Conference on Retroviruses and Opportunistic Infections, Clinical Provider Update, Jeffrey Goodman Clinic, March 7, 2003.

Lecture: “HIV Dynamics” USC Keck School of Medicine, to first year medical students; October 1999, 2000

Grand Rounds: LA HIV Intercity Rounds- Primary Pulmonary Hypertension; August 4, 2000

Lecture: “HIV Update” USC Family Medicine Board Review Course; June 26, 1999

Lecture: “HIV 1999: An Update” USC Family Medicine Primary Care Review Course; March 23, 1999

Lecture: “Anemia and HIV Disease” USC Family Medicine Grand Rounds; December 6, 1998

Lecture: “Sexually Transmitted Diseases” USC Family Medicine Board Review Course; June 13, 1998

Symposium Organizer and Speaker: “HIV Treatment Adherence: Toward an Understanding of Harmful Intrusions into Effective HIV Treatment Strategies.” November 1, 1997; USC School of Medicine.

Lecture: “ The Challenge of Medication in the Age of Anti-HIV Combination Therapy in the Mentally Ill Client” North Hollywood Medical Center Continuing Education Series; June 18, 1997

Lecture: “Primary HIV Infection” North Hollywood Medical Center Continuing Education Series; March 19,1997

Faculty Advisor and lecturer: “HIV/AIDS: What They’re Not Teaching You in School” Student Organization for Medical AIDS Awareness and Los Angeles AIDS Forum, Saturday January 6, 1996. USC School of Medicine.

Workshop: “Automated Medical Records, HIV managed care, and Clinical Outcomes Analysis”: 6th Annual Symposium: Clinical Care Options for HIV; May 2, 1996; Scottsdale

Workshop: “Managed Care and AETC Training”: Faculty Development Conference, AIDS Education and Training Centers; April 16, 1996; Asilomar

Workshop: “HIV Risk Reduction and Test Counseling”: Common Problems in Primary Care: 22nd Annual Review Course, April 2, 1996

Lecture: “HIV: Early Care” USC Student Health Clinic, February 16,1996.

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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

WHITMAN-WALKER CLINIC, INC., *et al.*,

Plaintiffs,

v.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, *et al.*,

Defendants.

Case No. 1:20-cv-1630

DECLARATION OF DR. WARD CARPENTER, MD
CO-DIRECTOR OF HEALTH SERVICES, LOS ANGELES LGBT CENTER

I, Ward Carpenter, declare as follows:

1. I am the Co-Director of Health Services for the Los Angeles LGBT Center (LA LGBT Center), where I was formerly the Associate Chief Medical Officer as well as the Director of Primary and Transgender Care.

2. I received my medical degree from the Robert Wood Johnson Medical School and had my residency at St. Vincent's Hospital Manhattan. I am board-certified in Internal Medicine and I hold certification in HIV Medicine. I am licensed to practice in the state of California. At the LA LGBT Center, I oversee all operations of the Federally Qualified Health Center ("FQHC"), including personnel, finances, clinical programs (mental health, psychiatry, primary care, HIV care, transgender health, substance abuse, and sexual health), nursing, case management, quality, risk management, and clinical research. I also maintain a panel of patients for whom I provide direct care. A copy of my curriculum vitae is enclosed as **Exhibit A**.

3. I am submitting this Declaration in support of Plaintiffs' Motion for Preliminary Injunction to prevent the revised regulation under Section 1557 of the Affordable Care Act

("ACA"), published by the U.S. Department of Health and Human Services ("HHS") on June 19, 2020 (the "Revised Rule"), from taking effect.

4. As the Co-Director of Health Services, I oversee the health care of over 32,000 patients who come to the LA LGBT Center for their care; I personally provide care to a panel of 200 patients. All of my patients identify as LGBTQ, and approximately 30% of my patients are people living with HIV. My patient population is also disproportionately low-income and experiences high rates of chronic medical conditions, homelessness, unstable housing, extensive trauma history, and discrimination and stigmatization in health care services. Many of these patients come to me from different areas of California, other states, and even other nations to seek services in a safe and affirming environment.

5. I provide a wide spectrum of health care services, including, but not limited to, HIV treatment, testing and prevention; STD testing, treatment and prevention; general primary care with an LGBT focus; and comprehensive transgender care. I have worked in this field of medicine continuously since 2004 and have personally cared for over 4,000 people in that time. I have worked in two Federally Qualified Health Centers, in New York and Los Angeles, as well as a private practice in New York. I am a nationally-recognized expert in the field of transgender medicine.

6. Many if not most of the individuals in our very diverse patient population face considerable stigma and discrimination – as people living with HIV, as sexual or gender minority people, and/or as people of color. Transgender people have a 41% lifetime risk of attempting suicide. This shocking observation can be explained by the intense dysphoria inherent in living in a body and a society that does not reflect and validate who you know yourself to be at a core level. In order to avoid this tragic consequence, transgender people require compassionate, sensitive, and

competent care that often includes medical and/or surgical procedures. These patients have significantly improved mental health outcomes when able to proceed with the treatments they need. Treatments for gender dysphoria have been deemed medically necessary by the World Professional Association of Transgender Health (WPATH) and the Endocrine Society, as well as other major medical organizations, in the same way that the American College of Cardiology has deemed treatment for hypertension medically necessary. In fact, in the course of treating gender dysphoria, endocrinologists and other health care providers use the same medications to treat transgender people as they use to treat non-transgender people with hormone deficiencies.

7. Under the Revised Rule, not only are health care providers invited to discriminate against LGBTQ patients, but insurance providers are encouraged to stop providing coverage for medically necessary, life-saving procedures and medications to treat gender dysphoria. Medical personnel who are duty-bound to treat life-threatening conditions (*e.g.*, hypertension) are now being invited to refuse to treat or cover care for a condition that could become life-threatening if left untreated – gender dysphoria –despite having the necessary tools and expertise to do so. Health care discrimination like this will have immediate negative consequences for a distinct and oppressed minority group. It should not invited and encouraged, as it is in the Revised Rule.

8. There is every reason to believe that the Revised Rule encourages health care providers to claim a right to refuse care or opt out of serving patients with particular needs, based on religious or moral beliefs, and will result in more discrimination, mistreatment, and denials of health care services against LGBTQ patients and patients living with HIV at other clinics, doctors' offices, hospitals, pharmacies, and other health care facilities outside of the LA LGBT Center. Even before the Revised Rule was proposed or issued, I and the other providers that I supervise at the LA LGBT Center treated many patients who have experienced traumatic stigma and

discrimination – based on their sexual orientation, gender identity, HIV status, and/or other factors – when seeking care from other providers. For example:

a. A transgender patient went to a urologist due to uncomfortable urination lasting for several years after her vaginal surgery. She was repeatedly referred to as "sir" and "he" despite repeated requests to use the correct pronouns. When the patient confronted the clerk, the clerk said "this is what your ID says, so this is how we will refer to you." When she saw the doctor, he also called her "sir," completely humiliating her in the most unprofessional manner. He did not close the door to the exam room during their visit, so that the entire waiting room could hear his conversations with her, and he asked her to remove her pants in full view of the waiting room. She was so traumatized by this experience that four years later, she continues to live with daily pain rather than risk being subjected to discrimination by another transphobic urologist.

b. A transgender patient started bleeding profusely from her vagina one week after surgery. Because there are so few trans-competent surgeons in the United States, this patient's surgeon was thousands of miles away. When she finally spoke to an ER doctor, the physician looked disgusted and said "what do you want me to do about it?" then walked away. She had to pack her own vagina with gauze pads and leave the ER, not knowing if she would live or die, and only coming to see us three days later after having lost a significant amount of blood. These horrific incidents will increase as a result of the Revised Rule. The likely result: patients will die.

c. A gay male patient with a serious and concerning neurological condition went to a neurologist. At this visit, the doctor had religious brochures throughout the waiting room. On arrival in the exam room, he was given a brochure about a particular Christian faith and asked if he had any questions. The patient felt extremely uncomfortable with this insertion of religion into what he felt should be a neutral space. As a result, he did not return for care and experienced a delay of several more months trying to find a new doctor he could trust.

d. A person living with HIV was referred to a surgeon for a routine procedure. The surgeon sent a note back to the patient's primary care physician asking him to refer the patient to someone "who was more familiar with treating patients like him." Again, this patient waited another two months to have this surgery, which could have caused severe or life-threatening complications.

e. A lesbian woman went to her doctor and was told that lesbians are not at risk for HPV and, therefore, she did not need cervical cancer screening. This patient knew enough to find a new doctor, but many patients would accept this information as fact and never receive a Pap smear, significantly increasing their chances of dying from cervical cancer. This type of medical error based on discriminatory stereotypes demonstrates what will happen when medical personnel are invited to discriminate instead of focusing on the health needs of patients in their care.

f. A gay man went to his primary care physician with urinary burning and discharge. Because his health care provider did not ask, the provider did not know that this patient was sexually active with men. Therefore, the provider did only one test, which was negative, and sent him to a urologist. The urologist did another test, which was negative, then performed a procedure to look inside this man's bladder with a camera. It was not until he came to the LGBT Center that we performed a proper medical history and exam and were able to treat him immediately for his sexually transmitted infection. We also determined that he had sex with five other people from the time of his first symptoms to the time he was finally treated, weeks later. Had any of these providers stopped to ask the man about his sexual practices, they would have immediately tested him and treated him for a sexually transmitted disease. Instead, he saw three providers, received hundreds of dollars in unnecessary testing and passed his infection along to five other people who themselves had to go down similar testing and treatment paths.

9. In sum, the message of these examples is clear: when patients are discriminated against, stereotyped, and mistreated in medical establishments, patients stop seeking care or their care is detrimentally delayed out of fear of repeated discrimination and denials of care. As a result, their conditions remain untreated for a much longer period of time, if they ever get treatment, resulting in much more acute conditions, ultimately costing the health care system millions of dollars in unnecessary expenses while harming patients and public health, including by increasing costs on the Center. When medical staff fail to care for every patient in the best way that they can,

putting patients' best interests at the center of medical care, medical mistrust is worsened, care is delayed, and health care becomes more expensive.

10. These incidents reveal that many health care providers and other staff harbor explicit or implicit biases against LGBTQ people and people living with HIV. Because of legal requirements, health care facility nondiscrimination policies, and professional norms, many of them have kept their personal beliefs and feelings in check. By empowering health care staff to think that they have the right to act on their personal beliefs, even at the expense of patient needs, the Revised Rule is very likely to result in many more incidents of discrimination and greater harm to LGBTQ individuals and patients living with HIV who are struggling with mental health or substance use issues, including the patients whom I treat and whose treatment I supervise.

11. Such experiences are not only insulting and demoralizing for the patient, but can jeopardize the patient's health, when a screening or treatment is denied or postponed, or the patient is discouraged from seeking medical care out of fear of repeated discrimination. Many if not most of my and the LA LGBT Center's transgender patients express strong distrust of the health care system generally, and a demonstrative reluctance to seek care outside the LA LGBT Center unless they are in a crisis or in physical or mental stress. This is because they want to avoid discrimination or belittlement. Such incentives to avoid regular check-ups and other medical care can result in disease processes that are more advanced at diagnosis, less responsive to treatment, or even no longer curable in the case of some cancers. Already, my patients are arriving at the LA LGBT Center with more acute medical conditions than they would otherwise because anti-LGBTQ policies fomenting discrimination, like the Revised Rule, has caused patients to fear receiving necessary medical care.

12. It is extremely difficult to provide effective care after patients have been rejected or discriminated against by other providers. The patients' level of trust at that point is so low that they expect to mistreated, stereotyped, and discriminated against. This requires providers at the LA LGBT Center to spend a significant amount of time trying to undo the damage (often cumulative, particular with intersectional marginalized identities) of such care. Patients who have been discriminated against have lost complete trust in the system and in health care providers. The Revised Rule has caused and will continue to cause additional discrimination against our patients at other facilities. As a result, we physicians and the LA LGBT Center will need to hire extra mental health staff to assist in unpacking our patients' health care trauma so that our patients are able to engage in our services and trust our health care providers in a meaningful way. When patients are discriminated against elsewhere, every patient contact at our facility will need to spend more time and resources assisting those patients, from front desk to triage staff. Discrimination creates added health stressors that damage the patient-physician relationship, resulting in inferior health outcomes for patients. It takes a long time to re-earn the trust patients hope for, but are afraid to give us. The Revised Rule has and will continue to increase patient trauma, and in turn, increase the Center's workload, consume its resources and make it more difficult to provide patients with the care that they need.

13. With existing health and health care disparities that harm the LGBTQ community – particularly the shortage of LGBTQ/HIV culturally competent providers – the Revised Rule has and will continue to create chaos and confusion, which will further exacerbate existing barriers to health care and result in negative community health outcomes. I have already received countless calls and visits from LGBTQ patients, particularly transgender patients, concerned that their surgeries are canceled and that they will no longer have access to hormone therapy to treat gender

dysphoria as a result of the discriminatory Revised Rule. Patients are concerned that under the Revised Rule, they will no longer be able to access necessary medical services.

14. Good medical care is based on trust as well as frank and full communication between the patient and their provider. In many, if not most encounters, providers need patients to fully disclose all aspects of their health history, sexual history, substance-use history, lifestyle, and gender identity in order to provide appropriate care for the patients' health, both physical and mental. Incomplete communication, or miscommunication, can have dangerous consequences. For instance, a patient who conceals or fails to disclose a same-sex sexual history may not be screened for HIV or other relevant infections or cancers. A patient who fails to fully disclose their gender identity and sex assigned at birth may not undergo medically-indicated tests or screenings (such as tests for cervical or breast cancer for some transgender men, or testicular or prostate cancer for some transgender women). Patients need to be encouraged to fully disclose all information relevant to their health care and potential treatment, which can be achieved only when patients are assured that the information they provide will be treated confidentially and with respect.

15. The Revised Rule will cause LGBTQ patients to attempt to hide their LGBT identities when seeking health care services, especially from religiously-affiliated health care organizations, to avoid discrimination. The Revised Rule endangers the provider-patient relationship and is likely to harm many patients' health by discouraging patients from full disclosure about their gender identity, sexual orientation, or medical histories and encouraging providers to avoid topics that may offend their personal moral or religious beliefs in their encounters with patients. Patients will avoid raising any topics, questions, or facts that they fear could possibly offend their health care providers' personal beliefs, resulting in harm to patients. When patients are unwilling to disclose their sexual orientation and/or gender identity to health

care providers out of fear of discrimination and denial of treatment, their mental and physical health is critically compromised.

16. The Revised Rule will also cause an increase in demand for my health care services and the services of the providers whom I supervise. I have seen a spike in behavioral and mental-health issues resulting from discrimination and denials of health care services because discriminatory rules like the Revised Rule cause LGBTQ patients and patients living with HIV to lose trust in their health care providers (either out of fear of discrimination or on account of being denied care). As a result, there will be an increase in demand for my and my department's services that will limit my ability to provide adequate care and time to my patients. This will increase wait times for my patients, and the delays in care may worsen conditions for which my patients are seeking treatment and outcomes of care.

17. The Revised Rule is in direct conflict with the oath that I swore as a doctor and many of the federal, state, and insurance rules, regulations, and statutes that I am required to follow. Like all physicians, I swore an oath to do no harm and to care for the people who need me to the best of my ability. Physicians are not ethically allowed to refuse care even to someone because of who they are. The fact that the Revised Rule suggests that such discriminatory behavior is allowed, has personally caused me great confusion and stress. In light of the oath I took, it is unclear to me how I can work collaboratively with colleagues who may discriminate against my patients without violating current medical ethical and legal standards of care.

18. The Revised Rule makes it impossible for me and my patients to trust the specialists on whom we rely to serve as critical partners in the care team. Care for a patient cannot be effectively provided if there is no trust. A patient may not go to a specialist appointment outside the Center if they fear discrimination. And in such a situation, for example, a person who initially

had mild chest pain but who never received the proper care suddenly is in the ER with a massive heart attack, costing the workforce and the health care system hundreds of thousands of dollars.

19. The Revised Rule's removal of language access protections for Limited English Proficiency (LEP) patients will put our patients at an increased risk of receiving inferior care and improper testing and delayed diagnoses when they seek health care services from outside providers. This sea change is contrary to medical ethics and standards of care. Without necessary translations services, LEP patients tend to remain silent during consultations. For example, if translators are not required, LEP patients tend not to speak up and tell me that they are failing to take their medications or are feeling ill. Instead, the more typical patient response is "I'm fine, thank you," because of the difficulty of articulating in English their medical needs, concerns and pains. We sometimes do not even know that they are LEP patients until a translator is provided because patients are often embarrassed to mention their LEP. If health care providers are not mandated to provide translators, patients tend not to speak up about needing translation services. The result is that providers cannot provide proper services to such patients because they cannot understand the patients' full medical needs, histories, and the extent of their problems. This leads to misdiagnoses, delays in care, and improper treatment plans. And the end result is that our patients end up in the emergency room dying unnecessarily. By removing mandatory accommodations for LEP patients, the Revised Rule causes harm to patients and increases health care costs overall.

20. The Revised Rule is especially egregious and harmful during a pandemic like COVID-19 when patients most desperately need to know that they will have somewhere to go for nondiscriminatory health care should they contract the virus. During a pandemic, access to health care services is paramount. The Revised Rule's invitation for health care providers to discriminate

against LGBTQ people and LEP patients does the exact opposite. The Revised Rule sends a message to LGBTQ and LEP patients that they are not deserving of equal access to health care, deterring such populations from seeking care, even in cases of emergency. When you empower discrimination, people understand and believe "the health care system is not for me." This discrimination harms our patients and those around them during a global pandemic. People will not show up to the health care system, and they will then spread coronavirus to countless more people around them. We already have problem with transgender people avoiding the emergency room when they need care out of fear of discrimination. After a person has been told enough times by an ER: "we don't serve your kind here," they are not likely to go back even if it means they might die. I imagine LGBTQ people have died at home, avoiding an ER, out of fear of being subjected to such discrimination in their most vulnerable moments. The Revised Rule multiplies this very serious problem.

21. The Revised Rule will also adversely impact the LA LGBT Center and its individual health care providers, including me, by necessitating the diversion and reallocation of resources to address the increase in the numbers of referral requests resulting from the Revised Rule. The Revised Rule has increased requests for referrals to LGBTQ-affirming outside providers for services that the LA LGBT Center does not have sufficient resources to provide. The Center will also have more difficulty finding health care providers to refer patients to, especially those with niche specialties, given that the Revised Rule emboldens health care providers to discriminate against and refuse services to LGBTQ patients in complete contradiction to medical and ethical standards of care. There are cities or insurance networks with only 2 or 3 specialists of a certain type (e.g. electrophysiologists). If those few people discriminate, my patients could be in the very real position of having literally no access to that type of care.

22. This is also especially concerning for the Center's LGBTQ youth who may not even be out to many people. If our youth encounter providers who are homophobic or transphobic, this will result in serious suicide risks. In turn, we physicians will have to proactively call providers before referring patients to make sure that the outside providers will not discriminate against our patient and cause more harm than good. This effort will soak up more of the Center's time and money. Not having the 2016 Final Rule to reinforce health care providers' obligation to provide nondiscriminatory care will make these efforts much more difficult.

23. One of the guiding ethics of medicine is to treat all patients equally. We do not treat blue-eyed people better than brown-eyed people. We do not treat women better than men. We do not provide better care to blonde-haired people than red-haired people. Medical personnel see people in their most vulnerable states; the trust placed in us is sacred. Allowing the Revised Rule to go into effect will create division within the medical field, which must be united around values of inclusion and acceptance, especially at a time of a global pandemic. The Revised Rule frustrates the mission and activities of the LA LGBT Center, my mission and activities, medical ethics, and established standards of care.

[*Signature on next page*.]

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Dated this 6th day of July, 2020.

DocuSigned by:
Ward Carpenter
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Ward Carpenter, MD

EXHIBIT A

Curriculum Vitae of Ward S. Carpenter, MD

Relevant Experience

Co-Director of Health Services, Associate Chief Medical Officer: *Los Angeles LGBT Center* March 2018-present

- 80% administration: responsible for oversight of entire operations of FQHC including personnel, finances, clinical programs (mental health, psychiatry, primary care, HIV care, transgender health, substance abuse), nursing, case management, quality, risk management
- 20% clinical: general primary care, HIV care, comprehensive transgender care, office-based opiate treatment

Associate Chief Medical Office, Dir of Primary and Transgender Care: *Los Angeles LGBT Center* March, 2016 – present

- 60% clinical: general primary care, HIV care, comprehensive transgender care, office-based opiate treatment
- 40% administration
  - Practice management lead clinician
  - Quality management lead clinician
  - Health Information Systems lead clinician
  - Clinical supervision of advanced practice providers
  - Creation and management of PREP program
  - Creation and management of MAT program
  - Creation and management of Transgender Pre-Surgery Program
  - Operations of primary care and transgender health programs

Director of Primary Care and Transgender Care Services: *Los Angeles LGBT Center* Oct 2013-March 2016

- General adult primary care
- Comprehensive HIV care
- Transgender care including hormone management and general primary care
- Administration of primary care program including strategic planning and execution of quality measures, program improvement measures, direct supervision of advanced practice providers
- Administration of transgender care program including strategic planning and execution of quality measures, program improvement measures, direct supervision of advanced practice providers

Member, Participant Advisory Committee: *PRIDE Study @ UCSF* Jan, 2016 – present

- Represent the voices of the Los Angeles LGBT Center, healthcare providers, gay cisgender men and the greater Southern California region as we design and implement this transformative longitudinal study of LGBTQ health

President and Primary Care Internist: *Ward Carpenter Integrative Medicine, NY, NY* March, 2009 – Sept 2013

- Full-time primary care to 2000 adult patients and additional 500 HIV patients
- Management of staff, accounts, billing, supplies and marketing for practice

Primary Care Internist: *Callen – Lorde Community Health Center, New York, NY* July, 2004 – Oct, 2010

- General adult primary care
- Comprehensive HIV care

- Transgender medicine
- Clinical supervision and instruction of rotating medical and physician assistant students

Director of Operations: *Fire Island Volunteer Medical Clinics, Brookhaven, NY* January – November, 2006

- Responsible for all aspects of clinic management including recruiting providers, credentialing providers, obtaining insurance, purchasing medicines and supplies, managing patient charts and billing, training and supervising providers, creating training manual. Additionally served as volunteer provider

Acting Associate Medical Director: *Callen – Lorde Community Health Center, New York, NY* January – April, 2006

- Responsible for running weekly provider meetings, creating provider schedules, addressing patient complaints, representing provider concerns to senior management, assisting the Medical Director with all aspects of clinic management

Education & Training

Residency in Internal Medicine-Pediatrics	*SVCMC – St Vincent's Hospital Manhattan*	June, 2004
MD	*UMDNJ – Robert Wood Johnson Medical School, Camden, NJ*	May, 2000
BS	*University of Richmond, Richmond, Va.*, Psychology with Honors	May, 1996
BA	*University of Richmond, Richmond, Va.*, History with Honors	May, 1996

Lectures

Plenary Session: *Update on Transgender Health.* HIV/AIDS on the Front Line Annual Conference at University of California, Irvine. April 27, 2016

Licensure & Certification

Certificate in HIV Medicine	2007 - present
Board Certified in Internal Medicine	2004-2024
Licensed in California	2012 - present
Licensed in New York State	2004 – 2014
X-waiver for Buprenophine	2016-present

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

WHITMAN-WALKER CLINIC, INC., *et al.*,

Plaintiffs,

v.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, *et al.*,

Defendants.

Case No. 1:20-cv-1630

DECLARATION OF ADRIAN SHANKER, EXECUTIVE DIRECTOR, BRADBURY-SULLIVAN LGBT COMMUNITY CENTER

I, Adrian Shanker, declare as follows:

1. I am the Founder and Executive Director of Bradbury-Sullivan LGBT Community Center ("Bradbury-Sullivan Center").

2. I assumed that role in 2014 when Pennsylvania Diversity Network restructured into Bradbury-Sullivan Center. I received a Bachelor's degree from Muhlenberg College in Religion Studies and Political Science in 2009 and earned a Graduate Certificate in LGBT Health Policy & Practice from The George Washington University in 2017. I previously volunteered as Board President of Equality Pennsylvania, served on the Office of Health Equity Advisory Board for the Pennsylvania Department of Health, and co-chaired the community advisory committee for LGBT Healthlink, which was a CDC-funded national disparity network for LGBT tobacco and cancer disparity work.

3. Bradbury-Sullivan Center is a 501(c)(3) non-profit organization that is based in Allentown, Lehigh County, Pennsylvania, and incorporated in Pennsylvania. Bradbury-Sullivan Center is a comprehensive community center dedicated to advancing community and securing the health and well-being of the lesbian, gay, bisexual, and transgender (LGBT) people of the Greater

Lehigh Valley, a historically under-served region of Pennsylvania for the LGBT community. Bradbury-Sullivan Center provides programs and services to thousands of community members throughout the year.

4. At Bradbury-Sullivan Center, in addition to staff management, board development, fundraising, and strategic planning, I oversee administration of data collection for the Pennsylvania LGBT Health Needs Assessment. With Health Programs employees at Bradbury-Sullivan Center, I also develop health promotion campaigns to make behavioral, clinical, and policy changes to improve LGBT health. In 2017 and 2018, I led the successful community efforts to ban "conversion therapy" in the cities of Allentown, Bethlehem, and Reading, Pennsylvania. I currently serve as LGBTQ subcommittee chair of the Pennsylvania Department of Health's COVID-19 Health Equity Response Team.

5. I am submitting this Declaration in support of Plaintiffs' Motion for a Preliminary Injunction to prevent the revised regulation under Section 1557 of the Affordable Care Act ("ACA"), published by the U.S. Department of Health and Human Services ("HHS") on June 19, 2020 (the "Revised Rule"), from taking effect. The Revised Rule eliminates explicit regulatory protections for LGBT people in health care that were included in the 2016 Final Rule, which was promulgated under Section 1557 in May 2016.

6. Bradbury-Sullivan Center's programs and services for the LGBT community include arts and culture, health promotion, youth programs, pride programs, and supportive services. Youth services include healthy eating, active living, and HIV prevention in an every-day out-of-school program. Supportive services include providing non-judgmental HIV/STI testing, ACA open enrollment events, medical-marijuana enrollment assistance, and support groups, as well as hosting a free legal clinic. Bradbury-Sullivan Center also provides referrals to health care

providers, including providers engaged in services for transgender community members and family-planning services.

7. In addition to obtaining services from Bradbury-Sullivan Center, patrons of Bradbury-Sullivan Center often access health care services from health care providers in our area, including religiously-affiliated hospitals and organizations. Bradbury-Sullivan Center works with patrons who have experienced discriminatory treatment when accessing health care services from such organizations and advocates on behalf of those patrons by providing referrals to LGBT-welcoming health care providers and health care agencies, training agencies to provide LGBT-affirming health care services, and, when necessary, communicating with the agencies to inform them of their legal obligations to serve LGBT people. The Revised Rule has major effects on Bradbury-Sullivan Center's advocacy and ability to continue such services given that the Revised Rule invites health care providers to discriminate against LGBT patients and Pennsylvania has no explicit statutory protections against discrimination on the basis of sexual orientation, gender identity, or transgender status.

8. Bradbury-Sullivan Center has used the 2016 Final Rule's explicit regulatory protections for LGBT people and clear guidance in order to advocate on behalf of LGBT patrons and remind health care providers and insurance companies of their obligations to provide health care services in a nondiscriminatory manner. For example, last year Bradbury-Sullivan Center used the 2016 Final Rule to advocate on behalf of a transgender youth whose family insurer denied coverage for his hormone therapy to treat gender dysphoria. Only after the Bradbury-Sullivan Center contacted the insurer and advocated on the youth's behalf did the insurer reverse course, provide coverage for the child's medically necessary care, and apologize to our patron and their child for their discrimination. Bradbury-Sullivan Center used the 2016 Final Rule to inform the

insurer that its actions were at odds with the law and hold it accountable for its discrimination. If the Revised Rule takes effect, there will be additional instances of discrimination by health care providers and insurance companies,. At the same time, the Revised Rule's elimination of explicit nondiscrimination protections will make it more difficult for Bradbury-Sullivan Center to advocate for its patrons who encounter health care providers that discriminate against them or insurers that deny coverage for medically necessary treatments for LGBT patients.

9. Nondiscrimination protections in health care are necessary. Bradbury-Sullivan Center knows from its work with community members and from local and national research that we can never assume that care will be offered equitably to LGBT patients without these protections that reinforce health care providers' obligations to their patients. The 2016 Final Rule provided robust protections that strengthen Bradbury-Sullivan Center's ability to advocate for nondiscriminatory health care for its patrons who experience discrimination. The Revised Rule will make the success of our advocacy much more difficult if not impossible in many circumstances. Nondiscrimination protections in health care are essential to ensure that LGBT people receive health care necessary to survive.

10. Furthermore, it is particularly egregious for HHS to establish additional barriers to care for LGBT people during the global COVID-19 pandemic, when people may be in their most desperate times of need for medical care. Because of higher risk factors such as smoking, higher incidence of cancer and unsuppressed HIV, and decades of barriers to care that have caused many LGBT people to delay or avoid seeking healthcare when they are sick, LGBT people are uniquely vulnerable to COVID-19 and the worst effects of COVID-19.

11. Federal health care nondiscrimination protections, such as those in the 2016 Final Rule, are one of the most significant assurances Bradbury-Sullivan Center can provide to

community members to encourage them to seek care. For example, in late March 2020, early in the COVID-19 quarantine in Pennsylvania, a transgender community college student called Bradbury-Sullivan Center to ask if it would be safe to receive a COVID-19 test as a transgender person at one of the local hospitals in our region. Because of the 2016 Final Rule, I was able to assure the student that they should make an appointment for the COVID-19 test. I was then able to call an administrator at the hospital to remind them that the provision of COVID-19 testing and treatment must be done in a nondiscriminatory manner, in accordance with the 2016 Final Rule promulgated under Section 1557.

12. Because the Revised Rule will increase discrimination and, in turn, LGBT people's distrust in the health system, LGBT people are less likely to seek testing and treatment if they are experiencing symptoms potentially associated with COVID-19. This makes it harder for Bradbury-Sullivan Center and other health care organizations to help stem the pandemic, thereby potentially exposing more people to COVID-19, to which LGBT people are already more vulnerable.

13. Bradbury-Sullivan Center has already had to divert resources to educating the LGBT community about safety precautions necessary during the pandemic and their rights under the law to nondiscriminatory care should they need COVID-19 testing or emergency respiratory intervention. Bradbury-Sullivan Center also developed a specific webpage with local LGBT community information about COVID-19 and updated the site multiple times each week during the months of March, April, May, and June. And since the Revised Rule was published, given its invitation to discrimination against LGBT people, Bradbury-Sullivan Center has spent significant time contacting hospitals and treatment centers to ensure that they provide nondiscriminatory care

to LGBT patients throughout all of their practices, but particularly in their COVID-19 treatment and testing facilities.

14. The Revised Rule already has and will continue to frustrate the progress that Bradbury-Sullivan Center has made assisting access to health care for LGBT people. By increasing LGBT people's fear and distrust of health care providers, the Revised Rule has will continue to have devastating impacts on our patrons' lives and on the public health at large. Our patrons need to trust the health care system now more than ever during this pandemic. If people feel sick, we need them to receive a COVID-19 test and get treatment, if necessary. We cannot afford for people to avoid health care treatment when they are presenting COVID-19 symptoms out of fear of discrimination. The Pennsylvania Patient Safety Authority has already affirmed that "it is a patient safety issue if LGBT people delay or avoid seeking care due to a fear of mistreatment."

15. Bradbury-Sullivan Center knows from the 2018 Pennsylvania LGBT Health Needs Assessment that approximately 1 in 5 LGBT Pennsylvanians do not have a primary care physician to call if they fall ill. Patients right now are weighing the risk of COVID-19 versus the discrimination and attendant harms that they may face in the health care system when they arrive for COVID-19 treatment. In turn, Bradbury-Sullivan Center has had to redirect staff to focus on efforts to educate hospitals and patrons about COVID-19 and the importance of providing nondiscriminatory health care services to LGBT patients. The Revised Rule only increases people's fear and distrust of the health care system and causes them to further avoid testing and treatment, resulting in harm to our LGBT patrons, increased costs to the health care system, and harm to public health at large.

16. Bradbury-Sullivan Center services a region of Pennsylvania with limited options for LGBT-specific health care services. Finding LGBT-affirming health care options is already a struggle for the LGBT community in the region and becomes more challenging when seeking care for an LGBT-specific concern. LGBT patients experience both geographic barriers to health care and barriers to accessing LGBT-affirming health care. For some medical specialties, often only one or very few health care providers in the region have the training and experience necessary to treat a patient. The discrimination fostered by the Revised Rule could make it practically impossible for a patient to receive any specialty care at all. This is especially concerning given that several of the region's health care providers, including a hospital in the City of Allentown, are religiously-affiliated organizations that could claim religious-based objections to providing any and all care to LGBT patients, invoking the Revised Rule to claim an exemption from existing nondiscrimination laws, relevant medical ethical rules, and standards of care. The Revised Rule will worsen health disparities affecting the LGBT community and exacerbate the difficulties that members of the LGBT community have in finding and accessing necessary and respectful health care.

17. Bradbury-Sullivan Center patrons are already experiencing negative effects from discrimination in the provision of health care, compromising their health and wellbeing. For example:

a. We heard from a community member whose family member was a patient in an inpatient-care setting and was forced to participate in a so-called "conversion therapy" support group. When the patient complained about such requirements, he faced harassment and retaliation.

b. Another community member visited Bradbury-Sullivan Center for HIV testing after experiencing judgmental treatment from his primary health care provider. He told our staff that he did not feel comfortable receiving the service from his original health care professional as a result of the judgmental treatment.

c. Additionally, a program participant in one of our transgender support groups shared with a staff member that her doctor made negative, religious-based comments to her three years ago and as a result she avoided medical care for those three years. She went back for a physical examination this year and the doctor refused to touch her during her physical.

d. One patron struggled for years to find affirming providers to treat her gender dysphoria. After scheduling her gender confirmation surgery and preparing herself emotionally for the surgery, she learned that her surgeon was *not* in fact affirming and she was forced to cancel her surgery. She was devastated and called Bradbury-Sullivan Center in tears for our assistance. She had been so excited to finally live in the body that affirmed who she is. However, her discriminatory experiences caused her significant depression and distrust of health care providers. It took her two years to find another provider and reschedule her surgery. The nearest available surgeon with the appropriate medical training was 2.5 hours away from her home. Then, her second scheduled gender confirmation surgery was canceled due to COVID-19. This patron is at a loss for what to do next due to the

devastating impact of cancellation of medically-necessary gender affirming care.

18. Bradbury-Sullivan Center also assists patrons who contact the Center because they have difficulty finding LGBT-affirming health care services. Bradbury-Sullivan Center recently received an increase in referral requests. As a result of issuance of the Revised Rule, and the inevitable increase in denials of care and discrimination that will follow, Bradbury-Sullivan Center may need to hire a case-manager to address the community's need for referrals to welcoming providers. Faced with the Rule's imminent implementation, Bradbury-Sullivan Center already has invested additional staff time to strengthen its referral process through the creation of a supportive services referral guide. It is increasingly difficult for Bradbury-Sullivan Center to find local LGBT-affirming health care providers for certain specialties in particular, and the Revised Rule will further diminish the number of specialists available by emboldening additional providers to refuse health care treatment to LGBT patients and emboldening insurance companies to avoid coverage of medically necessary care that the LGBT community needs. This harms the community members whom Bradbury-Sullivan Center serves and results in a major drain on its resources that need to be diverted from other programming.

19. Bradbury-Sullivan Center spends a significant amount of resources documenting health disparities in the LGBT community. A copy of the Pennsylvania 2018 LGBT Health Needs Assessment that Bradbury-Sullivan Center helped conduct is attached as **Exhibit A**. Data gathered from that work confirmed that only about 17% of LGBT Pennsylvanians in 2018 had a provider whom they considered to be their personal physician. That means that in times of need, LGBT people are more likely to randomly select a health care provider with whom they do not have a relationship, putting them at increased risk of finding a provider who is not LGBT-welcoming.

With an increase in discrimination and refusals of care as a result of the Revised Rule, LGBT people will be far less likely to receive the health care treatment that they need because, after being discriminated against, they are unlikely to seek other care out of fear of repeated rejections and discrimination. Data from 2018 also indicated that over 50% of LGB and 75% of the transgender community fear going to a health care provider due to negative past experiences directly related to the patients' sexual orientation or gender identities.

20. These numbers will increase because additional health care providers will refuse to provide care to the LGBT community as a result of the Revised Rule. This directly affects the Bradbury-Sullivan Center because more community members will seek referrals to LGBT-affirming health care providers, there will be an increase in community members experiencing the trauma of discriminatory or unwelcoming health care experiences who will turn to its support groups, and community health outcomes among the population that Bradbury-Sullivan Center serves will worsen.

21. Bradbury-Sullivan Center's research into health disparities facing the LGBT community reveals that approximately one in four members of the community in our region experience a negative reaction from a health care provider when they come out as LGBT. More than half of respondents report fear of a negative reaction by a health care provider if they come out. Indeed, approximately three quarters of all transgender respondents fear such a negative reaction. Our research also identifies pervasive health disparities between LGBT people and the majority population with respect to tobacco use, cancer, HIV, obesity, mental health, access to care, and more, with LGBT people consistently experiencing worsened health outcomes. The same is true during the COVID-19 pandemic, where LGBT people are uniquely vulnerable to COVID-19. In other words, LGBT people, who are disproportionately likely to need a wide range

of medical care, already have reason to fear, and often do fear, negative consequences of disclosing to health care providers their sexual orientation, history of sexual conduct, gender identity, transgender status, history of gender-confirming medical treatment, and related medical histories.

22. By inviting discrimination against LGBT people based on their LGBT status, the Revised Rule encourages LGBT people to remain closeted to the extent possible when seeking medical care. Bradbury-Sullivan Center's research demonstrates that more than a quarter of LGBT respondents are not out to *any* of their health care providers. Fewer than half are out to all of them. The Revised Rule's removal of nondiscrimination requirements and invitation to discriminate on the basis of a providers' religious or moral beliefs undoubtedly will exacerbate those numbers.

23. Remaining closeted to a health care provider can result in significant adverse health consequences. When patients are unwilling to disclose their sexual orientation and/or gender identity to health care providers out of fear of discrimination and being refused treatment, their mental and physical health is critically compromised.

24. Bradbury-Sullivan Center will have to expend more resources on its health promotion campaigns to ensure that LGBT people have access to preventative screenings for cancer, testing services for COVID-19, HIV and other STIs, and tobacco-cessation services given that the Revised Rule will drastically change the health care landscape for the LGBT patient population. This is especially true for the transgender community because existing data predict that the transgender community will be especially afraid to seek out such care out of fear of mistreatment or rejection as a result of the Revised Rule that removes explicit protections based on gender identity and sexual orientation. Bradbury-Sullivan Center also anticipates it will have to initiate many other new services, including, but not limited to, education and community outreach programs, as a result of the Revised Rule. For example, Bradbury-Sullivan Center will

have to increase community-education efforts about the importance of having a primary health care provider to ensure that LGBT patients have a health care provider whom they can trust and do not avoid seeking necessary care. This is especially important given that Bradbury-Sullivan Center's patrons may need emergency assistance related to COVID-19.

25. Bradbury-Sullivan Center also works with independent clinics to help them implement nondiscriminatory policies and practices. Bradbury-Sullivan Center will have to work harder to ensure that these clinics maintain and establish clear policies that prevent discrimination against the LGBT community, including correct signage that will signal to LGBT people that they are still welcome and will not be mistreated despite the Revised Rule.

26. Bradbury-Sullivan Center has a dedicated team of employees who focus on fostering a welcoming, nondiscriminatory atmosphere for patrons to access supportive services. Many employees of Bradbury-Sullivan Center may be negatively impacted by the Revised Rule in the form of increased demand on their time and resources by patrons (especially to meet increased demand for referrals), a diminished number of affirming resources to provide, and the need to develop new resources and training materials from scratch.

27. The Revised Rule's elimination the unitary standard, as well as its removal of notice and tagline requirements, will also make it much more difficult for transgender and gender nonconforming patrons of Bradbury-Sullivan Center to understand their rights and how to advocate for such rights. The Revised Rule appears to have been drafted in such a manner that it will create public chaos and confusion. Bradbury-Sullivan Center patrons are further confused about the ramifications of the Revised Rule given its publication four days after the Supreme Court's ruling in *Bostock v. Clayton County, Georgia*, 590 U.S. ___, 2020 WL 3146686 (June 15, 2020), which held sex discrimination prohibitions necessarily protect LGBTQ people. Our patrons

are extremely confused and have been contacting our Center in panic about the Revised Rule and in need of our services.

28. As a result of confusion and panic the Rule has created, Bradbury-Sullivan Center has already expended and will continue to expend additional resources educating its clients and staff about the ramifications of the Revised Rule—resources that were already strained as a result of the COVID-19 pandemic. Many patrons have come to Bradbury-Sullivan Center after having been denied insurance coverage for transition related care, hormone treatment, Pre-exposure Prophylaxis (PrEP), birth control, and other medically necessary care. Right after the Revised Rule was released, our transgender and gender nonconforming patrons were panicked about their ability to receive care for gender dysphoria and the effects of the Revised Rule on insurance coverage for treatments and medications related to gender dysphoria. In our entire region of 800,000 people, for example, we have only three health care clinics who will market that they prescribe and manage clients on PrEP. This means that LGBT patients are forced to wait months to receive even the most basic health care services. Likewise, we already know that many insurance companies have tried to find ways to avoid paying for transition-related health care services and medications. If the Revised Rule takes effect and removes coverage requirements for insurance providers, our transgender and gender nonconforming patrons will most certainly experience increased denials of coverage for their medically necessary health care. The Revised Rule will decrease options for care for LGBT people and will result in increased discrimination against our patrons on all fronts, resulting in severe harm to our patrons and to public health generally.

29. As a result of the Revised Rule, Bradbury-Sullivan Center will be required to redirect additional staff and resources from providing our own services to assisting patrons in

finding health care providers in the region who will serve LGBT patients in a nondiscriminatory manner. Bradbury-Sullivan Center's staff and resources have already been diverted from other program activities to engage in advocacy, policy analysis, and creation of resources to address the ill-effects of the Revised Rule. For LGBT people in the Lehigh Valley, where Bradbury-Sullivan LGBT Community Center is located, the Revised Rule will have a chilling effect on the community's ability to access healthcare.

[*Signature in next page.*]

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Dated this 5th day of July, 2020.

DocuSigned by:
Adrian Shanker
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Adrian Shanker

EXHIBIT A

Pennsylvania 2018 LGBT Health Needs Assessment

Pennsylvania 2018 LGBT Health Needs Assessment – Summary Report

August 2018

Prepared for the Pennsylvania Department of Health
Division of Tobacco Prevention and Control

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Executive Summary

Background

Pennsylvania, like the nation and many states, has traditionally had limited data on LGBT health and wellness. In an effort to learn more about the health and wellness of Pennsylvania's LGBT communities, the Pennsylvania Department of Health partnered with LGBT centers across the state to gather health and wellness information in 2015/2016 and again in 2018. The 2018 Pennsylvania LGBT Health Needs Assessment collects data on LGBT health and supports identification of health disparities in tobacco use, cancer, HIV, obesity, mental health, access to care, and more.

In 2018, Pennsylvania partnered with Bradbury-Sullivan LGBT Community Center to reach a statewide purposeful sample. The Pennsylvania 2018 LGBT Health Needs Assessment was conducted in collaboration with LGBT HealthLink, a program of CenterLink. This collaboration allowed Pennsylvania to use a CDC-vetted tool, and opens future possibilities for improved trend analyses and state-to-state comparison data.

Key Findings

A total of 4,679 Pennsylvania LGBT respondents participated in the 2018 LGBT Health Needs Assessment. Respondents are from over 800 different ZIP codes across 64 of Pennsylvania's 67 counties.

One in four respondents sometimes, often, or always experience a health care provider react poorly when they come out as LGBT. In addition, more than half of all respondents sometimes, often or always fear a negative reaction by a health care provider if they come out as LGBT. Over a third of respondents report their health is fair, poor, or very poor. However, resiliency factors are strong and almost all respondents report at least some interest in incorporating healthy living strategies into their lives. While overall LGBT respondents report higher current smoking than the general population, smoking reports are even higher among transgender and gender non-conforming respondents. Health disparities also exist within LGBT communities in health screenings and other health areas. Respondents identify mental health needs as a priority when considering LGBT community health.

Recommendations

1. **Support Connection to LGBT-competent Providers**
2. **Encourage Health Screening Discussions**
3. **Prioritize Chronic Disease Prevention**
4. **Promote Tobacco Cessation Opportunities**
5. **Identify Community-wide Mental Health Supports**
6. **Continue and Enhance Data Collection**
7. **Partner with LGBT Community-Based Organizations**

Pennsylvania 2018 LGBT Health Needs Assessment Overview

Lesbian, gay, bisexual, transgender (LGBT) individuals and others in the LGBT community are disproportionately impacted by tobacco use.[1] [2] [3] Estimates across studies show LGBT adults smoke at rates between 35 and 200 percent higher than the general population.[4] [5] The Center for Disease Control and Prevention (CDC) estimates over 30,000 LGBT people die each year of tobacco-related diseases.[6] Of course, tobacco use is not a standalone issue. Higher prevalence rates in other high-risk behaviors, psychosocial and structural barriers, and reduced access to trusted care impact overall risk for negative health outcomes in the LGBT community.[7] [8] [9]

Pennsylvania, like the nation and many states, has traditionally had limited data on LGBT health and wellness. In an effort to learn more about the health and wellness of Pennsylvania's LGBT communities, the Pennsylvania Department of Health partnered with LGBT centers across the state to gather health and wellness information. In 2015 and 2016, Pennsylvania Department of Health and Bradbury-Sullivan LGBT Community Center piloted regional health needs assessments to better measure LGBT health disparities in Pennsylvania. Regional findings identified pervasive health disparities in tobacco use, cancer, HIV, obesity, mental health, access to care, and more. In 2018, Pennsylvania expanded the scope of the assessment to include a statewide purposeful sample, again partnering with Bradbury-Sullivan LGBT Community Center to facilitate connection with a broad network of Pennsylvania LGBT-focused service agencies.

The Pennsylvania 2018 LGBT Health Needs Assessment was conducted in collaboration with LGBT HealthLink, a program of CenterLink. CenterLink's LGBT HealthLink program, one of eight CDC-funded cancer and tobacco disparity networks, is a community of experts and professionals working to advance LGBT health by eliminating tobacco use, reducing cancer incidence, and improving wellness within LGBT communities. This collaboration has allowed Pennsylvania to use a CDC-vetted tool, and opens future possibilities for improved trend analyses and state-to-state comparison data.

The 2018 findings presented here cover a variety of health topics, chronic disease risks, and healthcare experiences. These data are intended to identify needs and inform plans to close gaps. Opportunities remain for additional data analyses and future data collection.

[1] CDC, Smoking and Tobacco use: https://www.cdc.gov/tobacco/disparities/lgbt/index.htm
[2] The DC Center for the LGBT Community: http://thedccenter.org/outtoquit/
[3] The Truth Initiative: https://truthinitiative.org/news/tobacco-social-justice-issue-smoking-and-lgbt-communities
[4] The Network for LGBT Health Equity, MPOWERED: http://www.lgbthealthlink.org/Assets/U/documents/mpowered.pdf
[5] Lee, J. G., Griffin, G. K., Melvin, C. L. (2009). Tobacco use among sexual minorities in the USA, 1987 to May 2007: a systematic review. Tobacco Control, 18(4), 275-282.
[6] CDC, Smoking and Tobacco use: https://www.cdc.gov/tobacco/disparities/lgbt/index.htm
[7] HealthyPeople2020: https://www.healthypeople.gov/2020/topics-objectives/topic/lesbian-gay-bisexual-and-transgender-health
[8] Emlet, C. A. (2016). Social, Economic, and Health Disparities Among LGBT Older Adults. Generations (San Francisco, Calif.), 40(2), 16–22. Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5373809/
[9] Hoffman, L., Delaharty, J., Johnson, S. E., and Zhao, X. (2018). Sexual and gender minority cigarette smoking disparities: An analysis of 2016 Behavioral Risk Factor Surveillance System dat. Preventative Medicine, 113, 109-115. Available at: https://www.sciencedirect.com/science/article/pii/S0091743518301646

Needs Assessment Methodology

In spring 2018, Pennsylvania Department of Health and Bradbury-Sullivan LGBT Community Center partnered to administer the 2018 LGBT HealthLink Wellness Needs Assessment. Over a seven-week period, the anonymous, internet-based survey was available for completion by any Pennsylvania resident who across their lifetime consider themselves to be lesbian, gay, bisexual, or transgender. LGBT HealthLink estimated the survey took approximately 15 minutes to complete.

The purposive, convenience, snowball style sample was supported by LGBT-focused community partners who distributed/posted the tool link and otherwise made the link available to their LGBT stakeholders. Additional indirect recruitment occurred via social media. No participant recruitment occurred in LGBT bars. Data collection partners are listed in Acknowledgment section of this report.

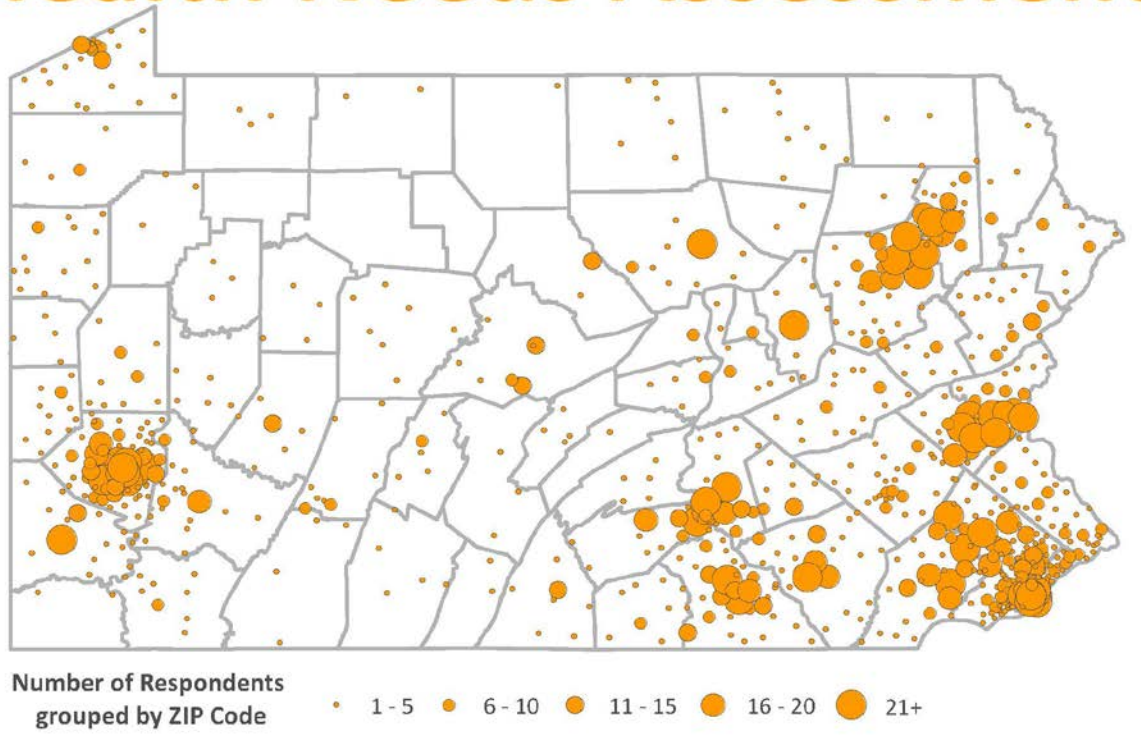
Method limitations include: online-only tool; English-only tool; cross sectional (single point in time) data collection.

Participants were informed the data they provided were being collected anonymously and they could stop the survey at any time or refuse to answer any questions. At the conclusion of the survey, participants were given the option to participate in an unlinked opportunity to be entered to win one of ten $50 gift cards for Amazon.[10]

[10] Raffle entries were at no point connected to needs assessment responses. All needs assessment responses remained anonymous regardless of entry into the incentive raffle.

Findings

A total of **4,679 Pennsylvania[11] LGBT[12] respondents participated** in the 2018 Needs Assessment. Respondents are from over 800 different ZIP codes across 64 of Pennsylvania's 67 counties.



Considering Pennsylvania's health districts and two most populated counties, respondents are part of all regions.

Northwest	Southwest[13]	Allegheny County	North Central	South Central	Northeast	Southeast[14]	Philadelphia County
4.1% 191	5.5% 259	17.2% 802	4.8% 224	12.9% 604	24.0% 1,123	20.7% 967	10.7% 501

[11] Respondent provided a Pennsylvania ZIP code (150xx-196xx) and/or selected PA as state. County name alone was used as a PA qualifier in one case.

[12] Respondent selected Yes to question: Across your lifetime, do you consider yourself to be Lesbian, Gay, Bisexual or Transgender?

[13] Excluding Allegheny County.

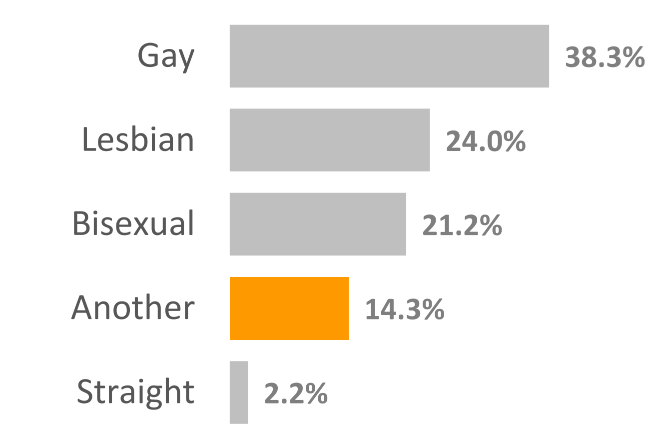
[14] Excluding Philadelphia County.

Sociodemographics

Respondents identify across LGBT communities. At the time of the survey, over a third of respondents identify as gay (38.3%), almost a quarter as lesbian (24.0%), bisexual (21.2%), another[15] (14.3%) and straight (2.2%).

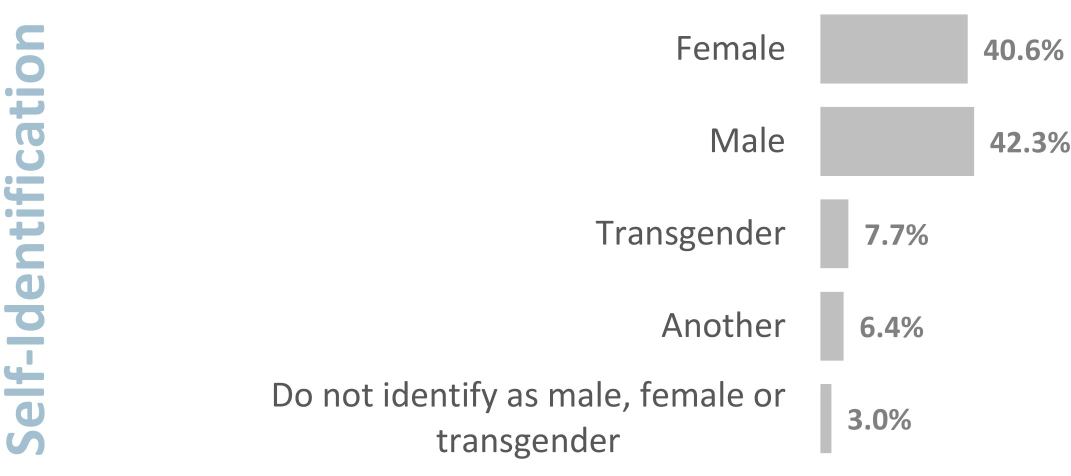
Sexual Orientation

538 respondents wrote-in their description, most commonly **Pansexual, Queer, and Asexual.**



Respondents identify as female, male, transgender and gender non-conforming. Two hundred and forty respondents provided a write-in response to the question: How do you describe yourself? The most common write-in responses included, non-binary, genderqueer, and genderfluid. When considering reported sex at birth, the respondent sample includes 21.7 percent transgender and/or gender non-conforming respondents.

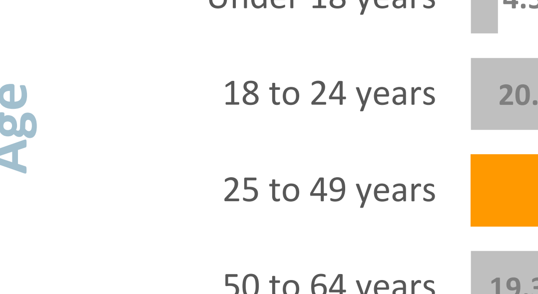
Self-Identification



[15] "Other" category in the original survey tool has been modified to "Another" on this report in order to use more inclusive language.

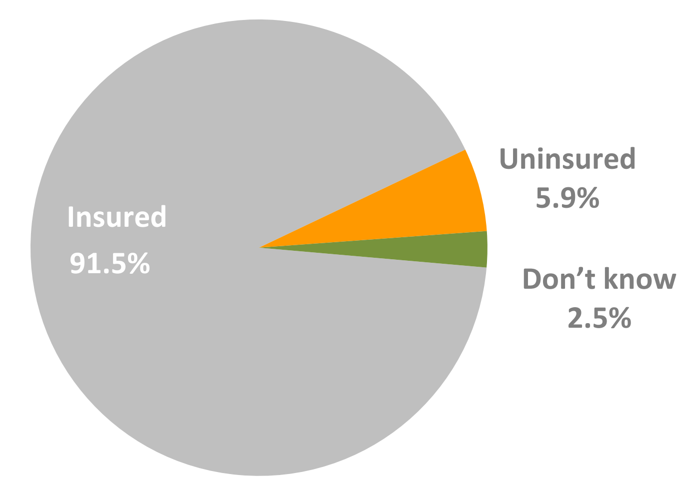
Respondents vary in age from 10 to 87, with an average age of 37.6.[16] A quarter of respondents are over 50 years of age (n=1,203, 25.7%) and a quarter are under 25 years of age (25.4%).

Just under half of all respondents are between ages **25 and 49**.



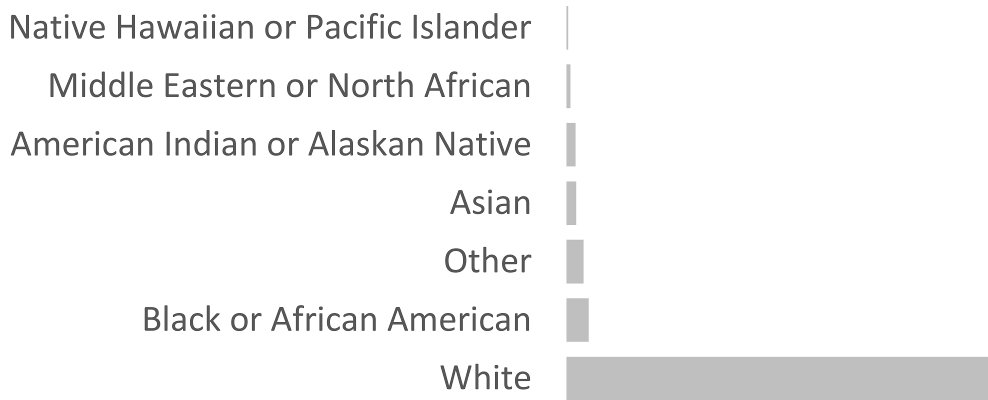
While the majority of respondents are insured, more than one in twenty are uninsured or are not sure of their insurance status. This is a slightly lower estimate than the Pennsylvania age 18-64 population, where 9 percent (CI:7-10%) have no health insurance (BRFSS[17], 2016).

Almost 6% of respondents have **no insurance** and not all are sure of their insurance status.

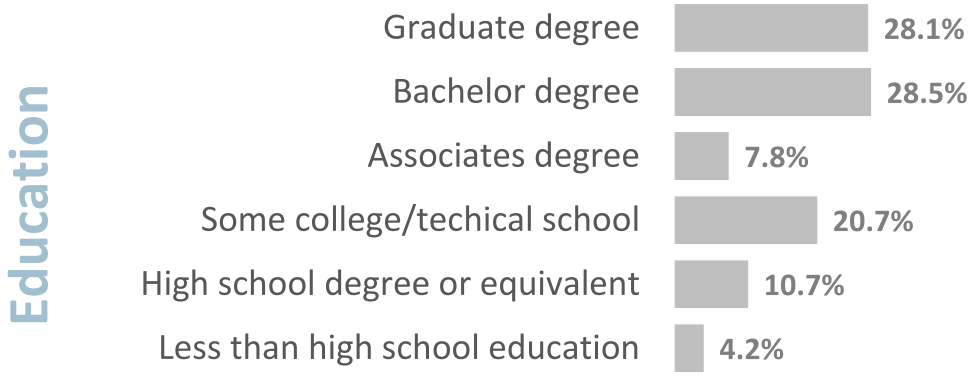


[16] Age was missing in only four cases.
[17] All Pennsylvania Behavioral Risk Factor Surveillance System (BRFSS) data in this report were provided by the Pennsylvania Department of Health. The Department specifically disclaims responsibility for any analyses, interpretations, or conclusions. Data available via https://www.phaim1.health.pa.gov/EDD/

The majority of respondents describe themselves as White (74.1%), but may also identify as another race. Six percent of respondents are Hispanic or Latino/a.



The vast majority of respondents have a high school degree or beyond for their education level. Three out of four respondents with less than a high school education are under 18 years of age.



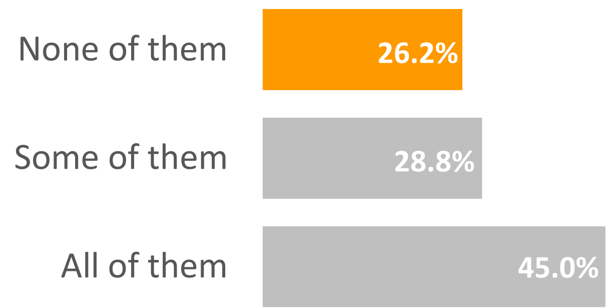
Additional data findings by select sociodemographic and geographic groups can be found in appendices.

Health Care

Most respondents had at least one personal doctor or health care provider, however, 17 percent do not or are unsure if they think of any provider as personal. This is a slightly higher estimate than the general Pennsylvania adult population, where 14 percent (CI:13-15%) do not have a personal health care provider (BRFSS, 2016). There is variation across respondents on whether they have advised their provider(s) that they are LGBT.

Communication with Providers

When asked: Have you advised your personal provider(s) that you are LGBT?
More than 1 in 4 report they have not advised any provider.



One in four respondents sometimes, often, or always experience a health care provider react poorly when they come out as LGBT (25.1%). In addition, more than half of all respondents sometimes, often or always fear a negative reaction by a health care provider if they come out as LGBT (56.8%). While this proportion is high on its own, fear of a negative reaction is significantly higher for transgender and gender non-conforming respondents (p=.000). Three in four transgender and gender non-conforming respondents sometimes, often or always fear a negative reaction by a health care provider if they come out as LGBT (75.1%).

Fear

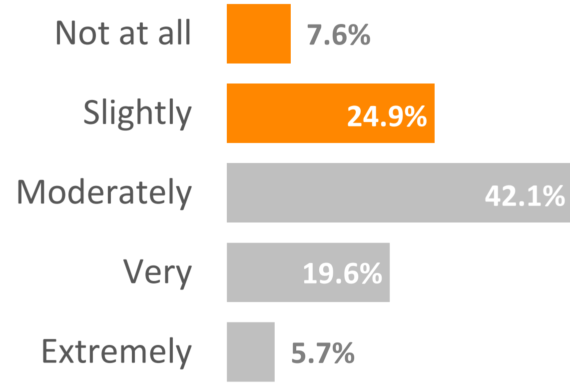
More than half of all respondents sometimes, often or always fear a negative reaction by a health care provider. **3 in 4 transgender and gender non-conforming respondents report this fear.**

Respondents find their health care providers, on average, vary in their knowledge about LGBT issues. While just under a quarter consider their health care providers to be extremely (5.6%) or very (18.2%) knowledgeable, over a third report much room for improvement with health care provider knowledge on LGBT issues reported as slight

(26.9%) or none (7.3%). Similarly, respondents report varied average competency about LGBT issues among health care providers. Respondents identify opportunities for improvement among providers in competency about LGBT issues with three in four respondents reporting average competency as moderate, slight or none (74.6%).

Provider Competency

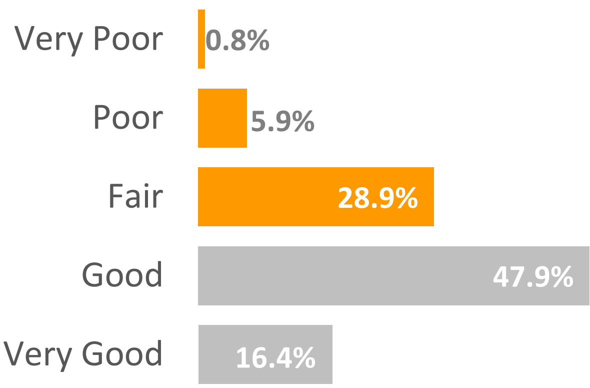
Respondents find their health care providers, on average, vary in their competency about LGBT issues. **Almost 1 in 3 report their provider is not at all or slightly competent**.



Personal Health

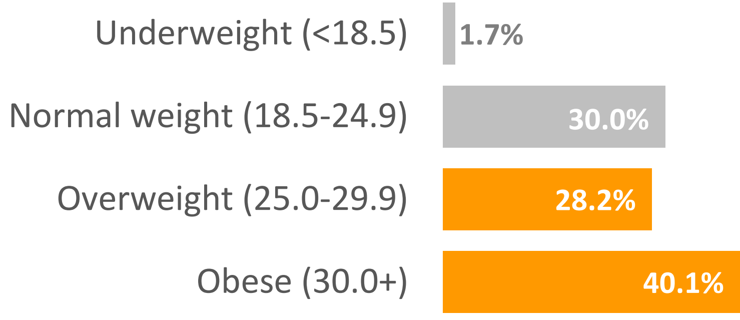
Respondents most commonly report their health as good (47.9%), but this leaves over a third of respondents who report their health is fair, poor, or very poor (35.6%). This is much higher than estimates for the general Pennsylvania adult population, with 17 percent (CI:15-18%) reporting being in fair or poor general health (BRFSS, 2016).

Over a third of respondents **report their health as fair, poor or very poor**.



As an indicator of health, respondents self-report height and weight and body mass index (BMI) was calculated. While BMI is limited as a health indicator,[18] BMI reports show the majority of adult respondents (18+) are overweight or obese based on standard BMI category breaks (68.3%). This is slightly higher than estimates for the general Pennsylvania adult population, with 64 percent (CI:63-66%) identified as overweight or obese (BRFSS, 2016). Underweight respondents fall in largely similar proportions across cisgender males (32.3%), cisgender females (29.0%) and transgender and gender non-conforming individuals (38.7%).

While **BMI is limited**, BMI varies with more than **2 in 3** adult respondents classified as **overweight or obese**.

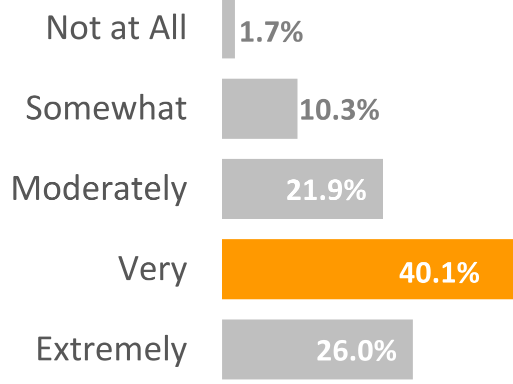


[18] National Heart Lung and Blood Institute (NIH): https://www.nhlbi.nih.gov/health/educational/lose_wt/BMI/bmicalc.htm

Another indicator of personal health and resiliency is interest in healthy living. Almost all respondents report at least some interest in incorporating healthy living strategies into their lives (98.3%).

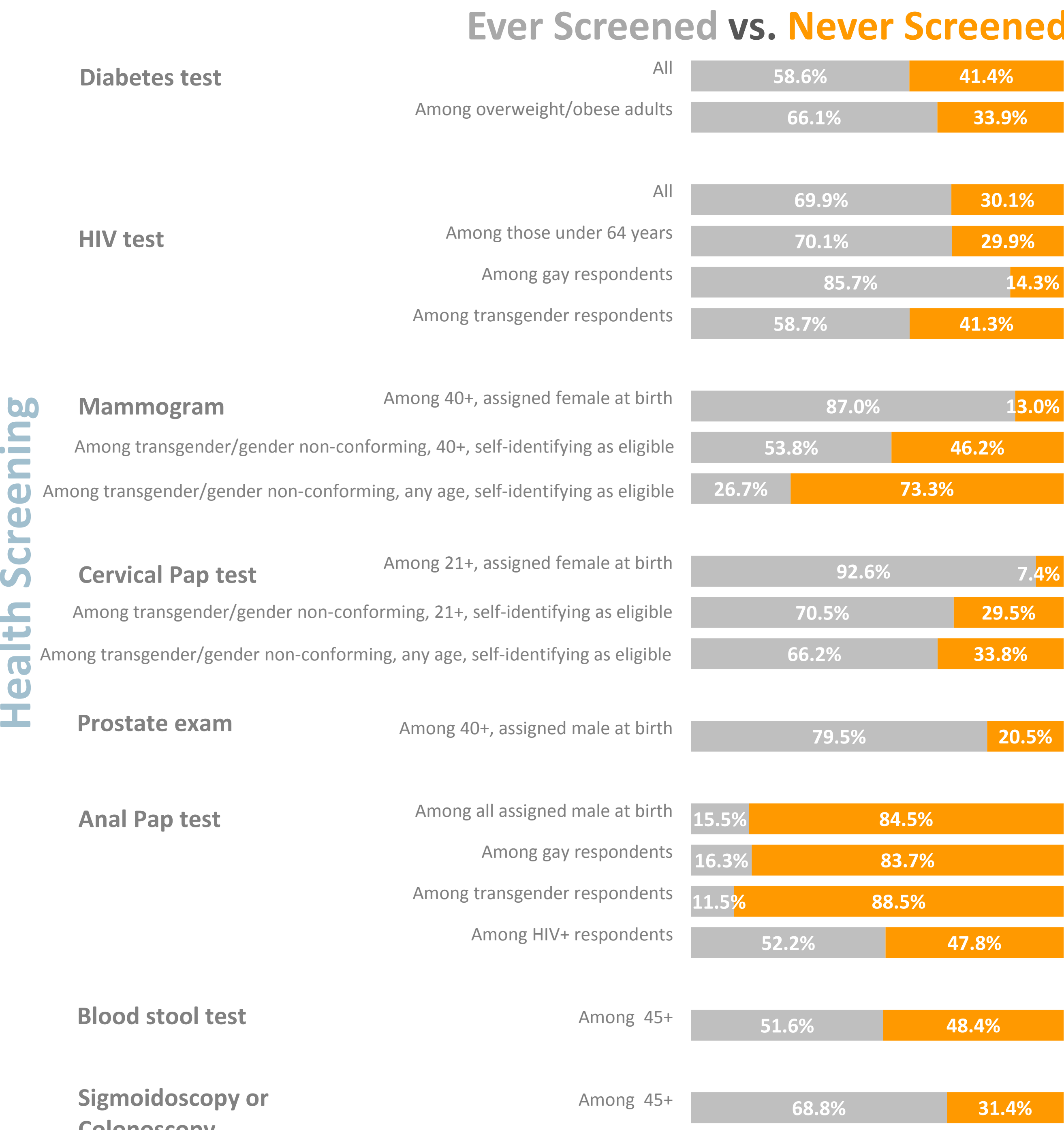
Healthy Living

Respondents are **interested in incorporating healthy living strategies** (such as healthy eating, exercise, tobacco cessation, etc.) into their lives.



Respondents had the opportunity to report specific healthy living practices as well. During the past month, three in four respondents report physical activity or exercise outside of their job (75.4%). Respondents also report sugar sweetened beverage intake. While the sugar sweetened beverage consumption recommendations largely focus on reduction rather than a limit to a certain number of soda/pop or other sugar sweetened drinks per week, more than one in 20 respondents report 15 or more sugar sweetened beverages per week in the past month (5.6%). This estimate is conservative as almost an additional one in 20 report estimates that may exceed 14 beverages across the two sugar sweetened beverage categories (4.7%). Related to healthy living, outside of pregnancy, more than three in 20 respondents report having been told by a health care professional they have pre-diabetes or borderline diabetes (16.7%).

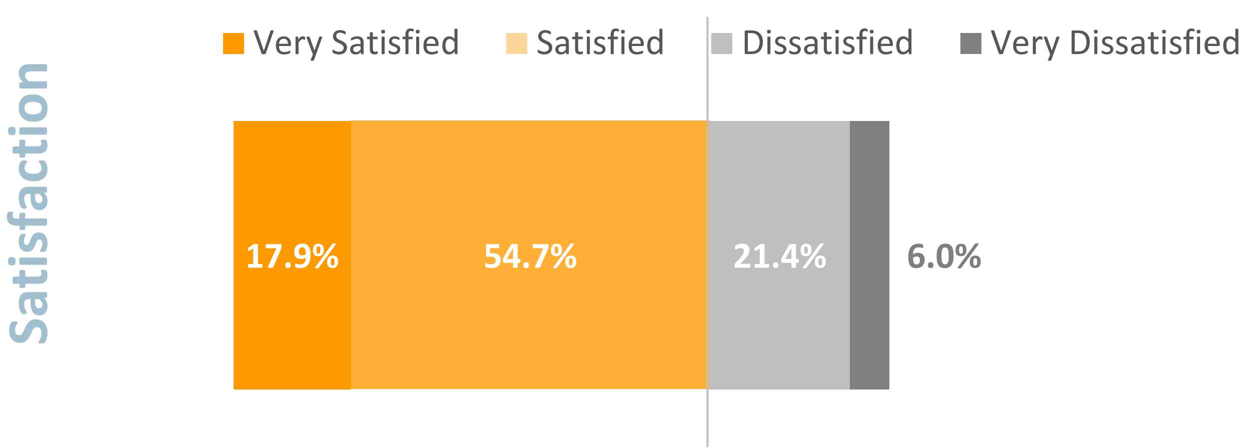
Health screenings may also serve as an indicator of personal health and/or access to care. Health screening recommendations vary and often have tailored conditions related to timing and frequency. Rates in chart below relate to ever being screened among the primary categories of eligible individuals. It is important to note individuals outside of the primary categories of eligible individuals may be recommended for screening based on personal health risk, family risk, gender-affirming hormone therapy or other hormone intake, and other discussions with care providers.



Mental Health

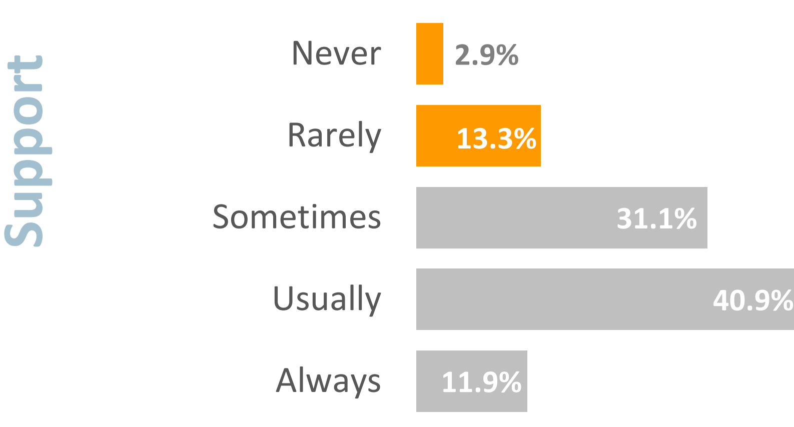
Several aspects of survey findings relate to mental health, both personally and among LGBT communities in general (see LGBT Community Health Section). While the majority of respondents report general satisfaction with their life (72.6%), more than one in four report not being satisfied with their life (27.4%).

In general, how satisfied are you with your life?

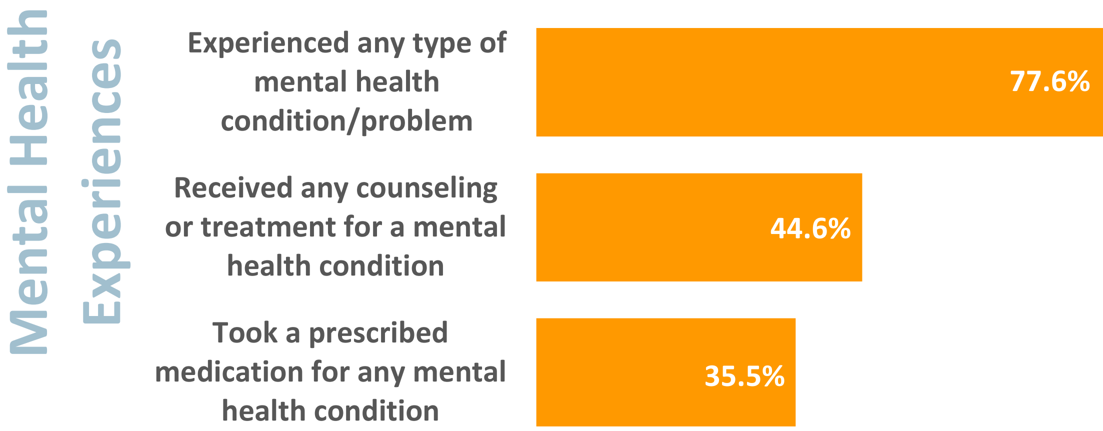


Respondents find it to be more common to get the social and emotional support they need than not, with just over half of respondents reporting they usually or always get the support they need (52.8%). Unfortunately, this leaves almost a third of respondents who get the support they need only some of the time (31.1%) and about one in six respondents who report not getting the support they need (16.2%).

1 in 6 report they rarely or never get the support they need.



When thinking about the past year, more than three in four respondents report experiences with a mental health condition or problem (77.6%). Counseling or treatment, as well as prescription medication for mental health conditions such as depression, anxiety, stress, suicidal ideation, etc. were also part of many respondents' recent experiences.



Experience with any type of mental health condition was more common among cisgender females, transgender, and gender non-conforming respondents. This same experience also shows a pattern by age group. The youngest age groups most often report experiencing a mental health condition/problem in the past year and reports decline with age group progression. Counseling or treatment was more than 1.5 times more likely among transgender and gender non-conforming respondents compared to cisgender counterparts and more common among younger age groups. Age group rates for taking prescribed medications hang together more closely and did not show the same ramp pattern.

HIV

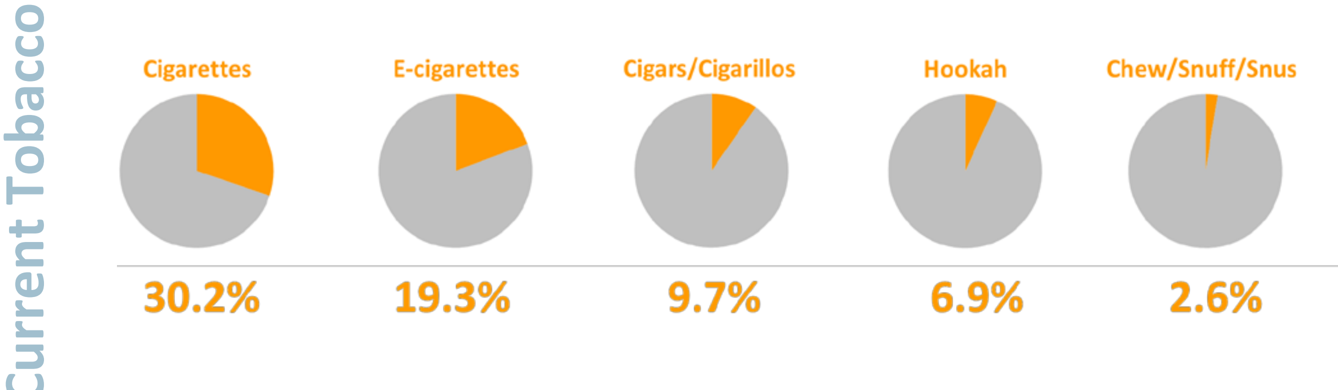
As reported in Health Screenings, three in ten respondents report never being tested for HIV (30.1%). HIV ever testing reports are highest among gay respondents (85.7%), followed by bisexual men (72.1%). HIV ever testing reports are lower among transgender respondents (58.7%). When considering most recent test, gay men (23.9%) and bisexual men (20.3%) were the most likely to report a test within the last three months. Almost half of gay men (48.6%) and more than two in five bisexual men (43.2%) report an HIV test within the past year. Just over one in 20 across all respondents report being HIV positive as of their last test. Respondents report feeling most comfortable getting an HIV test in an LGBT community-based setting and with a primary care provider.

Respondents report some risks for HIV at much higher rates than others. Most common risk reports include four or more partners in the past year (20.0%) and anal sex without a condom in the past year (26.8%). Less frequent risks among respondents include: intravenous drug use in past year (1.9%); past year exchange of sex for money or drugs (2.5%); and past year treatment for sexually transmitted disease (8.3%). Over one in three respondents have at least one of the BRFSS identified primary risk factors[19] for HIV (36.0%). Please note survey limitation: Risk factors questions did not account for PrEP usage.

[19] BRFSS primary risk factors are treated for STDs/VDs, traded money or drugs for sex, had anal sex without a condom or had 4+ sex partners in the past year.

Tobacco Use & Opinions

Cigarettes are the most commonly used tobacco product with almost a third of respondents reporting cigarette use every day or some days (30.2%). Based on this survey, current smoking among LGBT communities is well over the smoking rate estimate for all Pennsylvania adults at 18 percent (CI: 17-18%) (BRFSS, 2016).



While overall LGBT respondents report higher current smoking than the general population, smoking reports are even higher among transgender and gender non-conforming respondents (36.9%) than among cisgender males (28.8%) and cisgender females (28.1%).

Cigarette use reports also vary by age and region in Pennsylvania. Overall, the highest smoking rate estimates are among 18 to 24 year olds, averaging 42.6 percent. Regionally, the Northwest, Southwest, North Central, and Northeast have smoking estimates above the overall respondent estimate of 30.2 percent. All regions have rates higher than BRFSS 2016 estimates for all Pennsylvania adults.

	Under 18 years	18 to 24 years	25 to 49 years	50 to 64 years	65+ years	All LGBT	Transgender & Gender non-conforming
Northwest	n/a	50.0%	51.7%	40.9%	n/a	**42.9%**	n/a
Southwest[20]	n/a	62.5%	29.4%	38.5%	n/a	**35.4%**	n/a
Allegheny County	n/a	32.3%	29.8%	11.0%	n/a	**24.1%**	**33.8%**
North Central	n/a	38.5%	46.0%	30.4%	n/a	**40.4%**	**42.9%**
South Central	n/a	26.3%	38.6%	15.3%	n/a	**28.1%**	**34.2%**
Northeast	n/a	47.4%	42.0%	24.7%	n/a	**37.4%**	**44.9%**
Southeast[21]	n/a	52.8%	28.4%	20.0%	n/a	**27.3%**	**35.2%**
Philadelphia County	n/a	34.6%	23.1%	20.0%	n/a	**22.0%**	**31.8%**
Any Region	**n/a**	**42.6%**	**34.2%**	**21.3%**	**10.7%**	**30.2%**	**36.9%**

Note: Percent removed for categories with <5 respondents.

[20] Excluding Allegheny County.

[21] Excluding Philadelphia County.

Respondents have some interest in quitting, with about a one in four looking to quit within six months (24.3%). However, few are most likely to go to a Quitline for assistance (2.6%). When reporting where respondent would be most likely go for assistance to quit smoking, one in 20 respondents selected a cessation class or program at an LGBT organization (5.3%).

Respondents also share their opinions on several tobacco-related statements, demonstrating majority support for all smoke-free opportunities discussed. With greater than six in 10 respondents saying they would likely go to a smoke-free bar/club, pride event, or LGBT community center.

Tobacco Opinions

	Agree	Neutral	Disagree
LGBT people smoke more than the general population.	44.9%	42.9%	12.3%
Pride celebrations should be smoke-free events.	52.8%	31.6%	15.6%
I would be likely to go to a smoke-free bar/club.	60.4%	28.4%	11.2%
I would be likely to go to a smoke-free Pride event.	65.2%	28.8%	6.0%
I would be likely to go to a smoke-free LGBT Community Center.	67.6%	27.8%	4.6%

Substance Use & Alcohol

More than four in ten respondents report 5 or more alcoholic drinks per day (commonly referred to as binge drinking) at some point in the past year (43.1%), with close to one in 10 reporting this daily or weekly (9.1%). Respondents report use of 12 other substances outside of alcohol with wide variation. Over a third of respondents report past year use of marijuana (36.6%), with one in ten reporting daily or almost daily use (10.4%). Past year usage of other drugs include: opioids (6.7%); inhalants (5.5%); cocaine (4.8%); ecstasy (3.3%); and crystal meth (2.1%). All other drugs listed were reported by less than two percent of respondents.

Cancer

As reported in Health Screenings, reports of cancer screenings vary by test and population. Among respondents 40 and over assigned female at birth, three in four had a mammogram within the last three years (75.3%). Similarly, among respondents 21 and over assigned female at birth, over three in four had a cervical Pap test within the last three years (77.5%). Over one in four respondents report HPV vaccination[22] (26.6%). Among those who have not had the HPV vaccine, a portion report their provider refused to give the vaccine when they asked (2.4%).

When asked about specific skin cancer risks, almost four in 10 report prior indoor tanning (38.9%). Prior indoor tanning is more common among cisgender males (43.6%) than among cisgender females (39.1%) or transgender and gender nonconforming respondents (23.0%). More than four in 10 report infrequent or never use of sun protection during peak hours (44.2%). One in 10 respondents reports a cancer diagnosis during their lifetime (11.2%). Skin cancer is by far the most common, however, each of the other six cancers[23] listed is reported by no fewer than three respondents.

Regardless of experience with cancer prevention, screening, or treatment, respondents overwhelmingly agree services are needed to help LGBT cancer survivors.

Survivor Supports

	Agree	Neutral	Disagree
LGBT tailored cancer information	81.3%	16.4%	2.3%
LGBT support group	89.8%	8.9%	1.3%
LGBT welcoming caregivers group	89.9%	9.0%	1.1%
LGBT welcoming providers	91.4%	7.6%	1.0%
LGBT welcoming policies at hospitals	92.4%	6.4%	1.2%
LGBT legal planning	92.8%	6.1%	1.1%

[22] Survey question included additional terms for the HPV vaccine, including: cervical cancer or genital warts vaccine, HPV shot, Gardisil or Cervarix.
[23] Cancers list included: lung, skin, prostate, breast, cervical, colorectal, anal, and other.

LGBT Community Health

Respondents' perceptions of priority health issues for LGBT communities was also collected. Across 15 answer options the top three selections for issues perceived to be the most impactful for LGBT communities in Pennsylvania all relate to mental health. **Depression** is the most common issue selected, with recognition as a top three issue by over half of respondents (58.1%). **Suicide** (36.3%) and **Loneliness/Isolation** (34.1%) round out the top three most commonly selected issues. Over a quarter of respondents rank **HIV/AIDS** (28.6%) and **Access to Welcoming Care** (27.6%) as top issues. Over 280 respondents also wrote in other issues and comments in the ranking question. A wide variety of issues were covered that were not on the original list of 15 options, including, but not limited to: domestic violence; eating disorders; employment discrimination; gender-affirming care; homelessness; and trauma-informed care.

Some topic areas are selected more often by certain age groups. Alcohol use, for example, grew steadily as a top three issue from younger to older groups, peaking among 65+ respondents at almost 30 percent (29.1%). Elder care followed this same pattern, peaking at about a third of 65+ respondents (34.4%). Bullying, on the other hand, as a top three classification ramped in the other direction with <18 respondents classifying as a top three issue at over 40 percent (43.9%). Depression as an overall top three selection, was more frequently selected by the younger age groups with ramped decline in older age groups as well, but never dipping below 44.5 percent for any age group.

Also of note, several respondents critiqued the break out of specific drugs in the original 15 options. The identification of the top three issues may have been impacted if all drugs or addiction (general) were available for selection. One respondent summarized this issue by responding, "**Addition in general**, I don't think it can be narrowed down to just one addiction."

Discussion & Recommendations

LGBT+ respondents from across Pennsylvania shared critical information on personal and community health opportunities. Service gaps can be closed and support systems can be reinforced/expanded. A variety of players must be part of addressing LGBT community needs, including government agencies, community-based agencies, advocates/allies, and LGBT individuals.

Recommendations

Support Connections to LGBT-competent Providers – Support connections to LGBT-welcoming care for LGBT communities. Support training on LGBT issues for healthcare professionals through improved cultural competency, continuing medical education on LGBT health issues, and training for medical students in LGBT health.

Encourage Health Screening Discussions – Identify strategies to facilitate discussions on improving access to and frequency of health screenings for the LGBT community. Consider development of an online health screening recommendation summary tool to support a range of screenings discussions acknowledging the diversity within the LGBT community. Develop tailored messages specific to the LGBT community.

Prioritize Chronic Disease Prevention – Continue work to raise awareness about tobacco, HIV, obesity and cancer as LGBT issues among LGBT communities and Pennsylvanians at-large. Support service expansion to address tobacco use, HIV, obesity and cancer risks for LGBT communities. Maximize interest among LGBT communities for incorporating healthy living strategies by sharing resources and facilitating connections to LGBT-welcoming statewide and community-based services.

Promote Tobacco Cessation Opportunities – Expand promotion of free cessation opportunities available to all Pennsylvanians, like the PA Free Quitline. Build skills among tobacco cessation professionals and promote use of evidence-based cessation and tobacco recovery supports among LGBT communities. Develop LGBT focused tobacco-free campaigns. Engage in direct outreach to the LGBT community. Partner with LGBT community centers, LGBT bars, and pride celebrations to effectively reach the LGBT community with tailored tobacco-free messages.

Identify Community-wide Mental Health Supports – Identify ongoing opportunities to support mental health services within LGBT communities. Prioritize training for mental health clinicians on LGBT issues. Plan to incorporate discussions about depression management, suicide prevention and social isolation mitigation into provider education. Post vetted mental health resources on LGBT community organization websites and social media platforms. Increase availability of mental health programs at LGBT community-based organizations.

Continue and Enhance Data Collection – Maintain a 2-year schedule of the Pennsylvania LGBT Health Needs Assessment with broad administration. Maintain a commitment to collection of LGBT health and wellness data among a large geographically and demographically diverse LGBT population. Support further research and data collection to focus specifically on LGBT people of color, transgender people, LGBT youth, LGBT older adults, and LGBT adults without a college degree. Consider opportunities to expand responses from Hispanic/Latinx LGBT populations, including a Spanish-language survey instrument. Improve all tools over time with feedback from LGBT stakeholders and informed the survey field.

Partner with LGBT Community-Based Organizations – Healthcare professionals, public health agencies, and health researchers should consider partnerships with LGBT community-based organizations to develop and implement strategies to promote a high-quality of health for the LGBT community.

Acknowledgements

Thank you to all respondents for your time, feedback, and ideas.

The Pennsylvania Department of Health and Bradbury-Sullivan LGBT Community Center would also like to thank all of the 2018 data collection partners:

- Equality Pennsylvania
- Erie Gay News
- Fighting AIDS Continuously Together
- Greater Erie Alliance for Equality
- Grindr for Equality
- Human Rights Campaign
- LGBT Center of Central PA
- LGBT Equality Alliance of Chester County
- LGBTQmunity Center of Montgomery County
- Metropolitan Community Church of Lehigh Valley
- Montgomery County LGBT Business Council
- Pennsylvania Youth Congress
- Persad Center
- Philadelphia Gay News
- Rainbow NEPA
- Triversity
- Washington County GSA
- William Way LGBT Community Center

Special thanks to CenterLink's LGBT HealthLink program, for survey oversight and administration, and to Adrian Shanker from Bradbury-Sullivan LGBT Community Center, for recruitment coordination and ongoing commitment to data dissemination and use.

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Research & Evaluation Group at Public Health Management Corporation. (2018). *Pennsylvania 2018 LGBT Health Needs Assessment.* Philadelphia, PA: Author.

Appendices

2018 Findings Summary LGBT Health Needs Assessment

Pennsylvania has health and wellness feedback from 4,679 LGBT+ Pennsylvanians! These data can be used to inform program planning, outreach efforts, and service proposal. While these data have some limitations, we can use these data to better understand areas of resilience, health disparities and overall need. To collect these important data, Pennsylvania partnered with Bradbury-Sullivan LGBT Community Center to reach a statewide purposeful sample. The Pennsylvania 2018 LGBT Health Needs Assessment was conducted in collaboration with LGBT HealthLink, a program of CenterLink.

64.3% report good or very good health

98.3% have interest in healthy living strategies

44.6% report mental health treatment this year

30.2% are current smokers

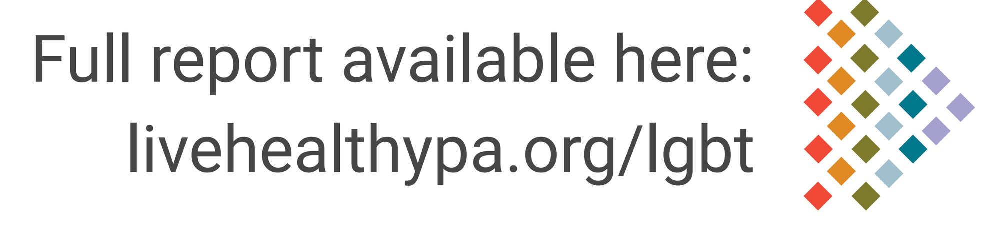
68.3% are overweight or obese

36.0% report a primary risk factor for HIV

LGBT+ respondents from across Pennsylvania shared critical information on personal and community health opportunities. Service gaps can be closed and support systems can be reinforced/expanded. A variety of players must be part of addressing LGBT community needs, including government agencies, community-based agencies, advocates/allies, and LGBT individuals. Data from the Pennsylvania 2018 LGBT Health Needs Assessment inform several recommendations for incorporation into future work:

1. **Support Connection to LGBT-competent Providers**
2. **Encourage Health Screening Discussions**
3. **Prioritize Chronic Disease Prevention**
4. **Promote Tobacco Cessation Opportunities**
5. **Identify Community-wide Mental Health Supports**
6. **Continue and Enhance Data Collection**
7. **Partner with LGBT Community-Based Organizations**

Full report available here: livehealthypa.org/lgbt



2018 Regional Summary

LGBT Health Needs Assessment

We have 2018 health and wellness feedback from 4,679 LGBT+ Pennsylvanians! These data can be used to inform program planning, outreach efforts, and service proposals. While these data have some limitations, we can also explore data from different parts of Pennsylvania. The Northwest Health District in Pennsylvania has information from 191 respondents. Check out some highlights below!

Northwestern PA

42.9% current smoking

18% BRFSS 2016 comparison for all PA adults

76.3% overweight or obese

64% BRFSS 2016 comparison for all PA adults

30.1% at least one primary risk factor for HIV*

7% BRFSS 2016 comparison for PA adults 18-64

Interest in Healthy Living

Not at All	Somewhat	Moderately	Very	Extremely
2.4%	8.9%	26.2%	41.7%	20.8%

Northwestern Pennsylvania respondents also demonstrate resiliency and are **ready to incorporate healthy living strategies** into their lives (such as healthy eating, exercise, tobacco cessation, etc.)... **62.5% report being very or extremely interested!**

Data sources: Pennsylvania' 2018 LGBT Health Needs Assessment and Pennsylvania BRFSS 2016.

*Risk factors are: treated for STDs/VDs, traded money or drugs for sex, had anal sex without a condom or had 4+ sex partners in the past year, age 18-64

2018 Regional Summary
LGBT Health Needs Assessment

We have 2018 health and wellness feedback from 4,679 LGBT+ Pennsylvanians! These data can be used to inform program planning, outreach efforts, and service proposals. While these data have some limitations, we can also explore data from different parts of Pennsylvania. The Southwest Health District* in Pennsylvania has information from 259 respondents. Check out some highlights below!

Southwestern* PA

* Excluding Allegheny County

35.4% current smoking

18% BRFSS 2016 comparison for all PA adults

68.5% overweight or obese

64% BRFSS 2016 comparison for all PA adults

30.6% at least one primary risk factor for HIV*

7% BRFSS 2016 comparison for PA adults 18-64

Interest in Healthy Living

Not at All	Somewhat	Moderately	**Very**	**Extremely**
3.5%	9.3%	30.4%	**34.4%**	**22.5%**

Southwestern Pennsylvania respondents also demonstrate resiliency and are **ready to incorporate healthy living strategies** into their lives (such as healthy eating, exercise, tobacco cessation, etc.)... **56.9% report being very or extremely interested!**

Data sources: Pennsylvania' 2018 LGBT Health Needs Assessment and Pennsylvania BRFSS 2016.

*Risk factors are: treated for STDs/VDs, traded money or drugs for sex, had anal sex without a condom or had 4+ sex partners in the past year, age 18-64

2018 Regional Summary
LGBT Health Needs Assessment

We have 2018 health and wellness feedback from 4,679 LGBT+ Pennsylvanians! These data can be used to inform program planning, outreach efforts, and service proposals. While these data have some limitations, we can also explore data from different parts of Pennsylvania. Allegheny County, Pennsylvania has information from 802 respondents. Check out some highlights below!

Allegheny County PA

24.1% current smoking

18% BRFSS 2016 comparison for all PA adults

65.1% overweight or obese

64% BRFSS 2016 comparison for all PA adults

38.4% at least one primary risk factor for HIV*

7% BRFSS 2016 comparison for PA adults 18-64

Interest in Healthy Living

Not at All	Somewhat	Moderately	Very	Extremely
1.8%	8.5%	19.8%	43.6%	26.3%

Allegheny County respondents also demonstrate resiliency and are **ready to incorporate healthy living strategies** into their lives (such as healthy eating, exercise, tobacco cessation, etc.)... **69.9% report being very or extremely interested!**

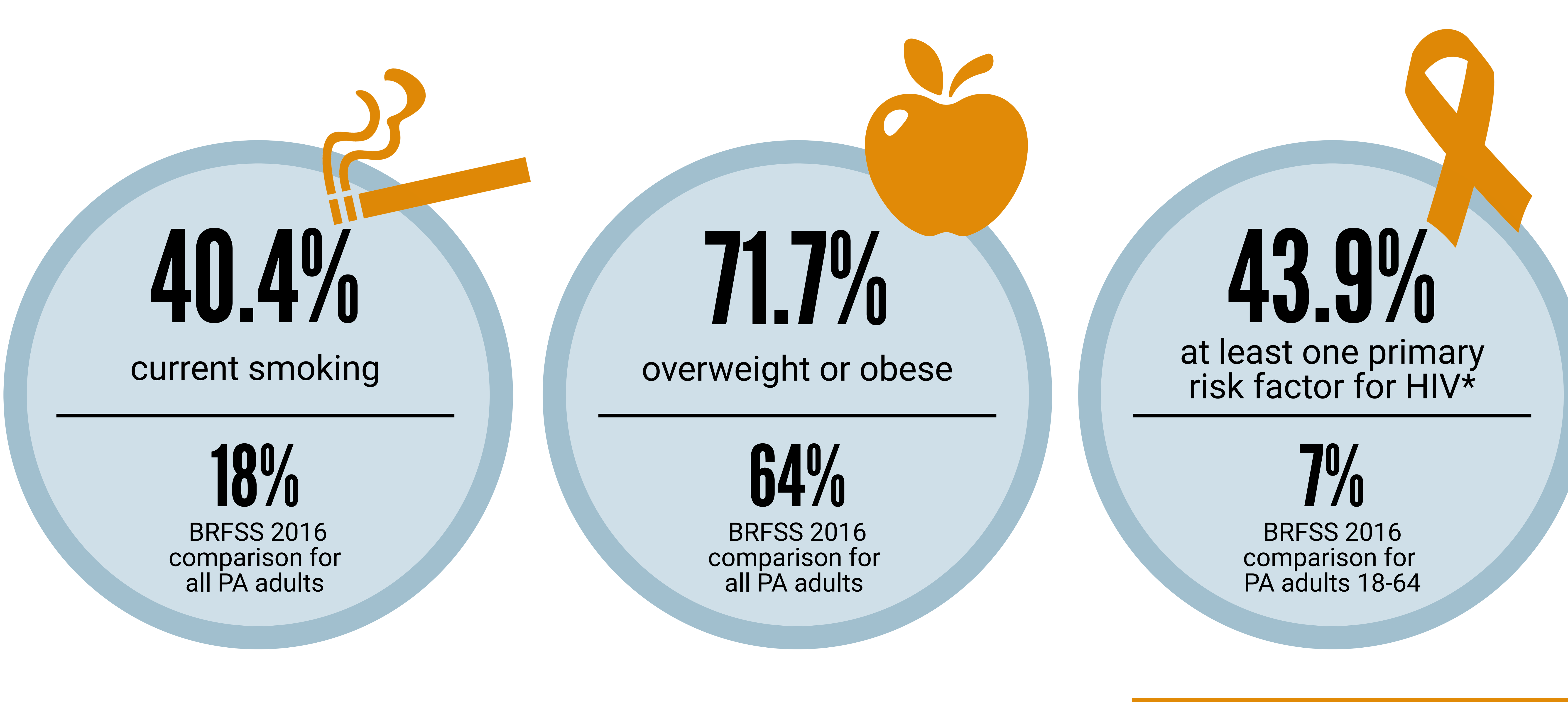
Data sources: Pennsylvania' 2018 LGBT Health Needs Assessment and Pennsylvania BRFSS 2016.

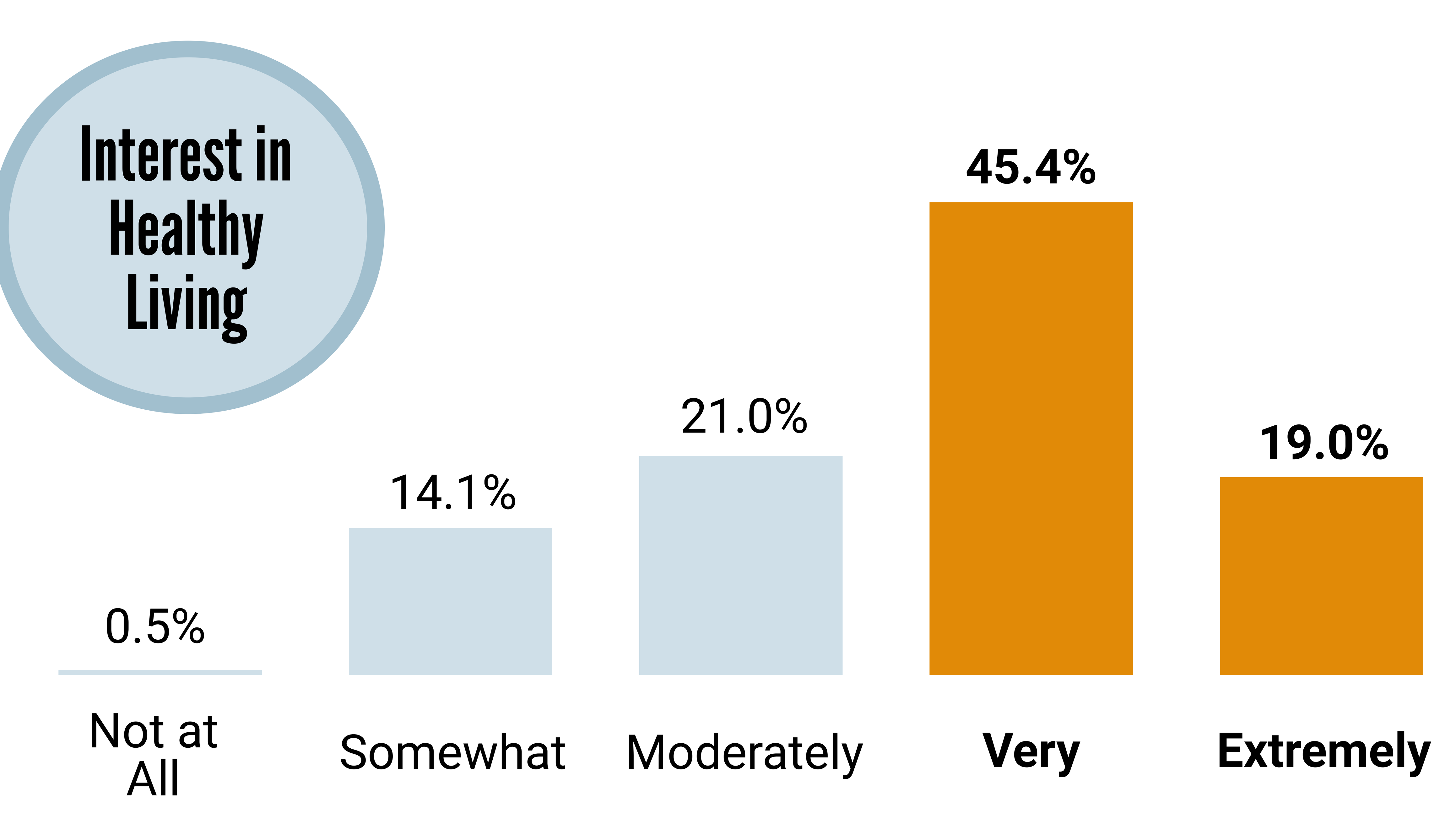
*Risk factors are: treated for STDs/VDs, traded money or drugs for sex, had anal sex without a condom or had 4+ sex partners in the past year, age 18-64

2018 Regional Summary
LGBT Health Needs Assessment

We have 2018 health and wellness feedback from 4,679 LGBT+ Pennsylvanians! These data can be used to inform program planning, outreach efforts, and service proposals. While these data have some limitations, we can also explore data from different parts of Pennsylvania. The North Central Health District in Pennsylvania has information from 224 respondents. Check out some highlights below!

North Central PA





North Central Pennsylvania respondents also demonstrate resiliency and are **ready to incorporate healthy living strategies** into their lives (such as healthy eating, exercise, tobacco cessation, etc.)... **64.4% report being very or extremely interested!**

Data sources: Pennsylvania' 2018 LGBT Health Needs Assessment and Pennsylvania BRFSS 2016.

*Risk factors are: treated for STDs/VDs, traded money or drugs for sex, had anal sex without a condom or had 4+ sex partners in the past year, age 18-64

2018 Regional Summary
LGBT Health Needs Assessment

We have 2018 health and wellness feedback from 4,679 LGBT+ Pennsylvanians! These data can be used to inform program planning, outreach efforts, and service proposals. While these data have some limitations, we can also explore data from different parts of Pennsylvania. The South Central Health District in Pennsylvania has information from 604 respondents. Check out some highlights below!

South Central PA

28.1% current smoking

18% BRFSS 2016 comparison for all PA adults

75.3% overweight or obese

64% BRFSS 2016 comparison for all PA adults

34.1% at least one primary risk factor for HIV*

7% BRFSS 2016 comparison for PA adults 18-64

Interest in Healthy Living

Not at All	Somewhat	Moderately	Very	Extremely
2.2%	12.0%	20.4%	40.9%	24.5%

South Central Pennsylvania respondents also demonstrate resiliency and are **ready to incorporate healthy living strategies** into their lives (such as healthy eating, exercise, tobacco cessation, etc.)... **65.4% report being very or extremely interested!**

Data sources: Pennsylvania' 2018 LGBT Health Needs Assessment and Pennsylvania BRFSS 2016.

*Risk factors are: treated for STDs/VDs, traded money or drugs for sex, had anal sex without a condom or had 4+ sex partners in the past year, age 18-64

2018 Regional Summary LGBT Health Needs Assessment

We have 2018 health and wellness feedback from 4,679 LGBT+ Pennsylvanians! These data can be used to inform program planning, outreach efforts, and service proposals. While these data have some limitations, we can also explore data from different parts of Pennsylvania. The Northeast Health District in Pennsylvania has information from 1,123 respondents. Check out some highlights below!

Northeastern PA

37.4% current smoking

18% BRFSS 2016 comparison for all PA adults

70.9% overweight or obese

64% BRFSS 2016 comparison for all PA adults

35.4% at least one primary risk factor for HIV*

7% BRFSS 2016 comparison for PA adults 18-64

Interest in Healthy Living

Not at All	Somewhat	Moderately	**Very**	**Extremely**
2.0%	10.0%	23.2%	**37.5%**	**27.3%**

Northeastern Pennsylvania respondents also demonstrate resiliency and are **ready to incorporate healthy living strategies** into their lives (such as healthy eating, exercise, tobacco cessation, etc.)... **64.8% report being very or extremely interested!**

Data sources: Pennsylvania' 2018 LGBT Health Needs Assessment and Pennsylvania BRFSS 2016.

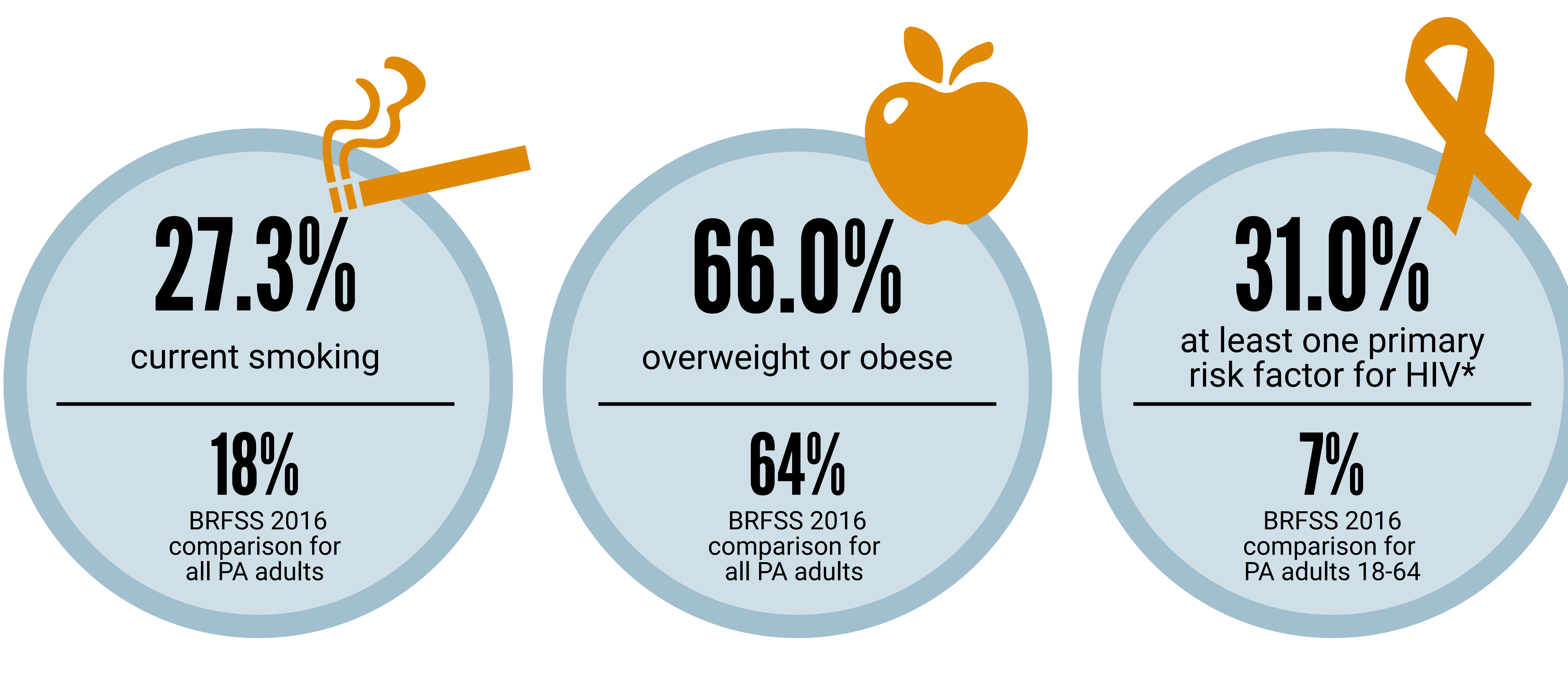
*Risk factors are: treated for STDs/VDs, traded money or drugs for sex, had anal sex without a condom or had 4+ sex partners in the past year, age 18-64

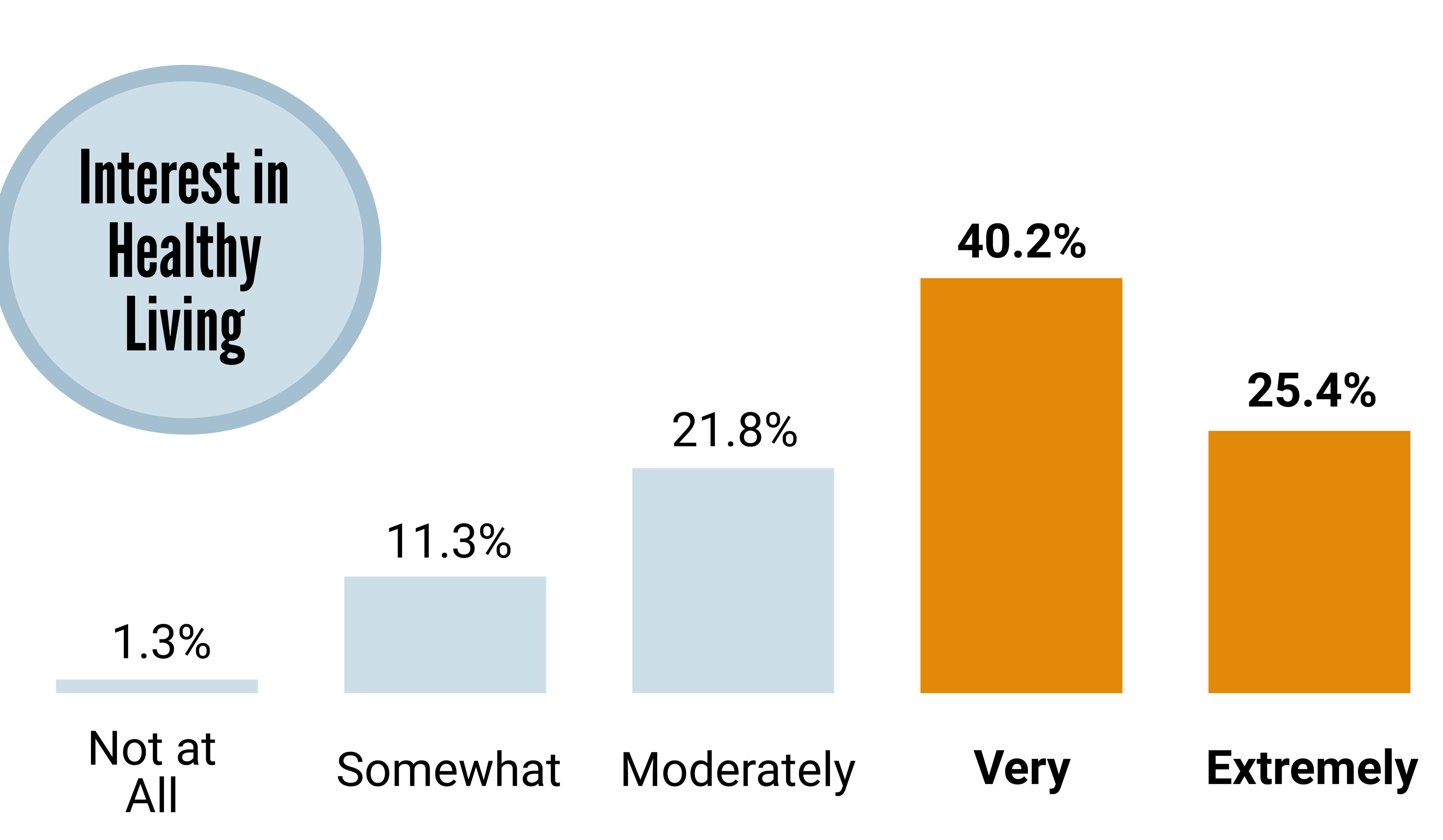
2018 Regional Summary
LGBT Health Needs Assessment

We have 2018 health and wellness feedback from 4,679 LGBT+ Pennsylvanians! These data can be used to inform program planning, outreach efforts, and service proposals. While these data have some limitations, we can also explore data from different parts of Pennsylvania. The Southeast Health District* in Pennsylvania has information from 967 respondents. Check out some highlights below!

Southeastern* PA

* Excluding Philadelphia County





Southeastern Pennsylvania respondents also demonstrate resiliency and are **ready to incorporate healthy living strategies** into their lives (such as healthy eating, exercise, tobacco cessation, etc.)... **65.6% report being very or extremely interested!**

Data sources: Pennsylvania' 2018 LGBT Health Needs Assessment and Pennsylvania BRFSS 2016.

*Risk factors are: treated for STDs/VDs, traded money or drugs for sex, had anal sex without a condom or had 4+ sex partners in the past year, age 18-64

2018 Regional Summary LGBT Health Needs Assessment

We have 2018 health and wellness feedback from 4,679 LGBT+ Pennsylvanians! These data can be used to inform program planning, outreach efforts, and service proposals. While these data have some limitations, we can also explore data from different parts of Pennsylvania. Philadlephia County, Pennsylvania has information from 501 respondents. Check out some highlights below!

Philadelphia County PA

22.0% current smoking

18% BRFSS 2016 comparison for all PA adults

59.1% overweight or obese

64% BRFSS 2016 comparison for all PA adults

46.2% at least one primary risk factor for HIV*

7% BRFSS 2016 comparison for PA adults 18-64

Interest in Healthy Living

Not at All	Somewhat	Moderately	Very	Extremely
0.9%	8.6%	18.6%	39.8%	32.1%

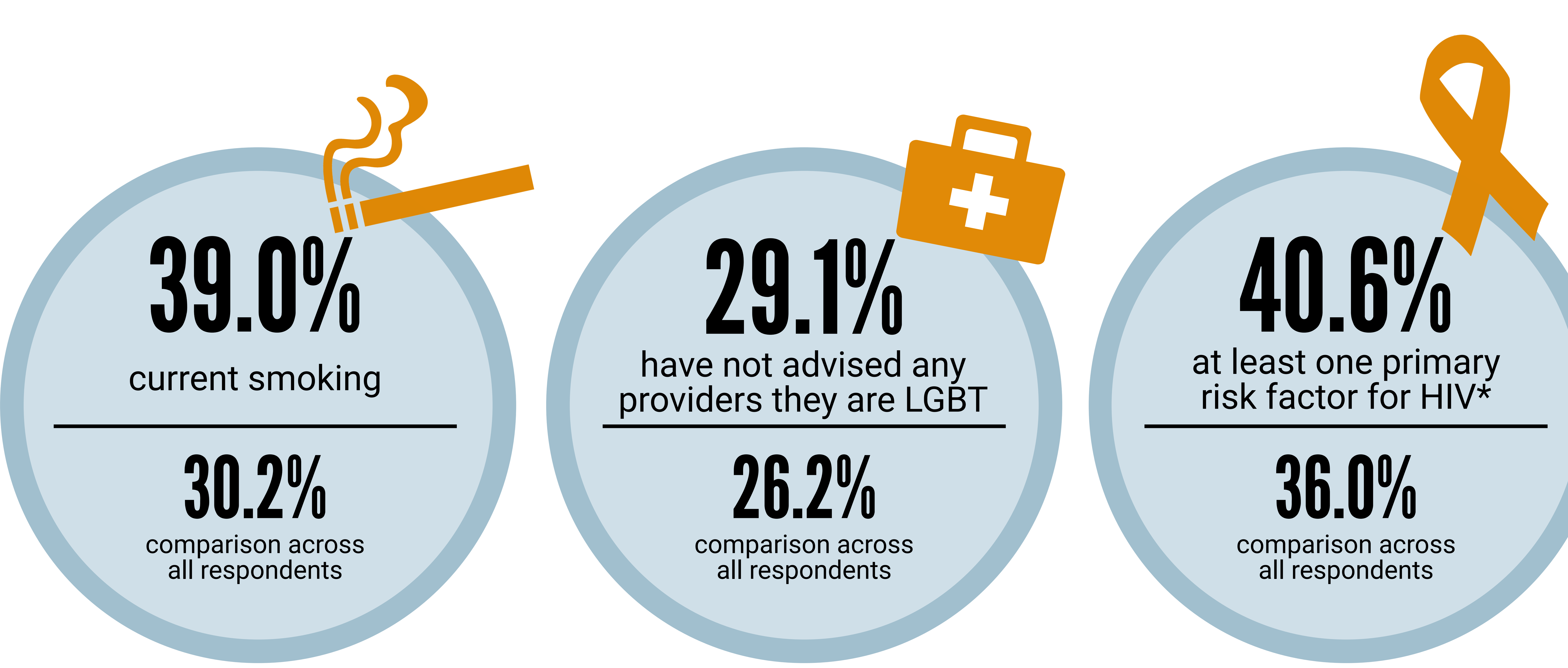
Philadelphia County respondents also demonstrate resiliency and are **ready to incorporate healthy living strategies** into their lives (such as healthy eating, exercise, tobacco cessation, etc.)... **71.9% report being very or extremely interested!**

Data sources: Pennsylvania' 2018 LGBT Health Needs Assessment and Pennsylvania BRFSS 2016.

*Risk factors are: treated for STDs/VDs, traded money or drugs for sex, had anal sex without a condom or had 4+ sex partners in the past year, age 18-64

2018 - Black & African American LGBT Health Needs Assessment

We have 2018 health and wellness feedback from 4,679 LGBT+ Pennsylvanians! These data can be used to inform program planning, outreach efforts, and service proposals. While these data have some limitations, we can explore health opportunities and differences within the LGBT community. One hundred eighty one of the 2018 needs assessment respondents are Black or African American. Below are a few data points specific to this subgroup and comparisons to all needs assessment respondents.



Priority Health Issues

Depression - 60.8%

HIV/AIDS - 40.9%

Priority of HIV/AIDS was recognized more often among Black and African American respondents than among respondents in general (28.6%)

Suicide - 40.3%

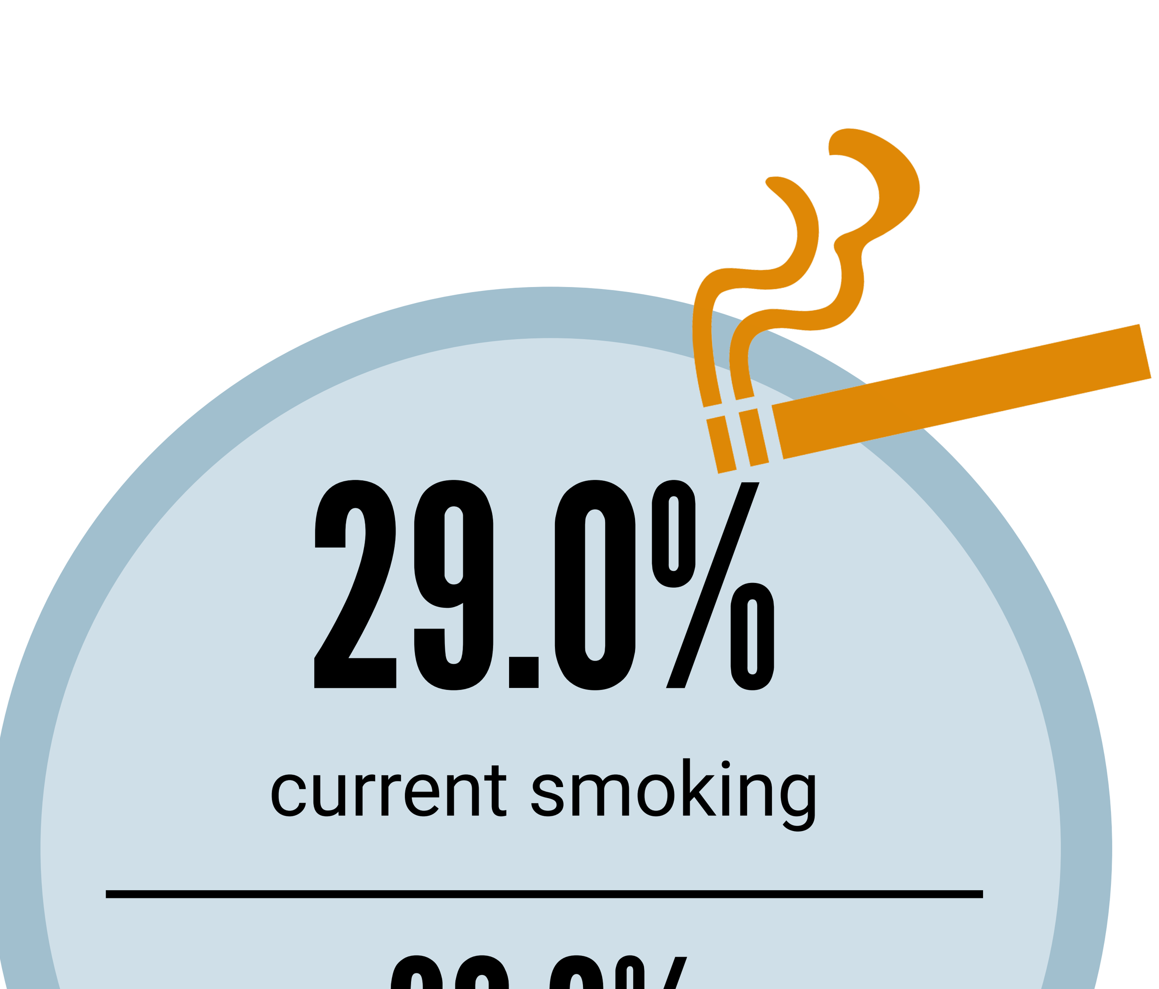
To better understand and address health opportunities and disparities, further research and data collection among LGBT people of color is needed.

Data sources: Pennsylvania' 2018 LGBT Health Needs Assessment

*Risk factors are: treated for STDs/VDs, traded money or drugs for sex, had anal sex without a condom or had 4+ sex partners in the past year, age 18-64

2018 - Hispanic and Latinx LGBT Health Needs Assessment

We have 2018 health and wellness feedback from 4,679 LGBT+ Pennsylvanians! These data can be used to inform program planning, outreach efforts, and service proposals. While these data have some limitations, we can explore health opportunities and differences within the LGBT community. Two hundred twenty three of the 2018 needs assessment respondents are Hispanic or Latino/a. Below are a few data points specific to this subgroup and comparisons to all needs assessment respondents.



29.0%
current smoking

30.2%
comparison across all respondents

29.9%
have not advised any providers they are LGBT

26.2%
comparison across all respondents

47.7%
at least one primary risk factor for HIV*

36.0%
comparison across all respondents

Depression - 70.0%

Suicide - 50.2%

HIV/AIDS - 44.8%
Priority of HIV/AIDS was recognized more often among Hispanic and Latino/a respondents than among respondents in general (28.6%)

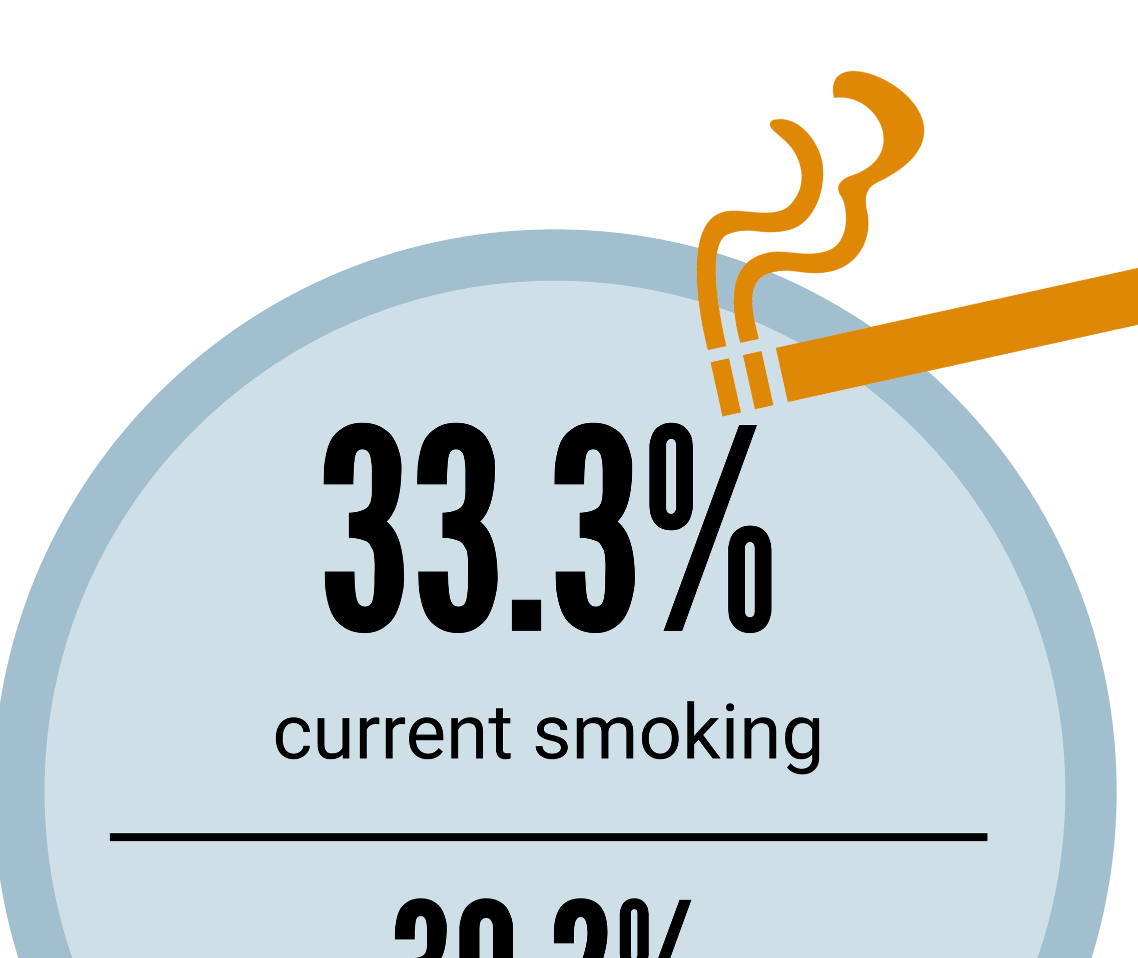
To better understand and address health opportunities and disparities, further research and data collection among Hispanic and Latinx LGBT is needed. Future LGBT needs assessments can incorporate Spanish survey tools.

Data sources: Pennsylvania' 2018 LGBT Health Needs Assessment

*Risk factors are: treated for STDs/VDs, traded money or drugs for sex, had anal sex without a condom or had 4+ sex partners in the past year, age 18-64

2018 - Transgender LGBT Health Needs Assessment

We have 2018 health and wellness feedback from 4,679 LGBT+ Pennsylvanians! These data can be used to inform program planning, outreach efforts, and service proposals. While these data have some limitations, we can explore health opportunities and differences within the LGBT community. Two hundred ninety one of the 2018 needs assessment respondents identify as transgender. Below are a few data points specific to this subgroup and comparisons to all needs assessment respondents.



33.3%
current smoking

30.2%
comparison across all respondents

90.4%
experienced any type of mental health issue in past 12 months

77.6%
comparison across all respondents

22.0%
at least one primary risk factor for HIV*

36.0%
comparison across all respondents

Priority Health Issues

Depression - 68.7%

Access to Welcoming Health Care- 55.0%

Priority of access to welcoming health care was recognized more often among transgender respondents than among respondents in general (27.6%)

Suicide - 50.9%

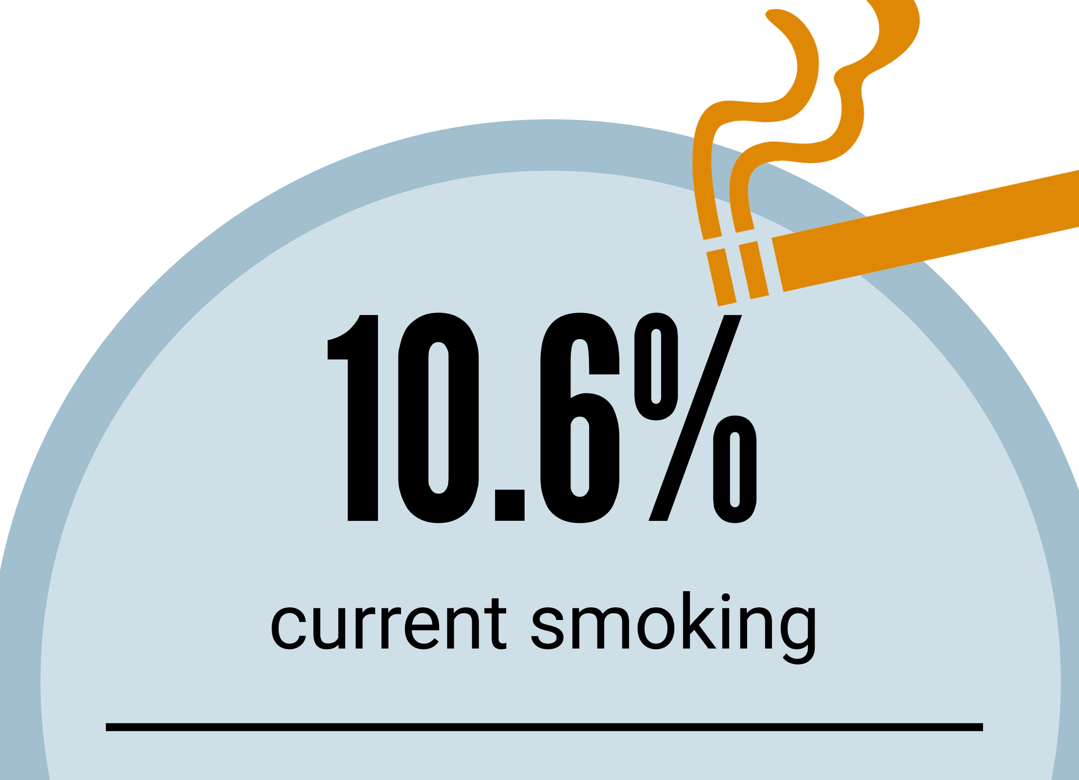
To better understand and address health opportunities and disparities, further research and data collection among transgender people is needed.

Data sources: Pennsylvania' 2018 LGBT Health Needs Assessment

*Risk factors are: treated for STDs/VDs, traded money or drugs for sex, had anal sex without a condom or had 4+ sex partners in the past year, age 18-64

2018 - Older Adults (65+ years)
LGBT Health Needs Assessment

We have 2018 health and wellness feedback from 4,679 LGBT+ Pennsylvanians! These data can be used to inform program planning, outreach efforts, and service proposals. While these data have some limitations, we can explore health opportunities and differences within the LGBT community. Two hundred ninety nine of the 2018 needs assessment respondents are 65 years or older. Below are a few data points specific to this subgroup and comparisons to all needs assessment respondents.



10.6% current smoking

30.2% comparison across all respondents

73.1% overweight or obese

66.0% comparison across all respondents

47.7% experienced any type of mental health condition in the past 12 months

77.6% comparison across all respondents

Priority Health Issues

- Isolation - 45.8%
- Depression - 44.5%
- HIV/AIDS - 37.1%
- Elder Care - 34.4%

To better understand and address health opportunities and disparities, further research and data collection among LGBT older adults is needed.

Data sources: Pennsylvania' 2018 LGBT Health Needs Assessment

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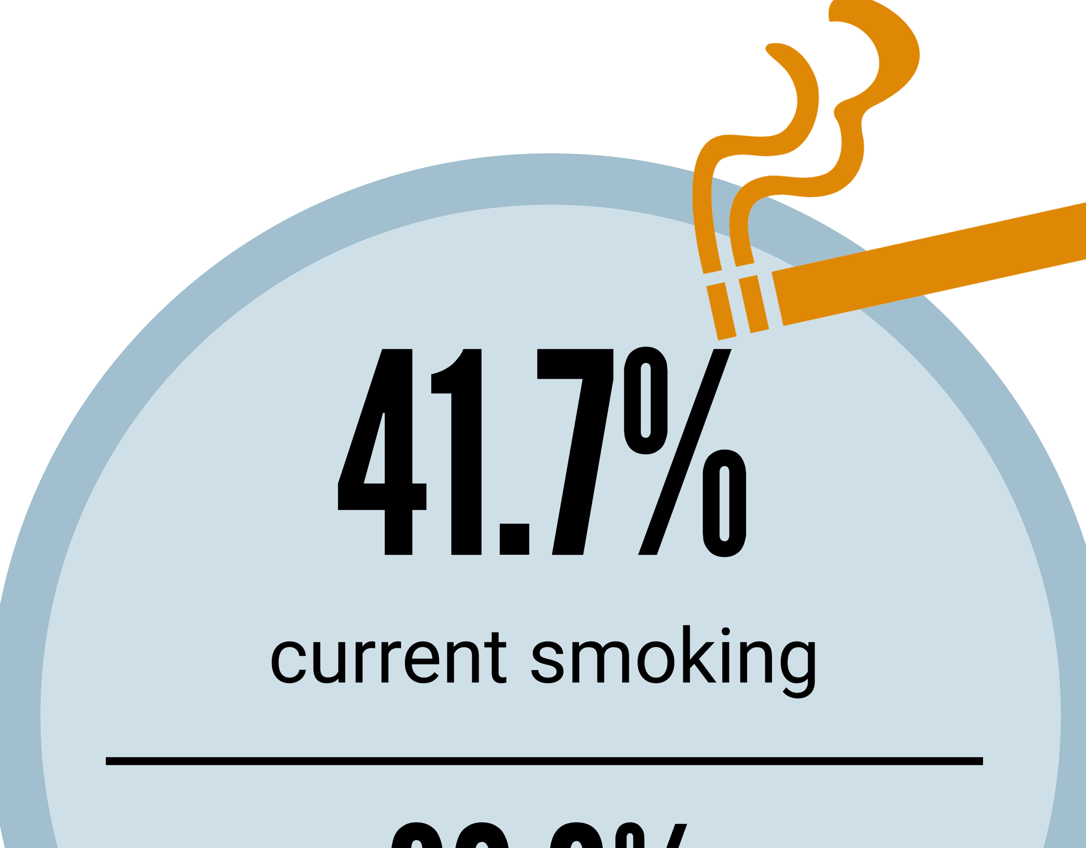
2018 - Young People (<25 years)
LGBT Health Needs Assessment

We have 2018 health and wellness feedback from 4,679 LGBT+ Pennsylvanians! These data can be used to inform program planning, outreach efforts, and service proposals. While these data have some limitations, we can explore health opportunities and differences within the LGBT community. One thousand one hundred eighty eight of the 2018 needs assessment respondents are under age 25. Below are a few data points specific to this subgroup and comparisons to all needs assessment respondents.



41.7%
current smoking

30.2%
comparison across all respondents

46.4%
have not advised any providers they are LGBT

26.2%
comparison across all respondents

92.7%
experienced any type of mental health condition in the past 12 months

77.6%
comparison across all respondents

Depression - 63.6%

Suicide - 49.5%

Isolation - 32.2%

Bullying - 30.2%

To better understand and address health opportunities and disparities, further research and data collection among LGBT youth and young adults is needed.

Data sources: Pennsylvania' 2018 LGBT Health Needs Assessment

RESEARCH & EVALUATION GROUP
at PHMC

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA**

WHITMAN-WALKER CLINIC, INC., *et al.*,

Plaintiffs,

v.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, *et al.*,

Defendants.

Case No. 1:20-cv-1630

DECLARATION OF HECTOR VARGAS, EXECUTIVE DIRECTOR, GLMA

I, Hector Vargas, hereby state as follows:

1. I am the Executive Director of the American Association of Physicians for Human Rights, Inc., d/b/a GLMA: Health Professionals Advancing LGBTQ Equality (f/k/a the Gay & Lesbian Medical Association) ("GLMA").

2. I received my Bachelor of Arts degree in political science and Spanish in 1989 and law degree in 1993 from the University of Georgia. I served on the Health Disparities Subcommittee of the Advisory Committee to the Director of the U.S. Centers for Disease Control and Prevention (CDC) and served for four years on President Obama's Advisory Commission on Asian Americans and Pacific Islanders. I have more than 20 years of LGBTQ and civil rights advocacy experience, including on staff with Lambda Legal, the National LGBTQ Task Force, and the American Bar Association's Section of Civil Rights and Social Justice.

3. I am submitting this Declaration in support of Plaintiffs' motion for preliminary injunction to prevent the revised regulation under Section 1557 of the Affordable Care Act ("ACA"), published by the U.S. Department of Health and Human Services ("HHS") on June 19,

2020 (the "Revised Rule"), from taking effect. The Revised Rule eliminates explicit regulatory protections for LGBT people in health care that were included in the 2016 Final Rule, which was promulgated under Section 1557 in May 2016.

4. GLMA is a 501(c)(3) national membership nonprofit organization based in Washington, D.C., and incorporated in California. GLMA's mission is to ensure health equity for lesbian, gay, bisexual, transgender, queer (LGBTQ) people and all sexual- and gender- minority (SGM) individuals, and equality for LGBTQ/SGM health professionals in their work and learning environments. To achieve this mission, GLMA utilizes the scientific expertise of its diverse multidisciplinary membership to inform and drive advocacy, education, and research. GLMA was founded in 1981 and its initial mission focused on responding with policy advocacy and public-health research to the growing medical crisis that would become the HIV/AIDS epidemic. Since then, GLMA's mission has broadened to address the full range of health concerns and issues affecting LGBTQ/SGM people, including ensuring that sound science and research inform health policy and practices regarding the LGBTQ community.

5. GLMA represents the interests of hundreds of thousands of LGBTQ health professionals, as well as millions of LGBTQ patients and families. GLMA's membership includes approximately 1,000 member physicians, nurses, advanced practice nurses, physician assistants, researchers and academics, behavioral health specialists, health profession students and other health professionals. GLMA's members reside and work across the United States, including states without any explicit protections against discrimination based on sexual orientation, gender identity, or transgender status, and in several other countries. Their practices represent the major health care disciplines and a wide range of health specialties, including internal medicine, family

practice, psychiatry, pediatrics, obstetrics/gynecology, emergency medicine, neurology, and infectious diseases.

6. GLMA's members who work for covered entities under Section 1557 are protected from discrimination with regards to terms and conditions of their employment, such as employee health benefits, pursuant to the 2016 Final Rule. In addition, many of GLMA's members are or work for covered entities subject to the Revised Rule.

7. The Revised Rule invites confusion about the meaning of the sex discrimination provision of Section 1557 of the ACA and directly conflicts HHS's previous guidance regarding the meaning of sex discrimination. In 2012, HHS Office of Civil Rights Director Leon Rodríguez wrote to me, among others, and clarified that "Section 1557's sex discrimination prohibition extends to claims of discrimination on the basis of gender identity or failure to conform to stereotypical notions of masculinity or femininity . . . sexual harassment and discrimination regardless of actual or perceived sexual orientation or gender identity of the individuals involved." A copy of OCR Director Rodríguez's letter is enclosed as **Exhibit A**.

8. The 2016 Final Rule, promulgated by HHS following a prolonged notice-and-comment process, reaffirmed this interpretation by defining discrimination "on the basis of sex" to include "discrimination on the basis of . . . sex stereotyping, and gender identity." 81 Fed. Reg. at 31,467.

9. The Revised Rule repeals entirely the 2016 Final Rule's definition of discrimination "on the basis of sex," without providing a different definition, while intimating that discrimination "on the basis of sex" is limited to discrimination based on the "biological binary of male and female that human beings share with other mammals." 85 Fed. Reg. at 37,161–62, 37,178– 79. These actions conflict with HHS's longstanding position regarding Section 1557, as noted in the 2012

letter and 2016 Final Rule, and creates confusion among health care providers, such as GLMA's members, and patients.

10. The Revised Rule also fosters greater discrimination against LGBTQ patients, who already experience widespread discrimination in obtaining health care and suffer significant health disparities in comparison to the general population. Research documents the history of this discrimination and the negative health outcomes that result. The majority of LGBTQ patients and patients living with HIV report having experienced providers refusing to touch them or using excessive precautions, providers using harsh or abusive language, providers being physically rough or abusive, and/or providers shaming LGBTQ patients and blaming these patients for their health status. A large percentage of transgender patients report having negative experiences related to their gender identity and transgender status when seeking medical care, including being exposed to verbal harassment or refusals of care.

11. LGBTQ patients face significant health disparities—higher risk factors for poor physical and mental health, higher rates of HIV, decreased access to appropriate health insurance, insufficient access to preventative medicine, and higher risk of poor treatment by health care providers. LGBTQ patients are vulnerable in other ways as well, including higher rates of poverty and limited access to LGBTQ-specific services, that present significant logistical and economic challenges to obtaining adequate health care. These harms are exacerbated by the Revised Rule. The Revised Rule will result in greater discrimination against LGBTQ patients, resulting in harm to patients and increased denials of services based not only on the medical services a patient seeks, but also on the patient's LGBTQ identity.

12. Among GLMA's strategic commitments is its ongoing collaboration with professional accreditation bodies, such as The Joint Commission, on the development,

implementation, and enforcement of sexual-orientation and gender-identity nondiscrimination policies as well as cultural-competency standards of care for the treatment of LGBTQ patients. Founded in 1951, The Joint Commission is the nation's oldest and largest standards-setting and accrediting body in health care. GLMA has worked with The Joint Commission and continues to work with similar professional bodies and health professional associations on standards, guidelines, and policies that address LGBTQ health, protecting individual patient health and public health in general.

13. The Revised Rule presents a direct conflict with nondiscrimination standards adopted by The Joint Commission and all major health professional associations, who have recognized the need to ensure LGBTQ patients are treated with respect and without bias or discrimination in hospitals, clinics, and other health care settings. Many of these efforts were prompted at least in part by GLMA's efforts through the years. For example, GLMA representatives, in coordination with other LGBTQ health experts, participated in the development and implementation of the hospital-accreditation nondiscrimination standards and guidelines developed by The Joint Commission to protect and ensure quality care for LGBTQ patients.

14. Similarly, GLMA has worked with the American Medical Association (AMA), among other health professional associations, over the last 15 years to ensure AMA policies prevent discrimination against LGBTQ patients and recognize the specific health needs of the LGBTQ community. All of the leading health professional associations—including the AMA, American Osteopathic Association, American Academy of PAs, American Nurses Association, American Academy of Nursing, American College of Physicians, American College of Obstetricians and Gynecologists, American Psychiatric Association, American Academy of Pediatricians, American Academy of Family Physicians, American Public Health Association,

American Psychological Association, National Association of Social Workers, and many more—have adopted policies articulating that health care providers should not discriminate in providing care to patients and clients because of patients' sexual orientation or gender identity. By carving out LGBTQ people from the regulatory health care nondiscrimination protections of the ACA and other regulations, the Revised Rule violates the ethical and medical standards of care that health care professionals are charged to uphold, and sends a confusing and conflicting message that such discrimination is acceptable.

15. In order for a health care organization to participate in and receive federal payment from Medicare or Medicaid programs, the organization must meet certain requirements, including a certification of compliance with health and safety requirements, which is achieved based on a survey conducted either by a state agency on behalf of the federal government or by a federally-recognized national accrediting organization. Accreditation surveys include standards that health care organizations do not discriminate based on sex, sexual orientation, or gender identity in the provision of services and in employment. A health care organization that discriminates on these bases in the provision of patient care or in employment, or that otherwise deviates from medical, professional and ethical standards of care is vulnerable to loss of accreditation. The Revised Rule conflicts with these requirements.

16. If not enjoined, the Revised Rule will harm GLMA members, the interests of the LGBTQ patients represented by GLMA, and GLMA members' patients. By removing explicit health care nondiscrimination regulatory protections for LGBTQ people, the Revised Rule prevents GLMA from achieving its goals with professional accreditation bodies. GLMA's goals include achieving and enforcing accreditation standards relating to nondiscrimination on the basis of sex, sexual orientation, and gender identity, and cultural-competency standards of care for

treatment of LGBTQ patients. GLMA also works with health professional associations to create nondiscrimination policies and ensure their members understand and adhere to such standards. However, the Revised Rule creates confusion among those professional accreditation bodies and health professional associations about health care providers accountable for discrimination against LGBTQ people and denials of care when the discriminatory conduct is justified on the basis of religious or moral beliefs. For example, the Revised Rule would prevent agencies, to the extent allowed by law, from recognizing the loss of accreditation of a health care organization due to a specified anti-LGBTQ belief. The Revised Rule also invites such facilities to discriminate against LGBTQ patients without concern about the impact such discrimination will have on the organization's ability to continue receiving federal funding. The revised rule, therefore, frustrates GLMA's goals, conflicts with professional accreditation standards, and invites discrimination against LGBTQ people in health care. GLMA will have to divert resources to address this frustrated goal.

17. The Revised Rule also impedes GLMA members' ability to do their jobs because nondiscrimination is core to the work of health care providers treating their patients. Some members of GLMA are employed by religiously-affiliated health care organizations (for example, hospitals, hospices, or ambulatory care centers) that receive federal funds and are covered entities under Section 1557. These health care providers also treat LGBTQ patients. The Revised Rule invites religiously-affiliated health care employers to discriminate against employees who are GLMA members for adhering to and enforcing their medical and ethical obligations to treat all patients in a nondiscriminatory manner, including providing all medically-necessary care that is in patients' best interests. The Revised Rule impinges on and conflicts with GLMA members' ethical

and medical standards of care that health care providers are charged to uphold and harms the patients that they serve.

18. The Revised Rule invites harassment and discriminatory treatment of GLMA members with regards to terms and conditions of employment based on their LGBTQ status. This is particular problematic for GLMA members who work for covered entities with fewer than 15 employees and that are therefore not subject to Title VII, and which are located in states without any statutory protections from discrimination based on sexual orientation, gender identity, or transgender status.

19. GLMA members and their LGBTQ patients are stigmatized and demeaned by the message, communicated by the Revised Rule, that their government privileges beliefs that result in the disapproval and disparagement of LGBTQ people in the health care context.

20. As an organization of health professionals who serve and care for patients from the LGBTQ community, GLMA knows that discrimination against LGBTQ individuals in health care access and coverage remains a pervasive problem. GLMA members have reported numerous instances of discrimination, especially those based on religious or moral objections to treating patients. Members have reported:

a. "I see patients nearly every day who have been treated poorly by providers with moral and religious objections. Patients with HIV who have been told that they somehow deserved this for not adhering to God's law. Patients who are transgender who have been told that 'we don't treat your kind here'. The psychological and physical damage is pervasive."

b. "[Some providers in my clinic] do not wish to have contact with transgender patients, mumbling religious incompatibilities when asked why. These

people have made our transgender patients feel very uncomfortable and unwelcome at times, making them potentially more hesitant to use the health services they may need."

c. "The impact on my patients who were directly denied care was both psychological and physical. With regard to their mental wellbeing they clearly felt marginalized and disrespected. With regard to their physical wellbeing, they experienced delay in care, and in some cases disruption of their routine medication dosing or diagnostic assessment."

21. GLMA members are also health care workers on the frontlines treating patients for COVID-19. GLMA members are, among other professionals, infectious disease specialists, residents, nurses, dentists, mental health providers and technicians treating COVID-19 patients in already overwhelmed health care systems. Discrimination against LGBTQ patients and health care providers is even more dangerous during this global health crisis. The pandemic is disproportionately affecting vulnerable communities, including LGBTQ people, for whom this Revised Rule adds another, often insurmountable, impediment to health care. Some GLMA members who are experiencing anti-LGBTQ animus on the frontlines fear sharing their stories for fear of being fired. Some GLMA members practice in workplaces with fewer than 15 employees and in states without explicit statutory protections on discrimination based on sexual orientation, gender identity, or transgender status. Those GLMA members who consented to share their stories explained that:

a. "During this pandemic, the curiosity of my genitalia struck a conversation while on shift and was brought to my attention. I made Human Resources

aware, no action has yet to be made. I am not protected from conversations like these at work."

b. "I am acutely aware of how COVID19 has in many ways disproportionately impacted the LGBTQ community. So many of my patients are no longer able to go to the support groups they joined to support them in the coming out process. Some are home from college and living in settings where they don't feel safe. Many remember the fear and isolation of living through the early days of the HIV epidemic."

c. "I am more concerned about discrimination towards LGBTQ+ patients, and stay on heightened awareness to call out ignorant comments or microaggressions that permeate the local culture, as well as systemic toxic masculinity."

d. "I actually had a few patients tell me that since 'the gays spread HIV' that 'the gays must be spreading this one too.'"

e. A transgender GLMA supporter on the frontlines during the pandemic reported that their own health care insurance refused to cover transition-related health care.

22. Based on what patients have told GLMA members about their history and fear of discriminatory treatment, it is clear that the Revised Rule will cause LGBTQ patients to attempt to hide their LGBTQ identities when seeking health care services, especially from religiously-affiliated health care organizations, to avoid such discrimination. When patients are unwilling to disclose their sexual orientation and/or gender identity to health care providers out of fear of

discrimination and being refused treatment, their mental and physical health is critically compromised.

23. The Revised Rule also harms patients with limited English proficiency ("LEP") who may not receive real-time good quality translator services. GLMA members treat LEP patients and GLMA represents LEP LGBTQ patients' interests. The Revised Rule adds another barrier to these LEP patients' health care because they will not have access to life-saving information, including the resources to appropriately communicate about their health status, diagnoses, or treatment details. This communication barrier will create confusion and harm the health of LEP patients.

24. As a result of the Revised Rule, GLMA is required to divert its resources to educate and assist its members and the LGBTQ patients its members serve to defend against the harms that the Revised Rule causes. GLMA's staff and resources already have been diverted from other program activities to engage in advocacy, policy analysis, and program-development to address the ill-effects of the Revised Rule. GLMA has worked tirelessly to get medical and other health associations to express their disapproval of the Revised Rule, which has diverted large amounts of resources away from other proactive projects and outreach efforts that are core to GLMA's mission. For example, GLMA coordinated efforts to release a message from over 1,000 medical and mental health providers condemning the then-proposed Revised Rule. A copy of this message is attached as **Exhibit B**. GLMA also spends resources answering GLMA members' inquiries about the Revised Rule given the pervasive concern that the Revised Rule contradicts medical ethical requirements and standards of care. GLMA must spend resources educating its members and the general health care community about GLMA's position on the Revised Rule and its effects on health care practices and providers.

25. The Revised Rule will also adversely impact GLMA and its members by necessitating the diversion and reallocation of resources to maintain its online list of LGBTQ-affirming health care providers for patient referrals. As a result of the Revised Rule, GLMA and its members expect to see increases in the use of this online service and must allocate additional staff time to support this increase in website traffic. GLMA will have to contact providers listed on the list to ensure that they will continue to provide nondiscriminatory care to LGBTQ patients and will continue to adhere to their medical and ethical standards of care to treat all patients equally. Patients have even expressed concern about traveling outside of their home cities for business because if they are ever in need of emergency medical assistance, they will not know where to go to ensure that they will receive nondiscriminatory, proper health care services. This makes GLMA's referral list so important and GLMA will need to be a resource for these patients.

26. The Revised Rule empowers and invites religious-based discrimination against GLMA members and will contribute to discriminatory and even hostile work environments for GLMA members, LGBTQ health care providers, and LGBTQ-affirming health care providers. GLMA members who insist on treating patients equally and in accordance with medical and ethical standards of care are likely to be required to shoulder extra burdens as fellow employees decline to provide certain care. GLMA members also are likely to encounter push-back, hostility, and even adverse employment actions from their employers or fellow employees for trying to enforce nondiscrimination policies and provide appropriate care to patients. Because the vast majority of GLMA members are LGBTQ themselves, seeing LGBTQ patients treated in a discriminatory way by their colleagues and supported by their employers will have a profound impact on the environment in which they work.

27. GLMA, in turn, sees and will continue seeing an increase in health care providers seeking its assistance with addressing such discrimination. The increased demand for GLMA's services will drain GLMA's resources and hamper its other work, especially since GLMA already has a very limited bandwidth for such services.

[*Signature on next page.*]

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Dated this 6th day of July, 2020.

Hector Vargas

EXHIBIT A

Letter from Leon Rodríguez, Director, Office for Civil Rights, U.S. Department of Health & Human Services (dated July 12, 2012)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary

Director
Office for Civil Rights
Washington, D.C. 20201

July 12, 2012

Maya Rupert, Esq.
Federal Policy Director
National Center for Lesbian Rights
1325 Massachusetts Ave. NW, Suite 700
Washington DC 20005

OCR Transaction Number: 12-000800

Dear Ms. Rupert:

Thank you for your letter to Secretary Kathleen Sebelius, which was forwarded for reply to the U.S. Department of Health and Human Services (HHS), Office for Civil Rights (OCR). In your letter, you requested that we issue guidance clarifying that sex-based discrimination includes discrimination on the basis of gender identity and sex stereotypes under Section 1557 of the Affordable Care Act.

As you may know, OCR enforces Section 1557 of the Affordable Care Act (42 U.S.C. 18116), which provides that an individual shall not be excluded from participation in, be denied the benefits of, or be subjected to discrimination on the grounds prohibited under 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), or Section 504 of the Rehabilitation Act of 1973, 29 U.S.C. 794 (disability), 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 Title I of the Affordable Care Act or its amendments. OCR has enforcement authority with respect to health programs and activities that receive Federal financial assistance from HHS or are administered by HHS or any entity established under Title I of the Affordable Care Act or its amendments.

We agree that Section 1557's sex discrimination prohibition extends to claims of discrimination based on gender identity or failure to conform to stereotypical notions of masculinity or femininity and will accept such complaints for investigation. Section 1557 also prohibits sexual harassment and discrimination regardless of the actual or perceived sexual orientation or gender identity of the individuals involved.

The HHS OCR is currently accepting and investigating complaints filed under Section 1557. We thoroughly review each complaint received; employ a case-by-case analysis of the facts and the relevant law; make a carefully considered decision on jurisdiction; and when warranted, issue a

finding that discrimination has (or has not) occurred. The HHS OCR intends to issue future guidance on Section 1557.

Until then, to make sure individuals, community organizations and providers know their rights and responsibilities, we ask you to help promote our website, www.hhs.gov/ocr, and:

- Learn about and connect with any one of our ten OCR regional offices http://www.hhs.gov/ocr/office/about/rgn-hqaddresses.html
- Learn how to file a complaint with OCR if you think your rights have been violated http://www.hhs.gov/ocr/civilrights/complaints/index.html
- Visit the HHS OCR You Tube channel (search for HHS OCR) for additional videos on topics like "Your Health Information, Your Rights" or "Communicating with Family, Friends and others Involved in Your Care".

I also want to underscore what we discussed and shared during OCR's January 30, 2012 LGBT/HIV Stakeholders Listening Session: my office is continuing and will continue to increase our outreach and education efforts with individuals, community organizations and providers regarding their rights and responsibilities under Section 1557. The Office for Civil Rights is absolutely committed to working with individuals and advocates to improving the health and well-being of members of the lesbian, gay, bisexual and transgender communities, and of course, the commitment to sincerely engage and partner with the LGBT community is a Department-wide commitment as demonstrated by the Secretary (see http://www.hhs.gov/secretary/about/lgbthealth.html) and the 2012 HHS LGBT Coordinating Committee Report which is available at http://www.hhs.gov/secretary/about/2012_lgbt_an_rpt.pdf.

Again, thank you for your leadership on these critical matters to the LGBT community and for your very thoughtful letter, and we look forward to our growing partnership and work together.

Sincerely,

Leon Rodriguez

cc:

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EXHIBIT B

Press Release, GLMA, 1,000+ Health Professionals Join Letter Opposing Healthcare Rights Law Rollback (dated May 29, 2020)

1,000+ Health Professionals Join Letter Opposing Healthcare Rights Law Rollback

PRESS RELEASE

CONTACT: press@glma.org or press@transequality.org

David Farmer (207) 557-5968

FOR IMMEDIATE RELEASE

May 29, 2020

Health Care Providers Urge Trump Administration To Delay Rule Change to the Affordable Care Act

WASHINGTON, D.C. – More than 1,000 medical and mental health providers have signed onto a letter in opposition to pending rules that would reinterpret nondiscrimination protections from the Affordable Care Act. The new rule sets the Trump administration's view that the law doesn't protect patients from discrimination because they are transgender, pregnant, or have a same-sex partner or family member. It also instructs hospitals and insurance companies that they are no longer required to provide patients with notices of their rights or how to get information in different languages.

The letter also urges the US Department of Health and Human Services to delay any rule change affecting access to health care until at least 90 days after the end of the COVID-19 public health emergency.

"As the death toll and hardships created by the COVID-19 pandemic continue to grow, the Trump administration and the Department of Health and Human Services should be working to expand access to health care, not creating excuses for providers to turn away transgender Americans," said Mara Keisling, executive director of the National Center for Transgender Equality, a co-organizer of the letter. "The pending rules are heartless and wrong-headed. The rules should be rejected. But the least the Trump administration could do to help protect the health of transgender people is to delay their implementation until we are through this crisis."

Section 1557 of the Affordable Care Act, also referred to as the Health Care Rights Law, prohibits discrimination on the basis of race, national origin, sex, age, or disability in health care programs or activities. It is the first federal civil rights law to prohibit discrimination based on sex in health care.

As proposed by the U.S. Department of Health and Human Services, this rule would falsely tell hospitals and health care insurance plans that they could:

- Refuse testing or treatment because a patient is transgender or doesn't conform to sex stereotypes.
- Refuse testing or treatment because a patient has had an abortion.
- Refuse testing or treatment to patients based on a provider or staff member's personal beliefs.
- Refuse testing or treatment based on sexual orientation, even in programs that have banned such discrimination since the G.W. Bush administration.

- Incorporate discriminatory plan benefit designs that eliminate/limit coverage critical to people with disabilities or preexisting conditions and place certain kinds of treatments needed by people with specific disabilities on the most expensive copay tiers.
- No longer notify patients of their right to receive information in their primary language.
- No longer notify patients of their right to file a grievance if they're mistreated.

"The pending rule changes will impede the delivery of life-saving health care even as the country grapples with more than 100,000 deaths with COVID-19," said Hector Vargas, executive director of GLMA: Health Professionals Advancing LGBTQ Equality and co-organizer of the letter. "Health care providers are the frontlines of this pandemic and know that our medical systems and essential workers are overwhelmed. We also know that Section 1557 is essential in our efforts to prevent deaths. The pending changes are irresponsible and unnecessary."

The letter addressed to Secretary Alex Azar of the US Department of Health and Human Services is below:

Re: Nondiscrimination in Health and Health Education Programs and Activities, Final Rule (RIN 0945-AA11)

On behalf of the more than 1,000 undersigned medical and mental health providers, we write to the administration in opposition to the pending final rule that would reinterpret the Affordable Care Act's nondiscrimination provisions so that the law will no longer protect patients from discrimination if they are transgender, pregnant, or have a same-sex partner or family member in a same-sex partnership. In addition, the new changes will direct hospitals and insurance providers that they will no longer have to provide notices of patient rights or instructions to get access to information in different languages.

As medical and mental health care providers, we vehemently oppose these rule changes and believe they will impede delivering of the highest quality of health care to the most marginalized, especially during a national public health crisis that has cost over 100,000 lives (1). We are on the frontlines of this pandemic and know firsthand that our medical systems and essential workers are heavily burdened and overwhelmed as the death toll continues to rise. We know that Section 1557 is essential in our efforts to prevent deaths during the current pandemic. Changes to this interpretation will be irresponsible and unnecessary as it will perpetuate discrimination and create unnecessary barriers for patients in accessing critical information about their rights and their health.

We know that this pandemic has already disproportionately impacted people of color. For example, data has already indicated that black and Latinx people in New York City are two times more likely to die compared to white people (2). In addition, we know that the LGBTQ community, especially LGBTQ people of color, are disproportionately impacted by this virus. This rule change will allow service providers to deny medical care, including testing and treatment for COVID-19, to many communities that are at greatest risk from this deadly virus and worsen health disparities. That's why we--and this nation's leading health professional associations, including the American Medical Association, American Nurses Association, American Academy of Pediatrics, American Psychiatric Association, American Psychological Association and National Association of Social Workers, among others -- have repeatedly opposed this proposal even before this current crisis.

As proposed by the U.S. Department of Health and Human Services, this rule would falsely tell hospitals and health plans that they could:

- Refuse testing or treatment because a patient is transgender or doesn't conform to sex stereotypes.
- Refuse testing or treatment because a patient has had an abortion.
- Refuse testing or treatment to patients based on a provider or staff member's personal beliefs.
- Refuse testing or treatment based on sexual orientation, even in programs that have banned such discrimination since the G.W. Bush administration.
- Incorporate discriminatory plan benefit designs that eliminate/limit coverage critical to people with disabilities or preexisting conditions and place certain kinds of treatments needed by people with specific disabilities on the most expensive copay tiers.
- No longer notify patients of their right to receive information in their primary language.
- No longer notify patients of their right to file a grievance if they're mistreated.

For all of these reasons, we urge the administration to suspend this rule change. At a minimum, this rulemaking process should be suspended until at least 90 days after the termination of the current COVID-19 Public Health Emergency declared by Secretary Azar on January 31, and after a large majority of states are no longer subject to stay-at-home orders and closure of non-essential businesses.

HHS has called this pandemic "an emergency of unprecedented magnitude", yet this administration has continued to fail us and the people that have been directly impacted by this crisis by creating barriers to testing, contact tracing, personal protective equipment and other critical supplies to save lives. We urge you to focus on the current crisis instead of exacerbating negative health outcomes from this deadly pandemic. If you have any questions, please contact Hector Vargas of GLMA or Debbie Ojeda-Leitner of NCTE.

Sincerely,

The Undersigned

(1) "Cases in the US." CDC. May 19, 2020. Anchorhttps://www.cdc.gov/coronavirus/2019-ncov/cases-updates/cases-in-us.html.

(2) Crear-Perry, Joia and McAfee, Michael. "To Protect Black Americans from the Worst Impacts of COVID-19, Release Comprehensive Racial Data." Scientific American. April 24, 2020.https://blogs.scientificamerican.com/voices/to-protect-black-americans-from-the-worst-impacts-of-covid-19-release-comprehensive-racial-data/.

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CERTIFICATE OF SERVICE

I hereby certify that on January 19, 2021, I electronically filed the foregoing brief with the Clerk of the Court for the United States Court of Appeals for the District of Columbia Circuit by using the appellate CM/ECF system. Participants in the case are registered CM/ECF users, and service will be accomplished by the appellate CM/ECF system.

/s/ Joshua Dos Santos
JOSHUA DOS SANTOS

[ORAL ARGUMENT NOT SCHEDULED]

No. 20-5331

IN THE UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

WHITMAN-WALKER CLINIC, INC., et al.,

Plaintiff-Appellees,

v.

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, et al.,

Defendants-Appellants.

On Appeal from the United States District Court
for the District of Columbia

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**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA**

WHITMAN-WALKER CLINIC, INC., *et al.*, *Plaintiffs,* v. U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, *et al.*, *Defendants*.	Case No. 1:20-cv-1630

**DECLARATION OF ROY HARKER, EXECUTIVE DIRECTOR,
AGLP: THE ASSOCIATION OF LGBTQ+ PSYCHIATRISTS**

I, Roy Harker, declare as follows:

1. I am the Executive Director of AGLP: The Association of LGBTQ+ Psychiatrists ("AGLP").

2. I have been the sole staff person for AGLP for over twenty-five years, first as National Office Director for five years, then as Executive Director since 1999. I am an alumnus of Drexel and Temple Universities in Philadelphia, and completed the American Society of Association Executives ("ASAE") Association Executive Certification in February of 2018, the highest professional credential for those engaged in association management.

3. I am submitting this Declaration in support of Plaintiffs' motion for a preliminary injunction to prevent the 1557 Revised Rule, published by the Department of Health and Human Services on June 19, 2020 (the "Revised Rule"), from taking effect.

4. AGLP: The Association of LGBTQ+ Psychiatrists is a 501(c)(3) national membership nonprofit organization based in Philadelphia, Pennsylvania, and incorporated in Pennsylvania. AGLP is a community of psychiatrists that educates and advocates on lesbian, gay, bisexual, and transgender mental health issues. AGLP's goals are to foster a fuller understanding of LGBTQ+

mental health issues; research and advocate for the best mental health care for LGBTQ+ people; develop resources to promote LGBTQ+ mental health; create a welcoming, safe, nurturing, and accepting environment for members; and provide valuable and accessible services to our members. AGLP strives to be a community for the personal and professional growth of all LGBTQ+ psychiatrists, and to be the recognized expert on LGBTQ+ mental health issues.

5. AGLP (formerly known as the Association of Gay and Lesbian Psychiatrists) represents the interests of about 450 LGBTQ+ psychiatrists who are members of the association. AGLP was founded in the 1970s when gay and lesbian members of the American Psychiatric Association (APA) met secretly at the annual meetings. At that time, in most states, homosexuality could be used as cause to rescind someone's license to practice medicine. In 1973, the APA removed homosexuality as a mental disorder from its Diagnostic and Statistical Manual of Mental Disorders (DSM). This allowed a more open association of lesbian and gay psychiatrists, who could be a little less fearful for their jobs if they were found out to be gay. Similarly, in 2012, the APA removed the term "Gender Identity Disorder," which had historically been used by mental health professionals to diagnose transgender individuals, from the DSM and instead added the term "Gender Dysphoria." The reason for the change was to emphasize that a person's identity is not disordered, but rather focus on the clinically significant distress they may suffer as a result of their experiences. The World Health Organization then removed gender dysphoria from psychiatric diagnosis in 2019. Even today, however, the mission of providing support and a safe space for LGBTQ psychiatrists to meet continues to be important to many of AGLP's members. AGLP is the oldest organized association of LGBTQ professionals in the country.

6. AGLP is an independent organization from American Psychiatric Association ("APA"), but works closely with APA through many projects, including but not limited to,

LGBTQ+ representation on the APA Assembly (the Minority Caucus of the APA and AGLP's own representative), APA position statements, LGBTQ+ Committees of the DSM, the creation and staffing of an AIDS Committee, and research and advocacy of particular interest to LGBTQ+ people through their quarterly *Journal of Gay and Lesbian Mental Health*, and seminars and discussion groups that are conducted concurrently with the APA's annual meeting. AGLP works within the APA to influence policies relevant to LGBTQ+ people, including issuing position statements educating about how discrimination and stigmatization of LGBTQ+ people adversely affects their mental health and right to happiness, as well as bringing awareness to and advocating against the misuse of religion to discriminate against LGBTQ+ people.

7. AGLP continues to work with APA and independently to support our members and advocate for LGBTQ+ patients. AGLP also assists medical students and residents in their professional development, encourages and facilitates the presentation of programs and publications relevant to gay and lesbian concerns at professional meetings; and serves as liaison with other minority and advocacy groups within the psychiatric community.

8. The Revised Rule fosters greater discrimination against LGBTQ+ patients, who already experience widespread discrimination in accessing health care. This discrimination increases negative health outcomes and results in health disparities in comparison to the non-LGBTQ+ population. AGLP's members inform us that their LGBTQ patients and patients living with HIV report having experienced frequent discrimination by other health care providers and suffer from more acute medical conditions resulting from such discrimination and fear of seeking medically-necessary health care services. A nationally representative survey from 2017 showed that 68.5% of LGBTQ people who experienced discrimination in the past year said it negatively

affected their psychological well-being, while 43.7% said it negatively affected their physical well-being.[1]

9. In addition, a large percentage of AGLP members' experiences are consistent with research findings that transgender patients report having negative experiences related to their gender identity when seeking medical care. A survey of almost 28,000 transgender people conducted in 2015 found that 33% of respondents had experienced a negative interaction with a health care provider because of their gender identity in the year preceding the survey.[2]

10. In comparison to other populations, LGBTQ patients face significant health disparities. For example, a nationally representative survey to collect data on sexual orientation found LGB people were at heightened risk of psychological distress, drinking, and smoking, and lesbian and bisexual women were at heightened risk of having multiple chronic conditions.[3] Data has also shown that transgender people in the United States are more likely to be overweight, be depressed, report cognitive difficulties, and forego treatment for health problems than cisgender people.

11. The Revised Rule will result in greater discrimination against LGBTQ+ patients, including those of AGLP's members, and in increased denials of services in violation of medical ethics and standards of care. The Revised Rule presents a direct conflict with nondiscrimination standards adopted by all the major health-professional associations, who have already recognized

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[1] Sejal Singh & Laura E. Durso, "Widespread Discrimination Continues to Shape LGBT People's Lives in Both Subtle and Significant Ways," *Center for American Progress*, May 2, 2017, https://www.americanprogress.org/issues/lgbt/news/2017/05/02/429529/widespread-discrimination-continues-shape-lgbt-peoples-lives-subtle-significant-ways.

[2] Sandy James et al., *Executive Summary of the Report of the 2015 U.S. Transgender Survey*, National Center for Transgender Equality (2016), https://transequality.org/sites/default/files/docs/usts/USTS-Executive-Summary-Dec17.pdf.

[3] Human Rights Watch, "You Don't Want Second Best": Anti-LGBT Discrimination in US Health Care (2018), https://www.hrw.org/report/2018/07/23/you-dont-want-second-best/anti-lgbt-discrimination-us-health-care.

the need to ensure LGBTQ+ patients are treated with respect and without bias or discrimination in hospitals, clinics, and other health care settings. All of the leading health-professional associations—including the American Medical Association, American Osteopathic Association, American Academy of Physician Assistants, American Nurses Association, American Academy of Nursing, American College of Physicians, American College of Obstetricians and Gynecologists, American Psychiatric Association, American Academy of Pediatricians, American Academy of Family Physicians, American Public Health Association, American Psychological Association, National Association of Social Workers, and many more—have adopted policies articulating that health care providers should not discriminate in providing care for patients and clients because of their sexual orientation or gender identity.

12. There is a consensus amongst scientists that gender identity is part of the natural spectrum of human experience and expression. This includes major medical organizations like the APA. Transgender and gender nonconforming people have been marginalized and continue to fight for basic civil rights. Discrimination and harassment are especially significant sources of stress for transgender youth who are navigating an especially challenging period of their life and are vulnerable to depression and suicide when not supported by family and schools. This is especially true when even their health care providers, the people whom they turn to in their most vulnerable times of need, discriminate against them or deny them care. As an organization of psychiatrists who often serve and care for patients who are LGBTQ+, AGLP knows that discrimination against LGBTQ+ individuals in health care access and coverage remains a pervasive problem. Discrimination by health care providers has been detrimental to the health of LGBTQ patients, and these harms would be exacerbated by the Revised Rule.

13. AGLP has long strongly held and publicly asserted that all people, whether LGBTQ+ or not, deserve equal rights under federal law and the Constitution; that religious liberty justifications for denying health care are thinly disguised efforts to return to marginalization and stigmatization of same-sex and transgender orientations and identities; that virtually every major mental-health organization has concluded that there is no credible scientific evidence that LGBTQ+ citizens are psychologically impaired *per se* or can change who they are; that LGBTQ+ citizens represent no more burden on American society than any other minority group, and, in fact, have made substantive contributions to the arts, sciences, and businesses in America; and that discrimination and stigmatization of LGBTQ+ citizens adversely affects their mental health and right to happiness. Therefore, AGLP steadfastly condemns all legislative and administrative efforts, including the Revised Rule, to deny access to health care to and discriminate against LGBTQ+ citizens.

14. The Revised Rule eliminates the definition of "on the basis of sex" and the specific regulatory prohibition of discrimination on the basis of gender identity, transgender status, and failure to conform to sex stereotypes. The Revised Rule also eliminates specific regulatory provisions related to discrimination against transgender individuals, as well as the provision relating to the discrimination on the basis of association. The elimination of these provisions, in addition to the Revised Rule's invitation to health care providers to discriminate based on their religious or moral beliefs, will result in direct harms to the LGBTQ+ patients that our members serve and to our members who advocate on behalf of their patients and condemn discrimination resulting from the Revised Rule. Additionally, our members' workloads will increase as a result of the Revised Rule because more LGBTQ+ patients will seek out their care as a result of discrimination or fear of discrimination from other, non-affirming providers. By inviting

discrimination against patients based on patients' sexual orientation, gender identity, or transgender status, the Revised Rule cannot be reconciled with the ethical standards that health care professionals are charged to uphold.

15. If not enjoined, the Revised Rule will harm AGLP members, LGBTQ+ patients whose interests AGLP also represents, and the patients who AGLP members treat. The Revised Rule invites health care facilities to discriminate against LGBTQ+ employees and patients without concern about the impact on ensuring the provision of medically necessary care for patients, adherence with medical standards of care, ethical requirements, accreditation requirements, and nondiscrimination requirements in employment and in the provision of patient care. The Revised Rule, therefore, frustrates AGLP's mission of achieving and enforcing safe workspaces for LGBTQ+ psychiatrists and nondiscriminatory health care services to AGLP members' LGBTQ+ patients. The Revised Rule frustrates AGLP's mission of advocating for nondiscrimination standards of care for patients and nondiscriminatory work environments for its members that protect against discrimination on the basis of sexual orientation and gender identity and advocating for cultural competency standards of care for treatment of LGBTQ+ patients.

16. The 2016 Final Rule, promulgated by HHS in 2016 pursuant to Section 1557 of the ACA, prohibits discrimination with regards to certain terms or benefits of employment, including employee health benefit programs. As a result of the Revised Rule, some of AGLP's LGBTQ+ members could lose regulatory protections from discrimination regarding these employment benefits as their employers are covered entities under the Revised Rule but not large enough to be subject to Title VII of the Civil Rights Act.

17. Similarly, some members of AGLP who are employed by religiously-affiliated health care organizations may be subjected to discrimination as a result of the Revised Rule, whose

incorporation of overly broad religious exemptions are inapposite in the health care context and conflict and also conflict with Title VII. AGLP has members who are medical directors and administrators in hospitals and clinics all over the country and, in the course of their employment, these health care providers treat LGBTQ+ patients. The Revised Rule invites religiously-affiliated health care employers to discriminate against employees who are AGLP members for adhering to their medical and ethical obligations to treat all patients in a nondiscriminatory manner, including providing all medically necessary care in the patient's best interest, and for advocating on behalf of patients who are discriminated against by other providers or their employers. The Revised Rule impinges on and conflicts with AGLP members' medical and ethical obligations as health care providers and harms the patients that they serve.

18. AGLP members and their LGBTQ+ patients are stigmatized and demeaned by the message communicated by the Revised Rule that their government privileges beliefs that result in the disapproval and disparagement of LGBTQ+ people in the health care context and refused to protect LGBTQ+ people from discrimination in health care. The Revised Rule invites discrimination against AGLP members as well as their LGBTQ+ patients.

19. Based on their years of working with LGBTQ+ patients who have reported concealing their identities out of fear of discrimination, AGLP members know that the Rule will cause LGBTQ patients to attempt to hide their LGBTQ identities when seeking health care services, especially from religiously-affiliated health care organizations, in order to avoid discrimination. When patients are unwilling to disclose their sexual orientation and/or gender identity to health care providers out of fear of discrimination and being refused treatment, their mental and physical health is critically compromised.

20. AGLP will need to be a resource to its members and their patients, who may be in need of medical services but may no longer know where to go for LGBTQ+-affirming health care as a result of the Revised Rule. The Revised Rule will predictably result in more discrimination and denials of care, and, consequently, more requests for referrals. With an increase in referral requests as a result of the Revised Rule, AGLP will need to allocate additional resources to assisting AGLP members and their patients with health care referrals. AGLP offers an online referral service to patients seeking LGBTQ+-affirming psychotherapy, support, and psychiatric treatment. The Revised Rule adversely impacts AGLP by necessitating the diversion and reallocation of resources in order to provide referrals to increasing numbers of patients. The Revised Rule will make it more difficult and resource-intensive for AGLP to locate and monitor appropriate referrals that will not cause further harm to AGLP patients who have already been discriminated against or who fear discrimination on the basis of objections to the patients' gender identities or sexual orientation. AGLP will have to update its online referral search engine, especially because many health care providers currently listed on the website are affiliated with religious hospitals and organization. As a result of the Revised Rule, AGLP will have to allocate additional staff time to support the increase in referral requests.

21. AGLP will be required to expend its resources to educate and assist its members and the LGBTQ+ patients its members serve to defend against the harms that the Revised Rule causes. AGLP has been working with other medical and health associations, including the APA, to express disapproval of the Revised Rule. Such work has diverted resources away from other proactive projects and outreach efforts that are core to AGLP's mission. AGLP will also spend resources answering AGLP members' inquiries about the Revised Rule given the pervasive and real concern

that the Revised Rule invites behavior that contradicts medical ethical requirements and standards of care.

22. The Revised Rule empowers and invites discrimination against AGLP members and their patients and will create discriminatory work environments for AGLP members. AGLP, in turn, sees and will continue seeing an increase in psychiatrists seeking its assistance with addressing such discrimination. AGLP will need to help its members navigate through these hostile environments and may need to intervene on behalf of its members when necessary. The increased demand for such services will further hamper AGLP's other work because AGLP already has a very limited bandwidth for such services.

[*Signature on next page.*]

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Dated this 6th day of July, 2020.

Roy Harker

Roy Harker

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

WHITMAN-WALKER CLINIC, INC., *et al.*, *Plaintiffs,* v. U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, *et al.*, *Defendants*.	Case No. 1:20-cv-01630

DECLARATION OF DR. DEBORAH FABIAN, MD

I, Deborah Fabian, declare as follows:

1. I am a 70-year-old transgender woman.

2. I am an orthopedic surgeon and an employee of the Indian Health Service, a health care agency within the U.S. Department of Health and Human Services ("HHS"). The Indian Health Service is responsible for providing federal health care services to Native Americans and Alaska Natives.

3. I received my medical degree from Hahnemann Medical College (now part of Drexel University College of Medicine) in Pennsylvania in 1975. I was a resident in general surgery (1975-77), and later orthopedic surgery (1980-83) at Dartmouth Medical School in New Hampshire. I am board certified by the American Board of Orthopedic Surgery and am a Fellow in the American Academy of Orthopedic Surgeons.

4. I served in active duty in the United States Navy from 1977 to 1980, and served in the active reserves from 1991 to 1997.

5. I am a member of GLMA: Health Professionals Advancing LGBTQ Equality.

6. I currently work as an orthopedic surgeon at Gallup Indian Medical Center ("GIMC"), a 99-bed hospital in Gallup, New Mexico run by the Indian Health Service. GIMC is on the border of the Navajo Nation. Our patient population is over 99% Native Americans, primarily Navajo, as well as Apache and Pueblo. Clinical specialties at GIMC include Internal Medicine, Cardiology, Anesthesia, OB/GYN, General Surgery, Orthopedics, Ophthalmology, ENT, Radiology, Pathology, Pediatrics, Psychiatry, Emergency Medicine, and Urology. GIMC is the only hospital that provides these specialty health care services in over a 100-mile radius. The workload at GIMC is one of the largest within the Indian Health Service with 250,000 outpatient encounters and 5,800 inpatient admissions annually.

7. I am submitting this Declaration in support of Plaintiffs' Motion for a Preliminary Injunction to prevent the revised regulation under Section 1557 of the Affordable Care Act ("ACA"), published by HHS on June 19, 2020 (the "Revised Rule"), from taking effect. The Revised Rule eliminates explicit regulatory protections for LGBTQ people in health care that were included in the original regulation under Section 1557, which was promulgated in May 2016 ("2016 Final Rule").

8. I have practiced orthopedic surgery for nearly 40 years, including as the Chief of Surgery at Metrowest Medical Center in Framingham, Massachusetts.

9. I began to transition to live as the woman that I am in 2009. I was fortunate to have the loving support of my wife and family during this process. I began fully presenting as female in all aspects of my life, including my medical practice, in 2011.

10. As a result, however, my medical practice suffered and, notwithstanding my years of experience and credentials, it was difficult for me to secure employment as a transgender woman.

11. Women—let alone transgender women—are a rarity in the highly-specialized field of orthopedic surgery, where, according to a 2018 report from the Association of American Medical Colleges, women make up just 5% of the active physicians in orthopedic surgery.[1]

12. Based on my experience, I have a deep appreciation for the legal understanding that discrimination based on transgender status is discrimination based on sex. In March 2016, in a case in which I was a plaintiff, a federal district court held that "Employment discrimination on the basis of transgender identity is employment discrimination 'because of sex' and constitutes a violation of Title VII of the Civil Rights Act." *Fabian*, 172 F. Supp. 3d 509, 527 (D. Conn. 2016). This ruling is consistent with the 2016 Final Rule promulgated by HHS a few months later.

13. Having encountered difficulty securing employment after my transition to live openly as a transgender woman, I was finally able to secure employment as an orthopedic surgeon at Bayne-Jones Army Community Hospital at Fort Polk, a United States Army base in Vernon Parish, Louisiana.

14. Living and working in health care as a transgender woman in Louisiana was not easy.

15. I have had numerous former colleagues at Fort Polk tell me they did not want me to work there or were apprehensive about my becoming their colleague because of my transgender status, but that after meeting me and getting to see me work, they appreciated me as a colleague.

16. I encountered more overt forms of discrimination as well. In early 2017, following the start of the Trump Administration, a colleague rose up to speak during an all-staff meeting at the hospital at Fort Polk. There were approximately 350-400 staff members at this meeting. This

[1] Association of American Medical Colleges, *Physician Specialty Data Report: Active Physicians by Sex and Specialty, 2017* (2018), https://www.aamc.org/data-reports/workforce/interactive-data/active-physicians-sex-and-specialty-2017.

colleague then proceeded to refer to me by male pronouns—misgendering me—and to say that I was "disgusting" and that "God thinks you're disgusting."

17. In 2018, I moved to New Mexico and began working as an orthopedic surgeon at GIMC.

18. As a transgender physician, HHS's announcement of the Revised Rule has caused me a great deal of distress and frustration. Having had personal experience with discrimination and having had my right to be free from such discrimination recognized by a court because discrimination based on transgender status is discrimination based on sex, I have a unique appreciation for the regulatory protections contained in the 2016 Final Rule and what they mean for health care professionals like myself and for our LGBTQ patients.

19. As a result of the Revised Rule, I worry that LGBTQ health care professionals and patients will now face more discrimination in the course of their employment and health care, respectively. Indeed, the Revised Rule invites such discrimination and adopts the narrow view of discrimination "on the basis of sex" that was rejected in my case in 2016.

20. I also worry that the Revised Rule will cause patients to delay necessary health care as a result of fear of discrimination. This in turn will have negative health outcomes for the patients, whose conditions may worsen and become more acute.

21. In addition, the Revised Rule no longer treats the Indian Health Service, of which GIMC is a part, as a covered entity under Section 1557 of the ACA. This means that health care professionals like myself and our patients, including LGBTQ patients, will no longer, according to HHS, be protected from discrimination in health care pursuant to Section 1557. And while New Mexico has explicit statutory protections from discrimination based on sexual orientation and gender identity, such protections are inapplicable to a federal entity like GIMC.

22. GIMC provides health care services, including gender affirming care, to approximately 100-150 transgender, gender nonconforming, and two-spirit Native American patients. I have asked GIMC management what the Revised Rule will mean for these patients and whether GIMC will commit publicly not to discriminate on the basis of sexual orientation, gender identity, or transgender status. To date, I have been told only that GIMC is part of HHS and they cannot contradict what HHS has said.

23. I am particularly worried about how the Revised Rule will affect GIMC's and our nation's efforts to stem the COVID-19 pandemic.

24. GIMC has already seen a large shift in how it operates as a result of the COVID-19 pandemic. Over 90% of the hospital beds GIMC are currently full as a result of COVID-19. GIMC has also stopped providing some of its specialty services, directing patients to hospitals that are at least 2 hours away, and my colleagues and I have mostly been working on COVID-19 testing and the treatment of patients who test positive for COVID-19 and develop symptoms.

25. Just a couple of weeks ago, one of my transgender patients tested positive for COVID-19. I worry about what may happen to this patient if the Revised Rule were allowed to take effect and she were to develop COVID-19 symptoms.

* * * * *

26. As a health care professional, I have experienced discrimination on the basis of my transgender status. The Revised Rule defies the legal and medical understanding of discrimination "on the basis of sex," an understanding that encompasses discrimination based on gender identity or transgender status and from which I have previously benefited. The Revised Rule poses serious and ongoing threats to the health and overall wellbeing of transgender, gender nonconforming, and two-spirit people, including those I care for at GIMC.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Dated this 5 day of July, 2020.

Deborah Fabian, MD

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

WHITMAN-WALKER CLINIC, INC., *et al.*,

Plaintiffs,

v.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, *et al.*,

Defendants.

Case No. 1:20-cv-1630

EXPERT DECLARATION OF DR. RANDI C. ETTNER, Ph.D.

I, Dr. Randi C. Ettner, declare as follows:

1. I am a licensed clinical and forensic psychologist with expertise concerning the diagnosis and treatment of gender dysphoria.

2. I have been retained by counsel for Plaintiffs Whitman-Walker Clinic, Inc. d/b/a Whitman-Walker Health, The TransLatin@ Coalition, Los Angeles LGBT Center, Bradbury-Sullivan LGBT Community Center, American Association of Physicians for Human Rights d/b/a GLMA: Health Professionals Advancing LGBTQ Equality, AGLP: The Association of LGBTQ+ Psychiatrists, Dr. Sarah Henn, Dr. Randy Pumphrey, Dr. Robert Bolan, and Dr. Ward Carpenter as an expert in connection with the above-captioned matter.

3. I submit this declaration in support of Plaintiffs' motion for a preliminary injunction to prevent the revised regulation under Section 1557, published by the U.S. Department of Health and Human Services ("HHS") on June 19, 2020 (the "Revised Rule"), from taking effect.

4. I have actual knowledge of the matters stated herein. If called to testify in this matter, I would testify truthfully and based on my expert opinion.

5. I prepared this declaration to set forth the opinions to which I may testify in this case and the bases for my opinions. The opinions expressed in this declaration are based on the information that I have reviewed to date. I reserve the right to revise and supplement this report if any new information becomes available in the future.

6. A copy of my curriculum vitae is attached to this declaration as **Exhibit A**. Materials that I considered in forming my opinions are listed in **Exhibit B** or referenced in this report.

7. The content and opinions set forth in this declaration reflect in large part information I conveyed to Defendant Roger Severino, Director of the Office of Civil Rights of HHS, and other members of his staff in November 2017 in a "listening session" Mr. Severino held regarding the health care needs of transgender people and the medical treatment of gender dysphoria. Documentation of my participation in this listening session is attached hereto as **Exhibit C**.

I. BACKGROUND AND QUALIFICATIONS

Qualifications and Basis for Opinion

8. I received my doctorate in psychology (with honors) from Northwestern University in 1979. I am a Fellow and Diplomate in Clinical Evaluation of the American Board of Psychological Specialties, and a Fellow and Diplomate in Trauma/Posttraumatic Stress Disorder (PTSD).

9. I was the chief psychologist at the Chicago Gender Center from 2005 to 2016, when it moved to Weiss Memorial Hospital. Since that time, I have held the sole psychologist position at the Center for Gender Confirmation Surgery at Weiss Memorial Hospital. The center specializes in the treatment of individuals with gender dysphoria.

10. I have been involved in the treatment of patients with gender dysphoria since 1977, when I was an intern at Cook County Hospital in Chicago. Over the course of my career, I have evaluated, diagnosed, and treated between 2,500 and 3,000 individuals with gender dysphoria and mental health issues related to gender variance.

11. I have published four books related to the treatment of individuals with gender dysphoria, including the medical text entitled *Principles of Transgender Medicine and Surgery* first edition (Ettner, Monstrey & Eyler, 2007) and second edition (Ettner, Monstrey & Coleman, 2016). I have also authored numerous articles in peer-reviewed journals regarding the provision of health care to this population. I serve as a member of the editorial boards for the International Journal of Transgenderism and Transgender Health.

12. I am the Secretary and member of the Executive Board of Directors of the World Professional Association for Transgender Health ("WPATH") and an author of the *WPATH Standards of Care for the Health of Transsexual, Transgender and Gender-nonconforming People* (7th version), published in 2011. The WPATH-promulgated *Standards of Care* ("*Standards of Care*") are the internationally recognized guidelines for the treatment of persons with gender dysphoria and serve to inform medical treatment in the United States and throughout the world.

13. I have lectured throughout North America, South America, Europe, and Asia on topics related to gender dysphoria and present grand rounds on gender dysphoria at university hospitals. I have been an invited guest at the National Institute of Health to participate in developing a strategic research plan to advance the health of sexual and gender minorities, and I received a commendation from the United States Congress House of Representatives on February 5, 2019 recognizing my work for WPATH and on gender dysphoria in Illinois.

14. I have been retained as an expert regarding gender dysphoria and its treatment in multiple court cases in both state and federal courts as well as administrative proceedings, and have repeatedly qualified as an expert. I have also been a consultant regarding appropriate care for incarcerated transgender people and for transgender people enrolled in Medicaid in the state of Illinois.

15. My Curriculum Vitae, attached hereto as **Exhibit A**, further documents my education, training, research, and years of experience in this field.

16. A bibliography of the materials reviewed in connection with this declaration is attached hereto as **Exhibit B**. The sources cited therein are authoritative, scientific peer-reviewed publications. I generally rely on these materials when I provide expert testimony, and they include the documents specifically cited as supportive examples in particular sections of this declaration. The materials I have relied on in preparing this declaration are the same type of materials that experts in my field of study regularly rely upon when forming opinions on the subject.

Compensation

17. I am being compensated for my work on this matter at a rate of $375.00 per hour for preparation of declarations and expert reports. I will be compensated $500.00 per hour for any pre-deposition and/or pre-trial preparation and any deposition testimony or trial testimony. I will receive a flat fee of $2,500.00 for any travel time to attend deposition or trial, and will be reimbursed for reasonable out-of-pocket travel expenses incurred for the purpose of providing expert testimony in this matter. My compensation does not depend on the outcome of this litigation, the opinions I express, or the testimony I may provide.

Previous Testimony

18. In the last four years, I have testified as an expert at trial or by deposition in the following cases: *Eller v. Prince George's Cty. Public Sch.*, No. 8:18-cv-03649-TDC (D. Md. 2020); *Ray v. Acton*, No. 2:18-cv-00272 (S.D. Ohio 2019); *Monroe v. Jeffreys*, No. 3:18-cv-00156-NJR-MAB (S.D. Ill. 2019); *Soneeya v. Turco*, No. 07-12325-DPW (D. Mass. 2019); *Edmo v. Idaho Dep't of Correction*, No. 1:17-CV-00151-BLW, 2018 WL 2745898 (D. Idaho 2018); *Carillo v U.S. Dep't of Justice Exec.* (Office of Immig. Rev. 2017); *Broussard v. First Tower Loan, LLC*, 135 F. Supp. 3d 540 (E.D. La. 2016); *Faiella v. American Medical Response of Connecticut, Inc.*, No. HHD-CV15-6061263-S (Conn. Super. Ct. 2015).

II. EXPERT OPINIONS

Gender Identity and Gender Dysphoria

19. A person's sex is comprised of a number of components including, *inter alia*: chromosomal composition (detectible through karyotyping); gonads and internal reproductive organs (detectible by ultrasound, and occasionally by a physical pelvic exam); external genitalia (which are visible at birth); sexual differentiations in brain development and structure (detectible by functional magnetic resonance imaging studies and autopsy); and gender identity.

20. Gender identity is a well-established concept in medicine. Gender identity refers to a person's inner sense of belonging to a particular sex, such as male or female. It is a deeply felt and core component of human identity. All human beings develop this elemental internal view: the conviction of belonging to a particular gender, such as male or female. Gender identity is innate, has biological underpinnings, and is firmly established early in life.

21. When there is divergence between anatomy and identity, one's gender identity is paramount and the primary determinant of an individual's sex designation. Developmentally, it is

the overarching determinant of the self-system, influencing personality, a sense of mastery, relatedness, and emotional reactivity, across the life span. It is also the foremost predictor of satisfaction and quality of life. Efforts to change an individual's gender identity are harmful, futile, and unethical.

22. At birth, individuals are assigned a sex, typically male or female, based solely on the appearance of their external genitalia. For most people, that assignment turns out to be accurate, and their birth-assigned sex matches that person's actual sex. However, for transgender individuals, this is not the case.

23. For transgender individuals, the sense of one's self—one's gender identity—differs from the sex they were assigned at birth, giving rise to a sense of being "wrongly embodied."

24. The medical diagnosis for that feeling of incongruence and accompanying distress is gender dysphoria, a serious medical condition, formerly known as gender identity disorder ("GID"). Gender Dysphoria is a diagnosis codified in the fifth edition of the *Diagnostic and Statistical Manual of Mental Disorders* ("DSM-5").

25. The critical element of the Gender Dysphoria diagnosis is the presence of symptoms that meet the threshold for clinical impairment. This represents a change from GID, which focused on an individual's *identity* being disordered. This new diagnostic term, Gender Dysphoria, is also an acknowledgment that gender incongruence, in and of itself, does not constitute a mental disorder. As recently as June 16, 2018, the World Health Organization ("WHO") likewise announced it was reclassifying the gender incongruence diagnosis in the forthcoming International Classification of Diseases-11 ("ICD-11"). This is significant because it removes "gender identity disorder" from the chapter on mental and behavioral disorders,

recognizing that gender incongruence is not a mental illness, and instead incorporates it within a new chapter dedicated to sexual health.

26. Gender dysphoria is characterized by incongruence between one's experienced/expressed gender and assigned sex at birth, and clinically significant distress or impairment of functioning that results. Gender dysphoria is manifested by symptoms such as preoccupation with ridding oneself of the primary and/or secondary sex characteristics associated with one's birth-assigned sex. Untreated gender dysphoria can result in significant clinical distress, debilitating depression, and suicidality.

27. The diagnostic criteria for gender dysphoria in adults are as follows:

a. A marked incongruence between one's experienced/expressed gender and assigned gender, of at least 6 month's duration, as manifested by at least two of the following:

   i. A marked incongruence between one's experienced/expressed gender and primary and/or secondary sex characteristics.

   ii. A strong desire to be rid of one's primary and/or secondary sex characteristics.

   iii. A strong desire for the primary and/or secondary sex characteristics of the other gender.

   iv. A strong desire to be of the other gender.

   v. A strong desire to be treated as the other gender.

   vi. A strong conviction that one has the typical feelings and reactions of the other gender.

b. The condition is associated with clinically significant distress or impairment in social, occupational, or other important areas of functioning.

28. Gender dysphoria is a highly treatable condition. Without treatment, however, individuals with gender dysphoria experience anxiety, depression, suicidality, and other attendant mental health issues. They are also frequently isolated because they carry a burden of shame and low self-esteem, attributable to the feeling of being inherently "defective." This leads to stigmatization, and over time, ravages healthy personality development and interpersonal relationships. As a result, without treatment many such individuals are unable to function effectively in daily life. Studies show a 41%-43% rate of suicide attempts among this population, far above the baseline for North America (Haas et al., 2014).

29. Gender dysphoric patients who are assigned a male sex at birth but identify as female and lack access to appropriate care are often so desperate for relief that they may resort to life-threatening attempts at auto-castration—removal of the testicles—in the hopes of eliminating the major source of testosterone that kindles the distress (Brown, 2010; Brown & McDuffie, 2009).

30. Gender dysphoria generally intensifies with age. As gender dysphoric individuals approach middle age, they experience an exacerbation of symptoms (Ettner, 2013; Ettner & Wiley, 2013).

Treatment of Gender Dysphoria

31. The standards of care for treating gender dysphoria are set forth in the WPATH *Standards of Care*, first published in 1979. The *Standards of Care* are the internationally recognized guidelines for the treatment of persons with gender dysphoria, and inform medical treatment throughout the world, and in this country. The American Medical Association, the Endocrine Society, the American Psychological Association the American Psychiatric

Association, the World Health Organization, the American Academy of Family Physicians, the American Public Health Association, the National Association of Social Workers, the American College of Obstetrics and Gynecology and the American Society of Plastic Surgeons all endorse protocols in accordance with the WPATH standards. *See*, *e.g.*, American Medical Association (2008) Resolution 122 (A-08); *Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline* (2017); American Psychological Association Policy Statement on Transgender, Gender Identity & Gender Expression Non-discrimination (2008).

32. The Standards of Care identify the following evidence-based protocols for the treatment of individuals with gender dysphoria:

- Changes in gender expression and role, consistent with one's gender identity (social role transition)
- Psychotherapy for purposes such as addressing the negative impact of stigma, alleviating internalized transphobia, enhancing social and peer support, improving body image, promoting resiliency, etc.
- Hormone therapy to feminize or masculinize the body
- Surgery to alter primary and/or secondary sex characteristics (e.g., breasts, external genitalia, facial features, body contouring)

33. The ability to live in a manner consistent with one's gender identity is critical to a person's health and well-being and is a key aspect in the treatment of gender dysphoria. The process by which transgender people come to live in a manner consistent with their gender identity, rather than the sex they were assigned at birth, is known as transition. The steps that each

transgender person takes to transition are not identical. Whether any particular treatment is medically necessary or even appropriate depends on the medical needs of the individual.

34. Once a diagnosis is established, a treatment plan should be developed based on the individualized assessment of the medical needs of the patient. WPATH specifies that treatment plans and provision of care must be undertaken by qualified professionals, with established competencies in the treatment of gender dysphoria.

35. **Psychotherapy:** Psychotherapy can provide support and help with many issues that arise in tandem with gender dysphoria. However, psychotherapy alone is not a substitute for medical intervention when medical interventions are required, nor is it a precondition for medically indicated treatment. By analogy, counseling can be useful for patients with diabetes by providing psychoeducation about living with chronic illness and nutritional information, but counseling does not obviate the need for insulin.

36. **Social Role Transition:** The *Standards of Care* establish the therapeutic importance of changes in gender expression and presentation—the ability to feminize or masculinize one's appearance—as a critical component of treatment. Known as the "real life experience," it requires dressing, grooming, and otherwise conveying, via social signifiers, a public face and role consistent with one's gender identity. This is an appropriate and essential part of identity consolidation. Through this experience, the transgender individual can begin to address the shame some experience of growing up living as a "false self" and the grief of being born in the "wrong body." (Greenberg and Laurence, 1981; Ettner, 1999; Devor, 2004; Bockting, 2007.)

37. **Hormone Therapy:** For individuals with persistent, well-documented gender dysphoria, hormone therapy is an essential, medically indicated treatment to alleviate the distress of the condition. Cross sex hormone administration is a well-established and effective treatment

modality for gender dysphoria. The American Medical Association, the Endocrine Society, the American Psychiatric Association and the American Psychological Association all concur that hormone therapy, provided in accordance with the WPATH *Standards of Care*, is the medically necessary, evidence-based, best practice care for most patients with gender dysphoria.

38. The goals of hormone therapy are (1) to significantly reduce hormone production associated with the person's birth sex, causing the unwanted secondary sex characteristics to recede, and (2) to replace the natal, circulating sex hormones with either feminizing or masculinizing hormones, using the principles of hormone replacement treatment developed for hypogonadal patients (i.e. those born with insufficient sex steroid hormones). *See Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline* (2017); *Endocrine Treatment of Transsexual Persons: An Endocrine Society Clinical Practice Guideline* (2009).

39. The therapeutic effects of hormone therapy are twofold: (1) with endocrine treatment, the patient acquires congruent secondary sex characteristics, i.e., breast development, redistribution of body fat, cessation of male pattern baldness, and reduction of body hair; and (2) hormones act directly on the brain, via receptor sites, attenuating the dysphoria and attendant psychiatric symptoms, and promoting a sense of well-being.

40. For many patients, hormones alone will not provide sufficient breast development to approximate the female torso. For these patients, breast augmentation has a dramatic, irreplaceable, and permanent effect on reducing gender dysphoria, and thus unquestionable therapeutic results.

41. **Surgical Treatment:** For individuals with severe gender dysphoria, hormone therapy alone is insufficient. In these cases, dysphoria does not abate without surgical intervention.

For transgender women, genital confirmation surgery has two therapeutic purposes. First, removal of the testicles eliminates the major source of testosterone in the body. Second, the patient attains body congruence resulting from the normal appearing and functioning female uro-genital structures. Both outcomes are crucial in attenuating or eliminating gender dysphoria. Additionally, breast augmentation procedures play the critical role in treatment mentioned in the paragraph immediately above.

42. Decades of methodologically sound and rigorous scientific research have demonstrated that gender confirmation surgery is a safe and effective treatment for severe gender dysphoria and, indeed, for many, it is the only effective treatment. The American Medical Association, the Endocrine Society, the American Psychological Association, and the American Psychiatric Association all endorse surgical therapy, in accordance with the WPATH *Standards of Care*, as medically necessary treatment for individuals with severe gender dysphoria. *See* American Medical Association (2008), Resolution 122 (A-08); *Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline* (2017) ("For many transgender adults, genital gender-affirming surgery may be the necessary step toward achieving their ultimate goal of living successfully in their desired gender role."); American Psychological Association *Policy Statement on Transgender, Gender Identity and Gender Expression Nondiscrimination* (2009) (recognizing "the efficacy, benefit and medical necessity of gender transition treatments" and referencing studies demonstrating the effectiveness of sex-reassignment surgeries).

43. Surgeries are considered "effective" from a medical perspective, if they "have a therapeutic effect" (Monstrey et al. 2007). More than three decades of research confirms that gender confirmation surgery is therapeutic and therefore an effective treatment for gender

dysphoria. Indeed, for many patients with severe gender dysphoria, gender confirmation surgery is the only effective treatment.

44. In a 1998 meta-analysis, Pfafflin and Junge reviewed data from 80 studies, from 12 countries, spanning 30 years. They concluded that "reassignment procedures were effective in relieving gender dysphoria. There were few negative consequences and all aspects of the reassignment process contributed to overwhelmingly positive outcomes" (Pfafflin & Junge 1998).

45. Numerous subsequent studies confirm this conclusion. Researchers reporting on a large-scale prospective study of 325 individuals in the Netherlands concluded that after surgery there was "a virtual absence of gender dysphoria" in the cohort and "results substantiate previous conclusions that sex reassignment is effective" (Smith et al. 2005). Indeed, the authors of the study concluded that the surgery "appeared therapeutic and beneficial" across a wide spectrum of factors and "[t]he main symptom for which the patients had requested treatment, gender dysphoria, had decreased to such a degree that it had disappeared."

46. As a general matter, patient satisfaction is a relevant measure of effective treatment. Achieving functional and normal physical appearance consistent with gender identity alleviates the suffering of gender dysphoria and enables the patient to function in everyday life. Studies have shown that by alleviating the suffering and dysfunction caused by severe gender dysphoria, gender confirmation surgery improves virtually every facet of a patient's life. This includes satisfaction with interpersonal relationships and improved social functioning (Rehman et al., 1999; Johansson et al., 2010; Hepp et al.; 2002; Ainsworth & Spiegel, 2010; Smith et al., 2005); improvement in self-image and satisfaction with body and physical appearance (Lawrence, 2003; Smith et al., 2005; Weyers et al., 2009); and greater acceptance and integration into the family (Lobato et al., 2006).

47. Studies have also shown that surgery improves patients' abilities to initiate and maintain intimate relationships (Lobato et al., 2006; Lawrence, 2005; Lawrence, 2006; Imbimbo et al., 2009; Klein & Gorzalka, 2009; Jarolim et al., 2009; Smith et al., 2005; Rehman et al., 1999; DeCuypere et al., 2005).

48. Given the decades of extensive experience and research supporting the effectiveness of gender confirmation surgery, it is clear that reconstructive surgery is a medically necessary, not experimental, treatment for gender dysphoria. Therefore, decades of peer-reviewed research and a medical consensus support the inclusion of gender confirmation surgery as a medically necessary treatment in the WPATH *Standards of Care*.

49. In 2016 WPATH issued a "Position Statement on Medical Necessity of Treatment, Sex Reassignment, and Insurance Coverage in the U.S.A." ("Position Statement"), affirming a statement originally issued in 2008. As the Position Statement explains, "These medical procedures and treatment protocols are not experimental: Decades of both clinical experience and medical research show they are essential to achieving well-being for the transsexual patient."

50. Similarly, Resolution 122 (A-08) of the American Medical Association states: "Health experts in GID, including WPATH, have rejected the myth that these treatments are 'cosmetic' or 'experimental' and have recognized that these treatments can provide safe and effective treatment for a serious health condition."

51. On May 30, 2014, the Appellate Division of the Departmental Appeals Board of HHS issued decision number 2576, in which the Board determined that Medicare's policy barring coverage for transition-related surgeries was not valid under the "reasonableness standard." The Board found that the ban "was based principally on" a report from 1981 that has been rendered obsolete by numerous "medical studies published in the more than 32 years since issuance of the

1981 report." The Board specifically concluded that transition-related surgeries are "safe and effective and not experimental." As a result, Medicare's exclusion was struck down and Medicare was directed to consider surgeries on a case-by-case basis.

52. Transition-related health care (also known as gender-affirming health care), such a cross sex hormones or gender confirmation surgery (previously known as gender reassignment surgery), *are not* sterilization procedures because they are not performed for the purpose of contraception.

53. The overwhelming scientific evidence indicates that transition-related care, including gender confirmation surgery, is medically necessary for the treatment of gender dysphoria in some patients.

<u>The Harmful Effects of the Revised Rule on Transgender People</u>

54. On June 19, 2020, HHS issued that the Revised Rule, which removes robust regulatory nondiscrimination protections for LGBTQ people, particularly transgender people, in the provision of health care and health insurance.

55. The Revised Rule attempts to diminish nondiscrimination protections in health care and health insurance for vulnerable patients, which will result in both specific denials of medically-necessary care, including gender affirming health care, and more general discrimination against LGBTQ people in health care settings. In so doing, the Revised Rule poses lifelong health risks to transgender and gender nonconforming individuals, including depression, posttraumatic stress disorder, cardiovascular and other disease, premature death, and suicide.

56. In addition, the Revised Rule directly and negatively affects the health and wellbeing of LGBTQ people, particularly transgender people, by sending a governmental message that they are not worthy of protection, that their identities need not be recognized, and that their

health care needs may be disregarded. The governmental message directly communicated through the Revised Rule is likely to result in significant distress, hopelessness, hypervigilance, depression, generalized anxiety disorder, and trauma for LGBTQ people, and more specifically for transgender people (Brown & Keller, 2018; Gonzalez et al., 2018; Rostosky, 2010; Russell, et al., 2011; Veldhuis et al., 2017).

57. The overarching goal of treatment for gender dysphoria is to eliminate clinically significant distress by aligning an individual patient's body and presentation with their internal sense of self, thereby consolidating identity. Developing and integrating a positive sense of self-identity formation is a fundamental undertaking for all human beings. Denial of medically-indicated care to transgender people, whether based on moral or religious objections or on other animus toward transgender people, signals that such people are "inferior" or "unworthy," and triggers shame.

58. Denying gender affirming care not only frustrates those treatment goals, but exacerbates gender dysphoria and its associated depression and suicidality. Conversely, Bauer et al. found a 62% reduction in risk of suicide ideation with the completion of medical transition. That corresponds to a potential prevention of 240 suicide attempts per 1,000 per year. Longitudinal studies have also shown that gender confirmation surgery has been linked with a reduction in the need for mental health treatment for transgender patients (Branstrom, et al., 2019). Withholding this care results in serious negative health outcomes for transgender patients.

59. More broadly, the negative effects of discrimination impacts transgender people throughout their lives. A wealth of research establishes that transgender people suffer from discrimination, stigma, and shame. The "minority stress model" explains that the negative impact of the stress attached to being stigmatized is socially based. The stress process can be both external,

i.e., actual experiences of rejection and discrimination (enacted stigma), and because of such experiences, internal, *i.e.*, perceived rejection and the expectation of being rejected or discriminated against (felt stigma). A 2015 study of 28,000 transgender and gender nonconforming individuals found that 30% reported being fired, discriminated or otherwise experiencing mistreatment in the workplace (James, et al., 2016). Similarly, 31% of respondents had been mistreated in a public place, including 14% who were denied service, 24% who were verbally harassed and 2% who were physically attacked.

60. Experiencing discrimination, including in health care settings, has negative impacts on patients' mental health and wellbeing. This discrimination, which often occurs in the form of violence, abuse, or harassment, as well as the fear thereof, is thus directly related to negative health outcomes. A 2012 study of transgender adults found fear of discrimination increased the risk of developing hypertension by 100%, owing to the intersectionality of shame and cardiovascular reactivity. Another 2012 study of discrimination and implications for health concluded that "living in states with discriminatory policies … was associated with a statistically significant increase in the number of psychiatric disorder diagnoses." And a 2019 study found that experiencing discrimination in health care settings posed a unique risk factor for heightened suicidality among transgender individuals, a population already at heightened risk compared with the general population (Herman et al., 2019). These negative outcomes are exacerbated when people experience discrimination based on intersectional identities, such as LGBTQ Latinx individuals (Schmitz et al., 2019).

61. Until recently, it was not fully understood that these experiences of shame and discrimination could have serious and enduring consequences. But it is now known that marginalization, stigmatization, and victimization are some of the most powerful predictors of

current and future mental health problems, including the development of psychiatric disorders. The social problems that young transgender people face actually create the blueprint for future mental health, life satisfaction, and even physical health. A recent study of 245 gender-nonconforming adults found that stress and victimization during childhood and adolescence was associated with a greater risk for post-traumatic stress disorder, depression, life dissatisfaction, anxiety, and suicidality in adulthood. A 2011 Institute of Medicine (IOM) report concurs: "the marginalization of transgender people from society is having a devastating effect on their physical and mental health." And the American Journal of Public Health recently reported that more than half of transgender women "struggle with depression from the stigma, shame and isolation caused by how others treat them."

62. While a growing body of research documents that structural forms of stigma (namely, policies sanctioning discrimination) harm the health of transgender people, a 2010 study was the first to show that structural stigma is associated with *all-cause mortality* (i.e. deaths from any cause). In other words, stigma—a chronic source of psychological stress—disrupts physiological pathways, increasing disease vulnerability, and leading to premature death.

63. Adding to the corpus of research in this area is a relatively new approach to the investigation of the relationship between discrimination and health. Neuroscientists have discovered that, in addition to causing serious emotional difficulties and physical harms, discrimination, harassment, and verbal abuse permanently alter the architecture of the brain. Deviations in the myelin sheathing of the corpus callosum and damage to the hippocampus cause cognitive difficulties in individuals who have been routinely subjected to humiliation and ostracism (Nickel, 2018; Ohashi et al., 2017; Teicher et al., 2010).

64. Transgender individuals currently face significant discrimination in health care settings and barriers to care. Forty percent (40%) fear accessing care, and forego routine screening and preventative care. A 2017 report by the Center for American Progress of 7,500 transgender adults found 29 % were refused treatment based on their gender identity and 21 % were verbally abused when seeking healthcare. The report also found that transgender individuals often had to travel to other states to find medical providers. A 2018 survey of 6,450 participants found 24% were denied treatment in doctor's offices or hospitals, 13% in emergency rooms, 11% in mental health clinics and 5% for ambulance or emergency medical services. As a result, transgender individuals have poorer health, greater stress, and higher rates of obesity, even when compared to lesbian and gay populations. Indeed, 23% of respondents to a 2015 study did not see a doctor when they needed to because of fear of being mistreated as a transgender person. These findings led to the Association of American Medical Colleges to convene an advisory committee to develop curricula based on competencies for medical education.

65. By contrast, the existence of nondiscrimination protections for transgender patients results in better health outcomes. A newly released, multi-year study of nearly 29,000 transgender and gender diverse people found that in the year immediately following the implementation of nondiscrimination policies in private health insurance, both suicidality and inpatient mental health hospitalization rates decreased across the survey population (McDowell, et al., 2020). Maintaining nondiscrimination protections for transgender patients is critical for their health and wellbeing.

III. CONCLUSION

66. The Revised Rule endangers the health and wellbeing of LGBTQ people, particularly transgender people. Should it become effective, the Revised Rule will cause distress on these vulnerable populations, as well as increased fear, hopelessness, trauma, and

hypervigilance. These negative health consequences can become intractable. In addition, by diminishing protections from discrimination in health care and health insurance, the Revised Rule exposes transgender people to increased discrimination which negatively affects health, exacerbates minority stress, and results in the denial medically-necessary and life-saving health care. The harms that will befall transgender people are predictable and dire: the exacerbation of symptoms of gender dysphoria, grave damage to mental and physical health, and the undermining of clearly established, evidence-based treatment protocols.

* * * * *

Signature on next page

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Dated on this 2nd day of July, 2020.

Randi C Ettner PhD

Randi C. Ettner, Ph.D.

EXHIBIT A

Curriculum Vitae of Randi C. Ettner, Ph.D.

RANDI ETTNER, PHD
1214 Lake Street
Evanston, Illinois 60201
847-328-3433

POSITIONS HELD

Clinical Psychologist
Forensic Psychologist
Fellow and Diplomate in Clinical Evaluation, American Board of Psychological Specialties
Fellow and Diplomate in Trauma/PTSD
President, New Health Foundation Worldwide
Secretary, World Professional Association for Transgender Health (WPATH)
Chair, Committee for Institutionalized Persons, WPATH
Global Education Initiative Committee, WPATH
University of Minnesota Medical Foundation: Leadership Council
Psychologist, Center for Gender Confirmation Surgery, Weiss Memorial Hospital
Adjunct Faculty, Prescott College
Editorial Board, *International Journal of Transgender Health*
Editorial Board, *Transgender Health*
Television and radio guest (more than 100 national and international appearances)
Internationally syndicated columnist
Private practitioner
Medical adjunct staff; Department of Medicine: Weiss Memorial Hospital, Chicago IL
Advisory Council, National Center for Gender Spectrum Health

EDUCATION

PhD, 1979	Northwestern University (with honors) Evanston, Illinois
MA, 1976	Roosevelt University (with honors) Chicago, Illinois
BA, 1969-73	Indiana University Bloomington, Indiana Cum Laude Major: Clinical Psychology; Minor: Sociology
1972	Moray College of Education Edinburgh, Scotland International Education Program
1970	Harvard University Cambridge, Massachusetts Social Relations Undergraduate Summer Study Program in Group Dynamics and Processes

CLINICAL AND PROFESSIONAL EXPERIENCE

2016-present	Psychologist: Weiss Memorial Hospital Center for Gender Confirmation Surgery
	Consultant: Walgreens; Tawani Enterprises Private practitioner
2011	Instructor, Prescott College: Gender-A multidimensional approach
2000	Instructor, Illinois Professional School of Psychology
1995-present	Supervision of clinicians in counseling gender non conforming clients
1993	Post-doctoral continuing education with Dr. James Butcher in MMPI-2 Interpretation, University of Minnesota
1992	Continuing advanced tutorial with Dr. Leah Schaefer in psychotherapy
1983-1984	Staff psychologist, Women's Health Center, St. Francis Hospital, Evanston, Illinois
1981-1984	Instructor, Roosevelt University, Department of Psychology: Psychology of Women, Tests and Measurements, Clinical Psychology, Personal Growth, Personality Theories, Abnormal Psychology
1976-1978	Research Associate, Cook County Hospital, Chicago, Illinois, Department of Psychiatry
1975-1977	Clinical Internship, Cook County Hospital, Chicago, Illinois, Department of Psychiatry
1971	Research Associate, Department of Psychology, Indiana University
1970-1972	Teaching Assistant in Experimental and Introductory Psychology Department of Psychology, Indiana University
1969-1971	Experimental Psychology Laboratory Assistant, Department of Psychology, Indiana University

INVITED PRESENTATIONS AND HOSPITAL GRAND ROUNDS

Legal Issues Facing the Transgender Community, Illinois State Bar Association, Chicago, IL, 2020

Providing Gender Affirming Care to Transgender Patients, American Medical Student Association, webinar presentation, 2020

Foundations in Mental Health for Working with Transgender Clients; Advanced Mental Health Issues, Ethical Issues in the Delivery of Care, Center for Supporting Community Development Initiatives, Vietduc University Hospital, Hanoi, Vietnam, 2020

The Transgender Surgical Patient, American Society of Plastic Surgeons, Miami, FL 2019

Mental health issues in transgender health care, American Medical Student Association, webinar presentation, 2019

Sticks and stones: Childhood bullying experiences in lesbian women and transmen, Buenos Aires, 2018

Gender identity and the Standards of Care, American College of Surgeons, Boston, MA, 2018

The mental health professional in the multi-disciplinary team, pre-operative evaluation and assessment for gender confirmation surgery, American Society of Plastic Surgeons, Chicago, IL, 2018; Buenos Aires, 2018

Navigating Transference and Countertransference Issues, WPATH global education initiative, Portland, OR; 2018

Psychological aspects of gender confirmation surgery International Continence Society, Philadelphia, PA 2018

The role of the mental health professional in gender confirmation surgeries, Mt. Sinai Hospital, New York City, NY, 2018

Mental health evaluation for gender confirmation surgery, Gender Confirmation Surgical Team, Weiss Memorial Hospital, Chicago, IL 2018

Transitioning; Bathrooms are only the beginning, American College of Legal Medicine, Charleston, SC, 2018

Gender Dysphoria: A medical perspective, Department of Health and Human Services, Office for Civil Rights, Washington, D.C, 2017

Multi-disciplinary health care for transgender patients, James A. Lovell Federal Health Care Center, North Chicago, IL, 2017

Psychological and Social Issues in the Aging Transgender Person, Weiss Memorial Hospital, Chicago, IL, 2017.

Psychiatric and Legal Issues for Transgender Inmates, USPATH, Los Angeles, CA, 2017

Transgender 101 for Surgeons, American Society of Plastic Surgeons, Chicago, IL, 2017.

Healthcare for transgender inmates in the US, Erasmus Medical Center, Rotterdam, Netherlands, 2016.

Tomboys Revisited: Replication and Implication; Models of Care; Orange Isn't the New Black Yet- WPATH symposium, Amsterdam, Netherlands, 2016.

Foundations in mental health; role of the mental health professional in legal and policy issues, healthcare for transgender inmates; children of transgender parents; transfeminine genital surgery assessment: WPATH global education initiative, Chicago, IL, 2015; Atlanta, GA, 2016; Columbia, MO, 2016; Ft. Lauderdale, FL, 2016; Washington, D.C., 2016, Los Angeles, CA, 2017, Minneapolis, MN, 2017, Chicago, IL, 2017; Columbus, Ohio, 2017; Portland, OR, 2018; Cincinnati, OH, 2018, Buenos Aires, 2018

*Pre-operative evaluation in gender-affirming surgery-*American Society of Plastic Surgeons, Boston, MA, 2015

Gender affirming psychotherapy; Assessment and referrals for surgery-Standards of Care- Fenway Health Clinic, Boston, 2015*Gender reassignment surgery*- Midwestern Association of Plastic Surgeons, 2015

Adult development and quality of life in transgender healthcare- Eunice Kennedy Shriver National Institute of Child Health and Human Development, 2015

Healthcare for transgender inmates- American Academy of Psychiatry and the Law, 2014

Supporting transgender students: best school practices for success- American Civil Liberties Union of Illinois and Illinois Safe School Alliance, 2014

Addressing the needs of transgender students on campus- Prescott College, 2014

The role of the behavioral psychologist in transgender healthcare – Gay and Lesbian Medical Association, 2013

Understanding transgender- Nielsen Corporation, Chicago, Illinois, 2013

Role of the forensic psychologist in transgender care; *Care of the aging transgender patient-* University of California San Francisco, Center for Excellence, 2013

Evidence-based care of transgender patients- North Shore University Health Systems, University of Chicago, Illinois, 2011; Roosevelt-St. Vincent Hospital, New York; Columbia Presbyterian Hospital, Columbia University, New York, 2011

Children of Transsexuals-International Association of Sex Researchers, Ottawa, Canada, 2005; Chicago School of Professional Psychology, 2005

Gender and the Law- DePaul University College of Law, Chicago, Illinois, 2003; American Bar Association annual meeting, New York, 2000

Gender Identity, Gender Dysphoria and Clinical Issues –WPATH Symposium, Bangkok, Thailand, 2014; Argosy College, Chicago, Illinois, 2010; Cultural Impact Conference, Chicago, Illinois, 2005; Weiss Hospital, Department of Surgery, Chicago, Illinois, 2005; Resurrection Hospital Ethics Committee, Evanston, Illinois, 2005; Wisconsin Public Schools, Sheboygan, Wisconsin, 2004, 2006, 2009; Rush North Shore Hospital, Skokie, Illinois, 2004; Nine Circles Community Health Centre, University of Winnipeg, Winnipeg, Canada, 2003; James H. Quillen VA Medical Center, East Tennessee State University, Johnson City, Tennessee, 2002; Sixth European Federation of Sexology, Cyprus, 2002; Fifteenth World Congress of Sexology, Paris, France, 2001; Illinois School of Professional Psychology, Chicago, Illinois 2001; Lesbian Community Cancer Project, Chicago, Illinois 2000; Emory University Student Residence Hall, Atlanta, Georgia, 1999; Parents, Families and Friends of Lesbians and Gays National Convention, Chicago, Illinois, 1998; In the Family Psychotherapy Network National Convention, San Francisco, California, 1998; Evanston City Council, Evanston, Illinois 1997; Howard Brown Community Center, Chicago, Illinois, 1995; YWCA Women's Shelter, Evanston, Illinois, 1995; Center for Addictive Problems, Chicago, 1994

Psychosocial Assessment of Risk and Intervention Strategies in Prenatal Patients- St. Francis Hospital, Center for Women's Health, Evanston, Illinois, 1984; Purdue University School of Nursing, West Layette, Indiana, 1980

Psychonueroimmunology and Cancer Treatment- St. Francis Hospital, Evanston, Illinois, 1984

Psychosexual Factors in Women's Health- St. Francis Hospital, Center for Women's Health, Evanston, Illinois, 1984

Sexual Dysfunction in Medical Practice- St. Francis Hospital, Dept. of OB/GYN, Evanston, Illinois, 1980

Sleep Apnea - St. Francis Hospital, Evanston, Illinois, 1996; Lincolnwood Public Library, Lincolnwood, Illinois, 1996

The Role of Denial in Dialysis Patients - Cook County Hospital, Department of Psychiatry, Chicago, Illinois, 1977

PUBLICATIONS

Ettner, R., White, T., Ettner, F., Friese, T., Schechter, L. (2018) Tomboys revisited: A retrospective comparison of childhood behaviors in lesbians and transmen. *Journal of Child and Adolescent Psychiatry*.

Narayan, S., Danker, S Esmonde, N., Guerriero, J., Carter, A., Dugi III, D., Ettner, R., Radix A., Bluebond-Langner, R., Schechter, L., Berli, J. (2018) A survey study of surgeons' experience with regret and reversal of gender-confirmation surgeries as a basis for a multidisciplinary approach to a rare but significant clinical occurrence, submitted.

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Schechter, L., Boffa, J., Ettner, R., and Ettner, F. Revision vaginoplasty with sigmoid interposition: A reliable solution for a difficult problem. The World Professional Association for Transgender Health (WPATH), 2007, *XX Biennial Symposium,* 31-32.

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White, T. and Ettner, R. Adaptation and adjustment in children of transsexual parents. *European Journal of Child and Adolescent Psychiatry,* 2007: 16(4)215-221.

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Witten, T., Benestad, L., Berger, L., Ekins, R., Ettner, R., Harima, K. Transgender and Transsexuality. Encyclopeida of Sex and Gender. Springer, Ember, & Ember (Eds.) Stonewall, Scotland, 2004.

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"Social and Psychological Issues of Aging in Transsexuals," proceedings, Harry Benjamin International Gender Dysphoria Association, Bologna, Italy, 2005.

"The Role of Psychological Tests in Forensic Settings," *Chicago Daily Law Bulletin,* 1997.

Confessions of a Gender Defender: A Psychologist's Reflections on Life amongst the Transgender. Chicago Spectrum Press. 1996.

"Post-traumatic Stress Disorder," *Chicago Daily Law Bulletin*, 1995.

"Compensation for Mental Injury," *Chicago Daily Law Bulletin*, 1994.

"Workshop Model for the Inclusion and Treatment of the Families of Transsexuals," Proceedings of the Harry Benjamin International Gender Dysphoria Symposium; Bavaria, Germany, 1995.

"Transsexualism- The Phenotypic Variable," Proceedings of the XV Harry Benjamin International Gender Dysphoria Association Symposium; Vancouver, Canada, 1997.

"The Work of Worrying: Emotional Preparation for Labor," Pregnancy as Healing. A Holistic Philosophy for Prenatal Care, Peterson, G. and Mehl, L. Vol. II. Chapter 13, Mindbody Press, 1985.

PROFESSIONAL AFFILIATIONS

University of Minnesota Medical School–Leadership Council
American College of Forensic Psychologists
World Professional Association for Transgender Health
World Health Organization (WHO) Global Access Practice Network
TransNet national network for transgender research
American Psychological Association
American College of Forensic Examiners
Society for the Scientific Study of Sexuality
Screenwriters and Actors Guild
Phi Beta Kappa

AWARDS AND HONORS

Letter of commendation from United States Congress for contributions to public health in Illinois, 2019
WPATH Distinguished Education and Advocacy Award, 2018
The Randi and Fred Ettner Transgender Health Fellowship-Program in Human Sexuality, University of Minnesota, 2016
Phi Beta Kappa, 1972
Indiana University Women's Honor Society, 1970-1972
Indiana University Honors Program, 1970-1972
Merit Scholarship Recipient, 1970-1972
Indiana University Department of Psychology Outstanding Undergraduate Award Recipient, 1970-1972
Representative, Student Governing Commission, Indiana University, 1970

LICENSE

Clinical Psychologist, State of Illinois, 1980

Exhibit B

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EXHIBIT C

Documentation of Meeting with HHS

From:	Frohboese, Robinsue (HHS/OCR) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=57B8853F66DA4CB99818C9E2632F77F8-FROHBOESE,>
To:	Severino, Roger (HHS/OCR) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=47bbbf66a9ec4d4b8b74ed8cb2029b31-Severino, R>; Bell, March (HHS/OCR) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b058f58ea03648bfbb1631467db5ff6d-Bell, March>; Brown, Louis (HHS/OCR) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b54bffae1d54fe7b32b8e7d91223d0b-Brown, Loui>; Hanrahan, Eileen (HHS/OCR) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user81e42d7e>
Subject:	2 new additions to listening session
Date:	2017/11/14 14:54:51
Importance:	High
Priority:	Urgent
Type:	Note

In addition to Dr. Hall and Dr. Levine, Dr. Levine's assistant, Parker Beene, as well as Dr. Randi Ettner are here. (Dr Leveine and Parker Beene were attending an Opiod event in DC this morning).

Randi Ettner, Ph.D., is a clinical and forensic psychologist based in Chicago, IL. Ettner specializes in treatment of gender conditions and has seen ~2500 persons who have been diagnosed with gender dysphoria.

Dr. Alexandra Hall is an adjunct faculty member and staff physician at the University of Wisconsin-Stout. Dr. Hall is a family physician who has been working in college health for over a decade and teaching undergraduates for the past four years. She is the author of the 2013 journal article, "Electronic medical records and the transgender patient: recommendations from the World Professional Association for Transgender Health EMR Working Group, *Journal of the American Medical Informatics Association* , *20*(4), 700-703. Her presentations include several on transgender health including: Transgender Care at the Student Health Center, half-day workshop for professionals, (2015); The Role of the Mental Health Provider in Transgender Health. Half-day workshop for area professionals, (2014), and Transgender Health: Tools to Providing Health Care and Advocacy on College Campuses, (2011). She is a member of the World Professionals for Transgender Health (WPATH).

Dr. Rachel Levine is currently the Acting Secretary of Health and Physician General for the Commonwealth of Pennsylvania and Professor of Pediatrics and Psychiatry at the Penn State College of Medicine. As Physician General, Dr. Levine has made significant strides combating the opioid epidemic and advocating on behalf of the LGBTQ population. She spearheaded the efforts to establish opioid prescribing guidelines and establish opioid prescribing education for medical students. She has also led an LGBTQ workgroup for the governor's office which has worked to create programs and processes that are fair and inclusive in healthcare, insurance, and many other areas. Her previous posts included: Vice -Chair for Clinical Affairs for the Department of Pediatrics and Chief of the Division of Adolescent Medicine and Eating Disorders at the

Penn State Hershey Children's Hospital-Milton S. Hershey Medical Center. Dr. Levine teaches at the Penn State College of Medicine on topics in adolescent medicine, eating disorders and transgender medicine. In addition, she has lectured nationally and internationally and has published articles and chapters on these topics.

Sender:	Frohboese, Robinsue (HHS/OCR) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=57B8853F66DA4CB99818C9E2632F77F8-FROHBOESE,>
Recipient:	Severino, Roger (HHS/OCR) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=47bbbf66a9ec4d4b8b74ed8cb2029b31-Severino, R>; Bell, March (HHS/OCR) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b058f58ea03648bfbb1631467db5ff6d-Bell, March>; Brown, Louis (HHS/OCR) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b54bffae1d54fe7b32b8e7d91223d0b-Brown, Loui>; Hanrahan, Eileen (HHS/OCR) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user81e42d7e>
Sent Date:	2017/11/14 14:54:51

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

WHITMAN-WALKER CLINIC, INC., *et al.*,

Plaintiffs,

v.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, *et al.*,

Defendants.

Case No. 1:20-cv-01630

DECLARATION OF ELENA ROSE VERA,
EXECUTIVE DIRECTOR, TRANS LIFELINE

I, Elena Rose Vera, declare as follows:

1. I am the Executive Director of Trans Lifeline.

2. I am submitting this declaration in support of Plaintiffs' Motion for a Preliminary Injunction to prevent the revised regulation under Section 1557 of the Affordable Care Act ("ACA"), published by the U.S. Department of Health and Human Services ("HHS") on June 19, 2020 (the "Revised Rule"), from taking effect.

3. Founded in 2014 as a peer-support crisis hotline, Trans Lifeline is a peer support and crisis hotline 501(c)(3) non-profit organization offering direct emotional and financial support to transgender people in crisis. It is the first transgender-specific crisis hotline in the United States or Canada. It is also the only hotline whose operators are all transgender or nonbinary. Currently, the organization operates thanks to the assistance of almost 100 volunteers in addition to a small number of paid staff. Our operators have logged thousands of hours of often life-saving talk time with trans people in our community, and, with new volunteers signing up all the time, our capacity is only growing.

4. Trans Lifeline's hotline is open 24 hours a day, seven days a week. It is the key component of the organization and helps to connect transgender people to the community, support, and resources they need to survive and thrive. Each month the hotline receives on average 4,506 calls from all over the country, as well as Canada.

5. On July 1, 2020, the hotline began providing our 24/7 peer support and crisis helpline service in Spanish due to receiving 23 times more calls from transgender Spanish speakers in 2019 as compared to 2018. The hotline also recorded a 146% spike in calls from transgender immigrants and a 386% increase in calls from Latinx transgender people during that same time.

6. Since HHS announced the finalization of the Revised Rule on June 12, 2020, the hotline has seen a remarkable increase in calls, up from 155 in a typical day in the first five-and-a-half months of 2020, to 534 calls per day between June 12, 2020 and June 19, 2020.

7. Of the calls received between June 12, 2020 and June 19, 2020, callers brought up the Revised Rule approximately 10% of the time. This increase strongly suggests widespread concerns about the implications of the Revised Rule for the transgender community.

8. In addition, for the month of June 2020, we received 200% more calls than the previous month, even when taking into account that the last few months have been unusual as result of the COVID-19 pandemic. We also received approximately 400% more first time callers than the previous month. And from May to June, calls in which the caller noted they "cannot access medical treatment" increased by over 85%.

9. Where appropriate, Trans Lifeline operators refer callers to public services to address their concerns. For example, operators may refer callers to state agencies that address

discrimination complaints. Callers in need of health care services might be referred to state agencies for coverage and services, such as state Medicaid offices, if income eligible.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Dated this 8th day of July 2020.

Elena Rose Vera

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

WHITMAN-WALKER CLINIC, INC., *et al.*,

Plaintiffs,

v.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, *et al.*,

Defendants.

Case No. 1:20-cv-1630

DECLARATION OF CARRIE DA IS,
CHIEF COMMUNIT OFFICER, THE TRE OR PRO ECT

I, Carrie Davis, declare as follows:

1. I am the Chief Community Officer of The Trevor Project.

2. I am submitting this Declaration in support of Plaintiffs' Motion for a Preliminary Injunction to prevent the revised regulation under Section 1557 of the Affordable Care Act ("ACA"), published by the U.S. Department of Health and Human Services ("HHS") on June 19, 2020 (the "Revised Rule"), from taking effect.

3. The Trevor Project is a 501(c)(3) nonprofit organization incorporated in California with offices in Los Angeles, California; New ork, New ork; and Washington, DC. The Trevor Project is the leading national organization providing crisis intervention and suicide prevention services to lesbian, gay, bisexual, transgender, queer, and questioning (LGBTQ) young people under age 25. The Trevor Project directly serves over 200,000 young people every year through their crisis services, suicide prevention, and peer support programs.

4. In order to fulfill its mission to end suicide among LGBTQ young people, The Trevor Project provides a wide array of programs and services for LGBTQ young people, including:

emergency crisis support and counseling available via phone, text, or online messaging; suicide prevention trainings for youths and adults; resources for LGBTQ youth and allies; creation of public service announcements; and online social networking for LGBTQ youth between the ages of 13-24. The Trevor Project also advocates for laws and policies that will reduce suicide among LGBTQ young people.

5. Many of the LGBTQ youth who need The Trevor Project's services often face discriminatory barriers to access to health care services from religiously affiliated organizations. In addition, some of the LGBTQ youth who call The Trevor Project in crisis live in foster care placements, or access services from programs for youth experiencing homelessness.

6. In addition to the direct services it provides to LGBTQ youth, The Trevor Project is also committed to producing innovative research that brings new knowledge and clinical implications to the field of suicidology. To accomplish this, The Trevor Project: (1) partners with external research organizations (such as academic institutions); and (2) analyzes and evaluates existing data collected from Trevor-served youth to produce insights into vulnerable populations, suicidal risk factors, and social factors influencing suicidal ideation and attempts. As part of this work, we know that internalization of anti-LGBTQ animus is a major contributor to depression and other mental health issues among LGBTQ people, and especially LGBTQ youth.

7. The statistics regarding young LGBTQ people and mental health are particularly sobering. Last year, The Trevor Project released the results of its 2019 National LGBTQ outh Mental Health Survey.[1] With over 25,000 respondents, it is the largest survey of LGBTQ youth

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The Trevor Project. (2019). National Survey on LGBTQ Mental Health. New ork, New ork: The Trevor Project. https://www.thetrevorproject.org/wp-content/uploads/2019/06/The-Trevor-Project-National-Survey-Results-2019.pdf.

mental health ever conducted and provides a critical understanding of the experiences impacting their lives. Among some of the key findings of the report from LGBTQ youth in the survey:

a. 39% of LGBTQ youth seriously considered attempting suicide in the past twelve months, with more than half of transgender and nonbinary youth having seriously considered it;

b. 71% of LGBTQ youth reported feeling sad or hopeless for at least two weeks in the past year; and

c. 87% of LGBTQ youth said it was important to them to reach out to a crisis intervention organization that focuses on LGBTQ youth.

8. In the weeks following the 2016 election, The Trevor Project saw a large spike in the number of calls, texts, and online chats to its crisis lines with LGBTQ youth expressing fear and anxiety that they would be discriminated against, that so-called "conversion therapy" would be permitted or promoted, or that they could be targeted to become a victim of hate crimes due to anti-LGBTQ animus. Indeed, in the days immediately following the election on November 8, 2016, The Trevor Project received more calls, texts, and online chats than it had ever received in a single day in four years, more than double its normal daily volume. Many callers worried that their rights would be taken away and they would be subjected to animus-fueled violence. Many callers, especially transgender and gender nonconforming youth, expressed that they were thinking about going back into the closet out of fear.

9. The past few years have proven some of the fears expressed following the 2016 election to be well-founded. The Revised Rule is just one of the latest examples of the current administration's efforts to roll back the rights of LGBTQ people, and it could not have come out at a worst time. The Revised Rule sends a dangerous and confusing message to health care

providers and LGBTQ patients. In the midst of a global pandemic with serious implications for the LGBTQ youth whom The Trevor Project serves, the last thing our nation needs is for the current administration to suggest, contrary to the Affordable Care Act, that health care providers do not have to treat LGBTQ people, particularly transgender persons, with the same care and respect as everybody else.

10. Following the announcement of the Revised Rule on June 12, 2019 and subsequent publication on June 19, 2019, The Trevor Project has seen a significant number of calls, texts, and online chats to its crisis lines from LGBTQ youth that specifically mention the Revised Rule as a source of worry and distress.

11. Unless enjoined, the Revised Rule will likely further increase the number of LGBTQ youth who need to access The Trevor Project's services. The Trevor Project will receive increased calls from LGBTQ youth who are in crisis because of discrimination and a denial of services from health care providers and due to general stigmatization and deprivation of dignity. In particular, The Trevor Project is already seeing an increased need for crisis services as a result of the COVID-19 pandemic, with many youth expressing anxiety and fear around having or getting COVID-19 specifically because LGBTQ youth are often unable to access affirming or adequate medical care, which can make seeking treatment for potential COVID-19 related symptoms more challenging or stressful than for non-LGBTQ youth.

12. By fostering the impression that providers may discriminate based on gender identity or sexual orientation, the Revised Rule leaves hundreds of thousands of people vulnerable to experiencing discrimination while seeking essential, life-saving care. In particular, the Revised Rule creates confusion and stigma that will adversely affect the mental health of at-risk LGBTQ

youth, many of whom are already reaching out to The Trevor Project in moments of suicidal ideation or crisis, in part because of their lack of faith in healthcare providers.

[*Signature on next page.*]

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Dated this 9th day of July, 2020.

Carrie Davis

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA**

WHITMAN-WALKER CLINIC, INC., *et al.*,

Plaintiffs,

v.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, *et al.*,

Defendants.

Case No. 1:20-cv-01630 (JEB)

DECLARATION OF OMAR GONZALEZ-PAGAN

I, Omar Gonzalez-Pagan, declare as follows:

1. I am a Senior Attorney at Lambda Legal Defense and Education Fund, Inc. and counsel of record for the plaintiffs in this action.

2. I am a member of the bar of the Commonwealth of Massachusetts and State of New York, and have been admitted *pro hac vice* to this court.

3. I submit this declaration, based on my personal knowledge, in support of Plaintiffs' Motion for a Preliminary Injunction to prevent the revised regulation under Section 1557 of the Affordable Care Act ("ACA"), published by the U.S. Department of Health and Human Services ("HHS") on June 19, 2020 (the "Revised Rule"), from taking effect.

4. Attached as **Exhibit 1** to this declaration is a true and correct copy of Defendants' Motion for Voluntary Remand and Stay in *Franciscan Alliance v. Price*, Case No. 7:16-cv-00108 (N.D. Tex., filed May 2, 2017).

5. Attached as **Exhibit 2** to this declaration is a true and correct copy of Defendants' Memorandum in response to Plaintiffs' Motion for Summary Judgment in *Franciscan Alliance v. Azar*, Case No. 7:16-cv-00108 (N.D. Tex., filed Apr. 5, 2019).

6. Attached as **Exhibit 3** to this declaration is a true and correct copy of Defendants' Motion to Modify Final Judgment in *Franciscan Alliance v. Azar*, Case No. 7:16-cv-00108 (N.D. Tex., filed Nov. 12, 2019).

7. Attached as **Exhibit 4** to this declaration is a true and correct copy of the court's Order in *Franciscan Alliance v. Azar*, Case No. 7:16-cv-00108 (N.D. Tex., filed Nov. 21, 2019), modifying the judgment.

8. Attached as **Exhibit 5** to this declaration is a true and correct copy of the comments by Lambda Legal Defense and Education Fund, Inc. in response to the Notice of Proposed Rulemaking, "Nondiscrimination in Health and Health Education Programs or Activities," 84 Fed. Reg. 27,846 (June 14, 2019), published by the U.S. Department of Health and Human Services ("HHS") and the Centers for Medicaid and Medicare Services ("CMS").

9. Attached as **Exhibit 6** to this declaration is a true and correct copy of the comments by GLMA: Health Professionals Advancing LGBTQ Equality in response to the Notice of Proposed Rulemaking, "Nondiscrimination in Health and Health Education Programs or Activities," 84 Fed. Reg. 27,846 (June 14, 2019), published by HHS and CMS.

10. Attached as **Exhibit 7** to this declaration is a true and correct copy of the comments by the American Psychiatric Association in response to the Notice of Proposed Rulemaking, "Nondiscrimination in Health and Health Education Programs or Activities," 84 Fed. Reg. 27,846 (June 14, 2019), published by HHS and CMS.

11. Attached as **Exhibit 8** to this declaration is a true and correct copy of the comments by the American College of Obstetricians and Gynecologists in response to the Notice of Proposed Rulemaking, "Nondiscrimination in Health and Health Education Programs or Activities," 84 Fed. Reg. 27,846 (June 14, 2019), published by HHS and CMS.

12. Attached as **Exhibit 9** to this declaration is a true and correct copy of the comments by the State Insurance Commissioners of California, Connecticut, Colorado, Delaware, District of Columbia, Illinois, Michigan, Minnesota, Nevada, New Jersey, New Mexico, New York, Oregon, Pennsylvania, Rhode Island, Vermont, Washington, and Wisconsin in response to the Notice of Proposed Rulemaking, "Nondiscrimination in Health and Health Education Programs or Activities," 84 Fed. Reg. 27,846 (June 14, 2019), published by HHS and CMS.

13. Attached as **Exhibit 10** to this declaration is a true and correct copy of the comments by the Cities of New York, Chicago, Baltimore, Bloomington, Los Angeles, Portland, Providence, and Seattle in response to the Notice of Proposed Rulemaking, "Nondiscrimination in Health and Health Education Programs or Activities," 84 Fed. Reg. 27,846 (June 14, 2019), published by HHS and CMS.

14. Attached as **Exhibit 11** to this declaration is a true and correct copy of the comments by the National Center for Transgender Equality in response to the Notice of Proposed Rulemaking, "Nondiscrimination in Health and Health Education Programs or Activities," 84 Fed. Reg. 27,846 (June 14, 2019), published by HHS and CMS.

15. Attached as **Exhibit 12** to this declaration is a true and correct copy of the comments by The California Endowment in response to the Notice of Proposed Rulemaking, "Nondiscrimination in Health and Health Education Programs or Activities," 84 Fed. Reg. 27,846 (June 14, 2019), published by HHS and CMS.

16. Attached as **Exhibit 13** to this declaration is a true and correct copy of the comments by the American Psychological Association in response to the Request for Information, "Reducing Regulatory Burdens Imposed by the Patient Protection and Affordable Care Act & Improving Healthcare Choices to Empower Patients," 82 Fed. Reg. 26,885 (June 12, 2017).

17. Attached as **Exhibit 14** to this declaration is a true and correct copy of the letter of James L. Madara, MD, Executive Vice President and CEO of the American Medical Association, to Roger Severino, Director, Office of Civil Rights, HHS, dated September 1, 2017 regarding the administration's reevaluation of "current policy addressing discrimination in health care programs on the basis of sex as outlined in the final rule implementing Section 1557 of the Affordable Care Act."

18. Attached as **Exhibit 15** to this declaration is a true and correct copy of the comments by the New York Legal Assistance Group (NYLAG) in response to the Notice of Proposed Rulemaking, "Nondiscrimination in Health and Health Education Programs or Activities," 84 Fed. Reg. 27,846 (June 14, 2019), published by HHS and CMS.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Dated this 29th day of July, 2020.

____
Omar Gonzalez-Pagan

EXHIBIT 1

Defendants' Motion for Voluntary Remand and Stay in
Franciscan Alliance v. Price

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
WICHITA FALLS DIVISION

FRANCISCAN ALLIANCE, INC., *et al.*,

Plaintiffs,

v.

THOMAS E. PRICE, M.D., Secretary of the United States Department of Health and Human Services, *et al.*,

Defendants.

No. 7:16-cv-00108

DEFENDANTS' MOTION FOR VOLUNTARY REMAND AND STAY

The United States Department of Health and Human Services ("HHS") should be given the opportunity to reconsider the regulation at issue in this case, based in part on the Department's desire to assess the reasonableness, necessity, and efficacy of the two aspects of the regulation that are challenged in this case, and to address issues identified by the Court in granting Plaintiffs a preliminary injunction. Defendants respectfully request that the Court remand this matter to HHS and stay this litigation pending the completion of rulemaking proceedings. A remand and stay would conserve the resources of the parties and of the Court by avoiding unnecessary briefing and consideration of a summary judgment motion that may become moot in light of subsequent administrative proceedings. Leadership at HHS should be given an opportunity to reevaluate the regulation and address the issues raised in this litigation

through proper rulemaking proceedings. And because the preliminary injunction would continue in force during the remand, a remand and stay would cause no prejudice to Plaintiffs.[1]

BACKGROUND

Plaintiffs challenge two provisions of a final rule issued by HHS in May 2016. First Am. Compl. ¶¶ 24-25 (Oct. 17, 2016), ECF No. 21;[2] *see Nondiscrimination in Health Programs and Activities* (the "Rule"), 81 Fed. Reg. 31,376 (May 18, 2016) (codified at 45 C.F.R. pt. 92). Specifically, "Plaintiffs challenge the Rule's interpretation of discrimination 'on the basis of sex' . . . as encompassing 'gender identity' and 'termination of pregnancy.'" Order at 3 (Dec. 31, 2016), ECF No. 62 (quoting 45 C.F.R. § 92.4).

On December 31, 2016, the Court granted Plaintiffs' motion for preliminary injunction and enjoined Defendants "from enforcing the Rule's prohibition against discrimination on the basis of gender identity or termination of pregnancy." *Id.* at 46. Among other things, the Court found Plaintiffs likely to succeed on their claim that those two provisions of the Rule violate the Administrative Procedure Act. Specifically, the Court concluded that, by purporting to define prohibited sex discrimination to include discrimination on the basis of gender identity, the Rule is likely contrary to Section 1557 because the statute instead "prohibit[s] sex discrimination on the basis of the biological differences between males and females." *Id.* at 32. The Court also found that the Rule is likely contrary to law because it does not incorporate certain statutory

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[1] Counsel for Plaintiffs have informed the undersigned that Plaintiffs will oppose the instant motion.

[2] On March 14, 2017, Plaintiffs voluntarily dismissed certain of their claims, *see* Pls.' Voluntary Dismissal (March 14, 2017), ECF No. 81, but it is unclear which of Plaintiffs' claims remain. Plaintiffs stated that they were "voluntarily dismiss[ing] without prejudice Counts III-X and XIII-XX of their First Amended Complaint," *id.* at 2, but in Counts I and II of their First Amended Complaint—which seemingly remain untouched by Plaintiffs' notice of voluntary dismissal—Plaintiffs incorporate by reference certain of the claims that they purported to dismiss, *see, e.g.*, First Am. Compl. ¶¶ 142-46, 176-79.

exemptions concerning religion and abortion. *See id.* at 37; *see also id.* at 42 (finding certain Plaintiffs likely to succeed on their Religious Freedom Restoration Act challenge to the Rule).

On April 4, 2017, in seeking an extension of their deadline to respond to Plaintiffs' summary judgment motion, Defendants stated that HHS was "considering whether further administrative action concerning the [Rule] would be appropriate." Defs.' Mot. for Ext. at 1-2 (April 4, 2017), ECF No. 86; *see also* Order (April 5, 2017), ECF No. 88 (granting Defendants' extension motion). New leadership at HHS has now had time to scrutinize the two aspects of the Rule at issue in this case and has concerns as to the need for, reasonableness, and burden imposed by those parts of the Rule. HHS takes the concerns of the Court seriously and should be given the opportunity to initiate rulemaking proceedings to reconsider the Rule.

ARGUMENT

"Courts have long recognized the propriety of voluntarily remanding a challenged agency action without judicial consideration of the merits, with or without admission of agency error." *Frito-Lay, Inc. v. U.S. Dep't of Labor*, 20. F. Supp. 3d 548, 552 (N.D. Tex. 2014) (citation omitted); *see, e.g.*, *Ohio Valley Envt'l Coalition v. Aracoma Coal Co.*, 556 F.3d 177, 215 (4th Cir. 2009) ("When a court reviews an agency action, the agency is entitled to seek remand 'without confessing error, to reconsider its previous position.'" (quoting *SKF USA Inc. v. United States*, 254 F.3d 1022, 1028 (Fed. Cir. 2001))). As the Fifth Circuit has observed, "[e]mbedded in an agency's power to make a decision is its power to reconsider that decision." *ConocoPhillips Co. v. U.S. E.P.A.*, 612 F.3d 822, 832 (5th Cir. 2010) (footnote omitted).

"'An agency's motion to remand for reconsideration of its own decision is usually granted.'" *Am. Wild Horse Preservation Campaign v. Salazar*, 115 F. Supp. 3d 1, 3 (D.D.C. 2012) (alteration in the original) (quoting *Edward W. Sparrow Hosp. Ass'n v. Sebelius*, 796 F. Supp. 2d 104, 107 (D.D.C. 2011)). Courts "commonly grant such motions, preferring to allow

agencies to cure their own mistakes rather than wasting the courts' and the parties' resources reviewing a record that both sides acknowledge to be incorrect or incomplete." *Ethyl Corp. v. Browner*, 989 F.2d 522, 524 (D.C. Cir. 1993); *see id.* at 524 n.3 (collecting cases); *Sierra Club v. EPA*, 705 F.3d 458, 463 (D.C. Cir. 2013) (remanding portion of rule that EPA stated functioned in a manner that EPA "did not intend"); *Citizens Against Pellissippi Parkway Extension, Inc. v. Mineta*, 375 F.3d 412, 416 (6th Cir. 2004) ("when an agency seeks a remand to take further action consistent with correct legal standards, courts should permit such a remand in the absence of apparent or clearly articulated countervailing reasons").

Remand is warranted here. First, a remand would permit HHS to reconsider the challenged aspects (or other aspects) of the Rule in light of its desire to assess the Rule's necessity, reasonableness, and efficacy—or lack thereof—and in light of Plaintiffs' challenges to it and this Court's conclusion that certain of those challenges are likely to succeed. *See Citizens Against the Pellissippi Parkway Extension*, 375 F.3d at 416 (it may be "an abuse of discretion to prevent an agency from acting to cure the very legal defects asserted by plaintiffs challenging federal action"). Second, granting a voluntary remand and staying this litigation while regulatory proceedings are ongoing "would preserve the Court's scarce judicial resources by providing [Defendants] the opportunity to cure" any legal errors that may exist in the Rule. *Frito-Lay, Inc.*, 20 F. Supp. 3d at 554 (alterations and citation omitted); *see id.* at 554-55 (surveying cases and noting that courts "often rely on the principle of judicial economy" in granting motions for voluntary remand); *Sierra Club v. Van Antwerp*, 560 F. Supp. 2d 21, 23, 25 (D.D.C. 2008) ("an agency wishing to reconsider its action should move the court to remand or hold the case in abeyance pending the agency's reconsideration," in part because remand "will serve the interest of allowing [the agency] to cure its own potential mistake rather than needlessly wasting the

Court's and the parties' resources").[3] Third, and finally, a remand and stay would not prejudice Plaintiffs because this Court's preliminary injunction would remain in effect during the impending regulatory proceedings.

CONCLUSION

Defendants request that the Court remand this matter to HHS, and stay this litigation, pending further rulemaking proceedings.

Dated: May 2, 2017

Respectfully Submitted,

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[3] *See, e.g.*, *Sierra Club, Inc. v. St. Johns River Water Mgmt. Dist.*, No. 6:14-cv-1877, 2016 WL 1317775, at *3 (M.D. Fla. April 5, 2016) (remanding to the agency and staying court proceedings); *FBME Bank Ltd. v. Lew*, 142 F. Supp. 3d 70, 76 (D.D.C. 2015) (same).

CERTIFICATE OF CONFERENCE

I hereby certify that on May 1, 2017, I emailed Plaintiffs' counsel to ask Plaintiffs' position on the relief requested in Defendants' Motion for Voluntary Remand and Stay, and that Plaintiffs' counsel responded that Plaintiffs will oppose this motion.

/s/ *Adam Grogg*
ADAM GROGG

CERTIFICATE OF SERVICE

I hereby certify that on May 2, 2017, I electronically filed a copy of the foregoing. Notice of this filing will be sent via email to all parties by operation of the Court's electronic filing system. Parties may access this filing through the Court's CM/ECF System.

/s/ *Adam Grogg*
ADAM GROGG

EXHIBIT 2

Defendants' Memorandum in response to Plaintiffs' Motion for Summary Judgment in Franciscan Alliance v. Azar

**IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
WICHITA FALLS DIVISION**

FRANCISCAN ALLIANCE, INC., *et al.*,

Plaintiffs,

v.

ALEX M. AZAR II, Secretary
of Health and Human Services, *et al.*.,

Defendants.

No. 7:16-cv-00108

**DEFENDANTS' MEMORANDUM
IN RESPONSE TO PLAINTIFFS' MOTIONS FOR SUMMARY JUDGMENT**

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INTRODUCTION[1]

Plaintiffs challenge a Rule issued by the Department of Health and Human Services (HHS) in 2016 that, among other things, construes Section 1557 of the Patient Protection and Affordable Care Act (ACA), 42 U.S.C. § 18116, to prohibit discrimination on the basis of gender identity and, without incorporating statutory protections relating to religious conscience and abortion, termination of pregnancy. Plaintiffs contend that these aspects of the Rule violate the Administrative Procedure Act (APA) and other statutory and constitutional provisions.

Defendants agree with Plaintiffs and the Court that the Rule's prohibitions on discrimination on the basis of gender identity and termination of pregnancy conflict with Section 1557 and thus are substantively unlawful under the APA. Since the Rule was issued, the United States has returned to its longstanding position that the term "sex" in Title VII does not refer to gender identity, and there is no reason why Section 1557, which incorporates Title IX's analogous prohibition on "sex" discrimination, should be treated differently.[2] The Rule also fails to incorporate Title IX's exemptions despite Section 1557's directive to the contrary, thereby prohibiting conduct the statute permits. Plaintiffs thus are entitled to summary judgment on their APA claim, and there is no need for this Court to resolve any other claim to provide them with the relief they seek.

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[1] In filing this response to Plaintiffs' Motions for Summary Judgment, Defendants withdraw their Motion for an Extension filed on April 4, 2019 (ECF No. 151).

[2] *See* Attorney General Memorandum, *Revised Treatment of Transgender Employment Discrimination Claims Under Title VII of the Civil Rights Act* (Oct. 4, 2017), *available at*: https://www.justice.gov/ag/page/file/1006981/download; Br. of Fed. Resp't in Opp'n to Cert. at 16-23, *R.G. & G.R. Harris Funeral Homes, Inc. v. EEOC*, No. 18-107 (U.S. Oct. 24, 2018); Br. in Supp. of Defs.' Mot. to Dismiss at 2-6, *U.S. Pastor Council v. EEOC*, No. 4:18-cv-00824-O (N.D. Tex. Dec. 17, 2018) (ECF 8).

Defendants nevertheless ask the Court to postpone ruling on Plaintiffs' summary judgment motions to allow Defendants to complete their ongoing efforts to amend the Rule. Defendants expect to be able to publish a proposed rule soon, which, if finalized, may moot this case. The Court should avoid issuing a decision that will likely be overtaken by events, particularly as any delay will not harm Plaintiffs given that the Rule's challenged prohibitions have already been preliminarily enjoined nationwide, and Defendants are conscientiously complying with that injunction. If the Court decides the pending motions, however, it should limit any relief to redressing the injuries of the named Plaintiffs.

BACKGROUND

I. Statutory And Regulatory Background

Section 1557 incorporates four federal anti-discrimination laws into the ACA: Title VI, Title IX, the Age Discrimination Act of 1975, and Section 504 of the Rehabilitation Act. Specifically, Section 1557 directs that

> [e]xcept as otherwise provided for in this title (or an amendment made by this title), an individual shall not, on the ground prohibited under title VI of the Civil Rights Act of 1964 (42 U.S.C. 2000d et seq.), title IX of the Education Amendments of 1972 (20 U.S.C. 1681 et seq.), the Age Discrimination Act of 1975 (42 U.S.C. 6101 et seq.), or section 504 of the Rehabilitation Act of 1973 (29 U.S.C. 794), 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] (or amendments). The enforcement mechanisms provided for and available under such title VI, title IX, section 504, or such Age Discrimination Act shall apply for purposes of violations of this subsection.

42 U.S.C. § 18116(a).

Title IX in turn provides that "[n]o person . . . 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).

Title IX's prohibition on sex discrimination is limited by various exemptions and rules of construction, two of which are relevant here. First, it does "not apply to an educational institution which is controlled by a religious organization if the application of [the provision] would not be consistent with the religious tenets of such organization." *Id.* § 1681(a)(3). Second, it shall not be "construed to require or prohibit any person, or public or private entity, to provide or pay for any benefit or service, including the use of facilities, related to an abortion." *Id.* § 1688.

Acting under its statutory authority to "promulgate regulations to implement" Section 1557, 42 U.S.C. § 18116(c), HHS issued the challenged Rule in May 2016. *See* Nondiscrimination in Health Programs and Activities, 81 Fed. Reg. 31,375 (May 18, 2016) (codified at 45 C.F.R. § 92.4). As relevant here, the Rule construes Section 1557's prohibition on sex discrimination to "include[] . . . discrimination on the basis of pregnancy, false pregnancy, termination of pregnancy, or recovery therefrom, childbirth or related medical conditions, sex stereotyping, and gender identity." 45 C.F.R. § 92.4. The Rule in turn defines "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.* Although the Rule incorporates the various exemptions under Title VI, the Age Act, and Section 504, 45 C.F.R. § 92.101(c), it does not incorporate Title IX's exemptions, or rules of construction, including those addressing religion and abortion, *see* 81 Fed. Reg. at 31,379-80, 31,388.

II. Procedural Background

Plaintiffs, several private healthcare providers and a coalition of states, challenged the Rule and sought partial summary judgment or, in the alternative, a preliminary injunction. On December 31, 2016, the Court issued a nationwide preliminary injunction barring HHS from enforcing the Rule's prohibitions on discrimination on the basis of gender identity and termination of pregnancy. *Franciscan All., Inc. v. Burwell*, 227 F. Supp. 3d 660, 696 (N.D. Tex. 2016). The

Court held that the challenged prohibitions were substantively unlawful under the APA 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, and by "not including" Title IX's religious and abortion exemptions, the Rule "expanded the 'ground prohibited under' Title IX that Section 1557 explicitly incorporated," *id.* at 691. The Court also concluded that the Private Plaintiffs were likely to succeed on the merits of their claim under the Religious Freedom Restoration Act (RFRA) because the Rule could be read to require them to perform gender-transition surgeries or abortions in violation of their sincere religious beliefs. *Id.* at 691-93.[3]

Defendants did not appeal the preliminary injunction. In March 2017, Plaintiffs moved for summary judgment. In response, Defendants sought a stay of the litigation and a voluntary remand to HHS to reconsider the reasonableness, necessity, and efficacy of the Rule. ECF No. 92. The Court granted a stay and required Defendants to file a status report every 60 days providing updates on the reconsideration of the Rule. ECF No. 105. As Defendants explained in their most recent status report on December 14, 2018, HHS continues to work on a new rule to replace the Rule challenged here, ECF No. 124, and Defendants expect to be able to publish a proposed rule soon.

In December 2018, the parties filed a motion to lift the stay, which the Court granted. ECF Nos. 125, 126. Plaintiffs then renewed their motions for summary judgment. ECF Nos. 132, 135. The State Plaintiffs seek summary judgment under (1) the APA, (2) Title VII, (3) the Spending Clause, (4) the Tenth Amendment, and (5) the Eleventh Amendment. The Private Plaintiffs seek summary judgment under (1) the APA, (2) RFRA, and (3) the Free Exercise Clause. Plaintiffs

[3] A district court in North Dakota subsequently entered a preliminary injunction against the Rule limited to the plaintiffs before it. *North Dakota v. Burwell*, No. 3:16-cv-386 (D.N.D. Jan. 23, 2017); *Catholic Benefits Ass'n v. Burwell*, No. 3:16-cv-432 (D.N.D. Injunction Orders of January 23, 2017). HHS remains subject to this injunction, and that litigation is currently stayed.

challenge only the Rule's prohibition of discrimination on the basis of gender identity and termination of pregnancy, and the Rule contains a severability provision, 45 C.F.R. § 92.2(c).

ARGUMENT

This Court has already ruled, as a matter of law, that the Rule's prohibitions of discrimination on the basis of gender identity and, without the accompanying statutory protections, termination of pregnancy are substantively unlawful under the APA. Defendants agree. The ordinary meaning of "sex" within Title IX does not encompass gender identity, and by failing to incorporate Title IX's exemptions, the Rule prohibits conduct that Title IX and, thus, Section 1557 permits. Plaintiffs, therefore, are entitled to summary judgment on their substantive APA claim (as the government recognizes that this Court ruled that it has jurisdiction for purposes of its preliminary-injunction order and nothing has changed that would call that holding into question). Because resolution of this claim is sufficient to afford Plaintiffs the relief they seek, the Court should not address the remaining statutory or constitutional claims.[4]

Defendants nevertheless respectfully request that the Court postpone ruling on Plaintiffs' motions for summary judgment. HHS currently is engaged in efforts to amend the challenged Rule, which may moot the case. In the meantime, the challenged portions of the Rule remain enjoined nationwide by this Court's preliminary injunction. Accordingly, the Court should refrain from deciding the instant motions until HHS has had time to publish a new rule for public notice

[4] Of course, Plaintiffs must establish jurisdiction to obtain summary judgment. Defendants acknowledge, but respectfully disagree with, the Court's earlier ruling that it has jurisdiction and incorporate their arguments on this question by reference. *See Franciscan All.*, 227 F. Supp. 3d at 678–84; ECF No. 50, at 22-32. This brief, however, accepts that this Court ruled that it had jurisdiction for purposes of its preliminary-injunction order and nothing has changed that would call that holding into question.

and comment. If the Court nonetheless rules on the pending motions, it should limit any relief to redressing any cognizable injuries of the named Plaintiffs.

I. THE RULE'S DEFINITION OF SEX DISCRIMINATION IS CONTRARY TO LAW.

Defendants agree with Plaintiffs and the Court that the Rule's definition of sex discrimination contravenes Section 1557 in at least two respects. Section 1557's prohibition on sex discrimination (1) unambiguously excludes discrimination on the basis of gender identity and (2) unambiguously includes Title IX's exemptions, including those addressing religion and abortion, 20 U.S.C. §§ 1681(a)(3), 1688. Because the Rule's definition of sex discrimination departs from Section 1557 in both respects, it is substantively unlawful under the APA.

A. Section 1557's Prohibition on Sex Discrimination Excludes Discrimination on the Basis of Gender Identity.

Section 1557 provides that "an individual shall not, on the ground prohibited under … title IX of the Education Amendments of 1972 . . . be excluded from participation in, be denied the benefits of, or be subjected to discrimination under, any health program or activity, any part of which is receiving Federal financial assistance." 42 U.S.C. § 18116(a). Title IX in turn prohibits discrimination "on the basis of sex." 20 U.S.C. § 1681(a). Title IX does not define the term "sex," so the term should "be interpreted as taking [its] ordinary, contemporary, common meaning." *Sandifer v. U.S. Steel Corp*., 571 U.S. 220, 227 (2014). When Title IX was enacted in 1972, "sex" meant biological sex; it "refer[red] to [the] physiological distinction[ ]" between "male and female." *Webster's New Int'l Dictionary* 2296 (2d ed. 1958); *see id.* ("One of the two divisions of organisms formed on the distinction of male and female; males or females collectively"; "The sum of the peculiarities of structure and function that distinguish a male from a female organism"; the character of being male or female, or of pertaining to the distinctive function of the male or female in reproduction"; "SEX refers to physiological distinctions; GENDER, to distinctions in

grammar"); *see also G.G. ex rel. Grimm v. Gloucester Cty. Sch. Bd.*, 822 F.3d 709, 736-37 (4th Cir. 2016) (Niemeyer, J., dissenting) (collecting dictionaries), *vacated and remanded*, 137 S. Ct. 1239 (2017); *Franciscan All.*, 227 F. Supp. 3d at 688 n.24 (same).[5]

Title IX therefore does not apply to discrimination on the basis of "gender identity," which the Rule defines as one's "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." 45 C.F.R. § 92.4. Congress has prohibited discrimination based on "gender identity" in other statutes, as a separate protected category in addition to "sex" or "gender." *See, e.g.*, 18 U.S.C. § 249(a)(2)(A) & (c)(4) (Matthew Sheperd and James Byrd, Jr. Hate Crimes Prevention Act) (prohibiting acts or attempts to cause bodily injury to any person "because of the actual or perceived religion, national origin, *gender*, sexual orientation, *gender identity*, or disability of any person," and defining "gender identity" as "actual or perceived gender-related characteristics" (emphasis added)); 34 U.S.C. § 12291(b)(13)(A) (Violence Against Women Act) (prohibiting discrimination in certain federally funded programs "on the basis of actual or perceived race, color, religion, national origin, *sex*, *gender identity* (as defined in [18 U.S.C. § 249(c)(4)]), sexual orientation, or disability" (emphases added)). Congress has not included similar language in Title IX as originally enacted in 1972 or in any amendment in the 47 years since. And Congress chose to incorporate, into Section 1557, the prohibition on the basis prohibited under Title IX, but not on the bases prohibited under the Matthew Sheperd and James Byrd, Jr. Hate Crimes Prevention Act or the Violence Against Women Act.

[5] The ordinary meaning of "sex" was the same when the ACA was enacted in 2010. *Franciscan All.*, 227 F. Supp. 3d at 688-89 & n.26; *see also Hively v. Ivy Tech Cmty. Coll. of Ind.*, 853 F.3d 339, 363 (7th Cir. 2017) (en banc) (Sykes, J., dissenting) (collecting contemporary dictionaries); *Doe 2 v. Shanahan*, 917 F.3d 694, 725 & n.6 (D.C. Cir. 2019) (Williams, J., concurring in the result) (addressing similar question with respect to laws enacted in 1998).

In addition, the Supreme Court has explained that Title VII's analogous prohibition "is directed only at '*discrimination* because of sex.'" *Oncale* v. *Sundowner Offshore Servs., Inc.*, 523 U.S. 75, 80 (1998) (brackets and ellipses omitted). "The critical issue" in determining whether an employer has engaged in discrimination, as "Title VII's text indicates, is whether members of one sex are exposed to disadvantageous terms or conditions of employment to which members of the other sex are not exposed." *Id.* (citation omitted). To be sure, the plurality opinion in *Price Waterhouse v. Hopkins*, 490 U.S. 228 (1989), concluded that, "in forbidding employers to discriminate against individuals because of their sex, Congress intended to strike at the entire spectrum of disparate treatment of men and women resulting from sex stereotypes." *Id.* at 251 (brackets and citation omitted). Thus, under that principle, an employer that treats a male or female employee disadvantageously based on a "sex stereotype[]" may violate Title VII, and evidence that an employer engaged in "sex stereotyping" may indicate that sex "played a motivating part in an employment decision." *Id.* at 250-51. But the statute is not properly construed to proscribe employment practices that take account of the sex of employees but do not impose different burdens on similarly situated members of each sex—such as sex-specific dress codes, *cf., e.g.*, *Jespersen* v. *Harrah's Operating Co.*, 444 F.3d 1104, 1109-10 (9th Cir. 2006) (en banc), or sex-specific restrooms.

There is no reason why Title IX's prohibition on sex discrimination should sweep more broadly than its Title VII counterpart. Both the Supreme Court and the Fifth Circuit have looked to Title VII precedents in construing Title IX's prohibition, and there is no basis for taking a different approach here. *See, e.g.*, *Franklin v. Gwinnett Cty. Pub. Schs.,* 503 U.S. 60, 75 (1992) (relying on *Meritor Sav. Bank, FSB v. Vinson,* 477 U.S. 57, 64 (1986), in addressing Title IX sexual-harassment claims); *Olmstead v. L.C. ex rel. Zimring*, 527 U.S. 581, 616-17 & n.1 (1999)

(Thomas, J., dissenting) ("This Court has also looked to its Title VII interpretations of discrimination in illuminating Title IX"); *Carder v. Cont'l Airlines, Inc.*, 636 F.3d 172, 180 (5th Cir. 2011) ("[T]his court has interpreted Title IX as being intended to prohibit a wide spectrum of discrimination against women in the same manner as Title VII."); *see also Wittmer v. Phillips 66 Co.*, 915 F.3d 328, 337-38 (5th Cir. 2019) (Ho, J., concurring) ("[B]ecause federal statutes governing educational institutions employ language indistinguishable from Title VII, th[e] debate [over whether sex discrimination under Title VII includes gender-identity discrimination] "affects virtually every school, college, dormitory, athletic activity, and locker room in America.").

In short, the relevant provisions of Title IX and Section 1557 unambiguously exclude gender-identity discrimination. The Rule's definition of sex discrimination to include discrimination on the basis of gender identity cannot stand under the APA.

B. Section 1557's Prohibition on Sex Discrimination Includes Title IX's Exemptions.

Section 1557's prohibition on sex discrimination is also limited by Title IX's exemptions, including its religious exemption—which provides that Title IX's prohibition on sex discrimination "shall not apply to an educational institution which is controlled by a religious organization if the application of this subsection would not be consistent with the religious tenets of such organization," 20 U.S.C. § 1681(a)(3)—and the abortion rule of construction—which provides that Title IX shall not "be construed to require or prohibit any person, or public or private entity, to provide or pay for any benefit or service, including the use of facilities, related to an abortion," *id.* § 1688. Notably, Section 1557 forbids discrimination "on the ground prohibited under . . . title IX of the Education Amendments of 1972 (20 U.S.C. 1681 *et seq.*)." 42 U.S.C. § 18116 (emphasis added). As this Court explained, Congress's decision to "include[] the signal

'et seq.' … after the citation to Title IX can only mean Congress intended to incorporate the entire statutory structure, including [Title IX's] exemptions." *Franciscan All.*, 227 F. Supp. 3d at 690.

In confirmation of this fact, Section 1557 also prohibits discrimination on "the ground prohibited under title VI of the Civil Rights Act of 1964 (42 U.S.C. 2000d *et seq.*), … the Age Discrimination Act of 1975 (42 U.S.C. 6101 *et seq.*), or section 504 of the Rehabilitation Act of 1973 (29 U.S.C. 794)," 42 U.S.C. § 18116 (emphases added), and the Rule explicitly confirms that those statutes' exemptions apply, *see* 45 C.F.R. § 92.101(c) ("The exceptions applicable to Title VI apply to discrimination on the basis of race, color, or national origin under this part. The exceptions applicable to Section 504 apply to discrimination on the basis of disability under this part. The exceptions applicable to the Age Act apply to discrimination on the basis of age under this part."). Thus, Section 1557's prohibition on racial discrimination, for instance, does not extend to "exclusion from benefits limited by Federal law to individuals of a particular race." 45 C.F.R. § 80.3(d) (titled "Indian Health and Cuban Refugee Services"). Nothing in Section 1557 justifies singling out Title IX's exemptions and rules of construction for disfavored treatment. Just as Section 1557's prohibitions on racial, disability, and age discrimination are limited by the exemptions in those anti-discrimination laws, so its prohibition on sex discrimination is limited by the exemptions in Title IX, including those dealing with religion and abortion. And those statutory provisions are particularly critical to understanding the scope of any prohibition on discrimination on the basis of termination of pregnancy. The Rule's failure to incorporate these provisions in its definition of sex discrimination is therefore contrary to law.[6]

[6] This Court has ruled in another case that the individual mandate is both unconstitutional and inseverable from the remainder of the ACA (and has stayed that decision pending appeal). *See Texas v. United States*, 352 F. Supp. 3d 665 (N.D. Tex. 2018). Plaintiffs in this case have not pressed that theory for challenging the Rule, and thus, for purposes of this case, the Court should

II. THE COURT SHOULD NOT ADDRESS PLAINTIFFS' REMAINING CLAIMS.

Because resolution of Plaintiffs' APA claim is sufficient to afford Plaintiffs the relief they seek, the Court need not—and should not—address Plaintiffs' remaining statutory and constitutional claims. As this Court recognized at the preliminary-injunction stage, "[b]oth parties agree that if the Court resolves the APA or RFRA claim, there is no need to reach the remaining constitutional issues." *Franciscan All.*, 227 F. Supp. 3d at 691 n.32. That consensus reflects the longstanding principle that "'[p]rior to reaching any constitutional questions, federal courts must consider nonconstitutional grounds for decision.'" *Jean v. Nelson*, 472 U.S. 846, 854 (1985). And because resolution of the substantive APA claim will provide complete relief to all Plaintiffs, there is no need to resolve the Private Plaintiffs' RFRA claim or the State Plaintiffs' Title VII claim.

III. THIS COURT SHOULD POSTPONE OR, AT A MINIMUM, LIMIT ANY RULING.

Although Defendants agree with Plaintiffs that the Rule's definition of sex discrimination cannot stand under the APA, the Court should postpone ruling on Plaintiffs' summary judgment motions. Defendants expect to be able to publish a proposed rule soon, which, if finalized, may moot this case. The Court should avoid issuing a decision that will likely be overtaken by events, especially as any delay in ruling will not harm Plaintiffs given that the preliminary nationwide injunction against the Rule's challenged prohibition remains in place and Defendants are conscientiously complying with the injunction.[7]

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simply rule that the Rule's challenged prohibition is contrary to the terms of Section 1557 of the ACA, the statutory provision under which the Rule was promulgated.

[7] Defendants previously agreed that the stay in this case could be lifted because they did not know how long it would take to "reevaluat[e] the reasonableness, necessity, and efficacy of the Rule." ECF No. 125. But Defendants now expect a new proposed rule to be issued soon, and thus, the reason for lifting the stay and briefing summary judgment has disappeared.

If this Court does rule in Plaintiffs' favor, however, any relief should be limited in scope to redressing any cognizable injuries of the Plaintiffs before the Court. Although Defendants acknowledge that the Court's preliminary injunction was nationwide in scope, *see Franciscan All.*, 227 F. Supp. 3d at 695, Defendants continue to maintain that nationwide injunctions that go beyond redressing any cognizable injuries of Plaintiffs are inappropriate under both Article III and equitable principles. *See* ECF 50, at 49-50; *see also Gill v. Whitford*, 138 S. Ct. 1916, 1934 (2018) ("A plaintiff's remedy must be tailored to redress the plaintiff's particular injury.").

The fact that this case involves the APA makes no difference, as the APA does not compel courts to abandon established equitable principles, including those governing nationwide relief. *See, e.g.*, *California v. Azar*, 911 F.3d 558, 582-85 (9th Cir. 2018) (vacating district court's grant of nationwide injunction in APA case); *Los Angeles Haven Hospice, Inc. v. Sebelius*, 638 F.3d 644, 664-65 (9th Cir. 2011) (same); *Va. Soc'y for Human Life, Inc. v. FEC*, 263 F.3d 379, 393 (4th Cir. 2001) (same), *overruled on other grounds by Real Truth about Abortion v. FEC*, 681 F.3d 544 (4th Cir. 2012). A court "do[es] not lightly assume that Congress has intended to depart from established principles" regarding equitable discretion, *Weinberger v. Romero-Barcelo,* 456 U.S. 305, 313 (1982), and the APA's general instruction that unlawful agency action "shall" be "set aside," 5 U.S.C. § 706(2), is insufficient to mandate such a departure. Indeed, the Supreme Court held that not even a provision directing that an injunction "shall be granted" with respect to a threatened or completed violation of a particular statute was sufficient to displace traditional principles of equitable discretion, *Hecht Co. v. Bowles*, 321 U.S. 321, 328-30 (1944), and Congress is presumed to have been aware of that holding when it enacted the APA's "shall" be "set aside" language two years later. In fact, the APA expressly confirms that, absent a special review statute, "[t]he form of proceeding for judicial review" is simply the traditional "form[s] of legal action,

including actions for declaratory judgments or writs of prohibitory or mandatory injunction," 5 U.S.C. § 703, and that the statutory right of review does not affect "the power or duty of the court to . . . deny relief on any . . . appropriate legal or equitable ground," *id.* § 702(1). The Supreme Court therefore has confirmed that, even in an APA case, "equitable defenses may be interposed." *Abbott Labs. v. Gardner*, 387 U.S. 136, 155 (1967). Accordingly, the Court should construe the "set aside" language in Section 706(2) as applying only to the named Plaintiffs, especially as no federal court had issued a nationwide injunction before Congress's enactment of the APA in 1946, nor would do so for more than fifteen years thereafter, *see Trump v. Hawaii*, 138 S. Ct. 2392, 2426 (2018) (Thomas, J., concurring).

CONCLUSION

For the foregoing reasons, Defendants respectfully request that the Court postpone ruling on Plaintiffs' motions for summary judgment. If the Court decides those motions, it should limit any relief to redressing any cognizable injuries of the named Plaintiffs.

Dated: April 5, 2019

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EXHIBIT 3

Defendants' Motion to Modify Final Judgment in
Franciscan Alliance v. Azar

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
WICHITA FALLS DIVISION

FRANCISCAN ALLIANCE, INC., *et al.* *Plaintiffs*, v. ALEX M. AZAR II, Secretary of Health and Human Services, *et al.*, *Defendants*.	Case No. 7:16-cv-00108-O

DEFENDANTS' MOTION TO MODIFY FINAL JUDGMENT

Defendants respectfully ask the Court to modify its October 15, 2019 Final Judgment, ECF No. 176, pursuant to Rule 59(e) to clarify that the Court vacated only the specific portions of the challenged rule, titled Nondiscrimination in Health Programs & Activities, 81 Fed. Reg. 31,376 (May 18, 2016) ("Rule"), that the Court determined to be unlawful. Defendants do not believe that the Court intended to or, in fact, did vacate the Rule in its entirety, based on the Court's clear statement in the accompanying Memorandum Opinion and Order that it was vacating only "the *unlawful portions* of the Rule." *See* ECF No. 175 at 23 (emphasis added). However, out of an abundance of caution, and to remove any doubt, Defendants respectfully ask the Court to modify the Final Judgment to make explicit that it vacated only those portions of the Rule that the Court found to be unlawful.

BACKGROUND

Plaintiffs brought this action to challenge only certain portions of the Rule—specifically the Rule's prohibition of discrimination on the basis of "gender identity" and "termination of pregnancy." *See, e.g.*, ECF No. 62 (describing Plaintiffs' objections to the Rule); *see also* ECF

No. 57 (describing the portions of the Rule Plaintiffs challenge). On December 31, 2016, the Court granted Plaintiffs' motion for a preliminary injunction, finding that those two challenged aspects of the Rule were contrary to law. *See id.* at 32-38. In that order, the Court was explicit that, because the Rule contains a severability clause, the Court was enjoining "[o]nly the Rule's command this Court finds is contrary to law and exceeds statutory authority—the prohibition of discrimination on the basis of 'gender identity' and 'termination of pregnancy.'" *Id.* at 46.

With the preliminary injunction in place, and in light of Defendants' request that the United States Department of Health and Human Services ("HHS") be given the opportunity to reconsider the regulations at issue in this case, the Court stayed the litigation until December 17, 2018. *See* ECF No. 126. After the stay was lifted, on February 4, 2019, Plaintiffs moved for summary judgment. *See* ECF Nos. 132-37. On October 15, 2019, the Court granted Plaintiffs' motions for summary judgment and entered Final Judgment in favor of Plaintiffs. *See* ECF Nos. 175, 176. As described below, Defendants respectfully ask the Court to modify its Final Judgment to be clear that the Court intended to vacate only the specific portions of the Rule the Court determined were unlawful, consistent with the Court's Memorandum Opinion and Order.

ANALYSIS

Based on the clear language in the Court's October 15, 2019 Memorandum Opinion and Order—and based on the Court's previous statements—Defendants believe that the Court intended to vacate only the specific portions of the Rule that the Court determined were unlawful, rather than the Rule in its entirety.

In the Court's October 15, 2019 Memorandum and Opinion, the Court specifically addressed the appropriate remedy, explaining that, if an agency action is found to be in excess of statutory authority under 5 U.S.C. § 706(2)(c), courts "may 'set aside' only the part of a rule found

to be invalid—for that is the only 'agency action' that exceeds statutory authority." ECF No. 175 at 22 n.7 (quoting *Catholic Soc. Serv. v. Shalala*, 12 F.3d 1123, 1128 (D.C. Cir. 1994)). And, as the Court explained, it would "exceed the statutory scope of review for a court to set aside an entire rule where only a part is invalid, and where the remaining portion may sensibly be given independent life." *Id.* Accordingly, and because the challenged Rule includes a severability provision, the Court indicated that it vacated "only the portions of the Rule that are unlawful under the APA and RFRA." *Id.*; *see also id.* at 23 ("[T]he Court **VACATES and REMANDS** the *unlawful portions* of the Rule for Defendants' further consideration in light of this opinion and the Court's December 31, 2016 Order." (italics added)).

Despite the Court's clear intent as stated in the Memorandum Order and Opinion to vacate only the discrete portions of the Rule that the Court found unlawful, the Court's Final Judgment—by referring to the Rule as a whole and without distinguishing between those portions of the Rule that the Court found unlawful and the remainder of the Rule—could arguably be read to mean that the Rule as a whole is unlawful and is therefore vacated in its entirety. *See* ECF No. 176 (stating that the Court "now **HOLDS** that Nondiscrimination in Health Programs & Activities ('the Rule'), 81 Fed. Reg. 31376 (May 18, 2016), codified at 45 C.F.R. § 92, violates the APA and RFRA," and, accordingly, that the Court "**VACATES and REMANDS** *the Rule* for further consideration" (italics added)).

To clarify the record—and to ensure that the portions of the Rule the Court has not found to be unlawful remain operable—Defendants respectfully ask the Court to modify its Final Judgment to make clear its intent to vacate only the Rule's prohibition of discrimination on the basis of "gender identity" and "termination of pregnancy." Without Defendants' requested relief, HHS arguably would be unable to implement and/or enforce the remaining aspects of the Rule that

the Plaintiffs in this case do not challenge, potentially resulting in serious programmatic challenges for HHS in areas unrelated to those at issue in this litigation. That result, as the Court itself explained in its Memorandum Opinion and Order, would also ignore the Rule's severability provision at 45 U.S.C. § 92.2(c).

Defendants respectfully submit that the Court should modify its Final Judgment to clarify that the Court intended to vacate only the portions of the Rule that the Court concluded are unlawful, as reflected in the attached Proposed Order. Specifically, Defendants ask that the Court make clear that the Court intended to vacate the phrases "gender identity" and "termination of pregnancy" in the definition of "On the basis of sex" in 45 C.F.R. § 92.4 and that the rest of 45 C.F.R. § 92 should remain in effect.[1]

CONCLUSION

For the foregoing reasons, Defendants respectfully request that this Court grant their motion to modify the October 15, 2019 Final Judgment consistent with the Court's Memorandum Opinion and Order and Defendants' accompanying Proposed Order.

Dated: November 12, 2019

Respectfully Submitted,

JOSEPH H. HUNT
Assistant Attorney General

JENNIFER D. RICKETTS
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Assistant Branch Director, Federal Programs Branch

[1] Defendants do not understand the Court's holding with respect to RFRA to provide any different relief than its holding with respect to the APA because the Private Plaintiffs' RFRA claim challenged the same prohibitions on discrimination based on gender identity and termination of pregnancy as did their APA claim. That said, to the degree the Court's RFRA analysis applies to any other portion of the Rule beyond the definition of "On the basis of sex" in 45 C.F.R. § 92.4, the appropriate relief would not be to vacate any such portion, but rather to declare it unlawful under RFRA as to the Private Plaintiffs only.

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EXHIBIT 4

Court's Order in Franciscan Alliance v. Azar

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
WICHITA FALLS DIVISION

FRANCISCAN ALLIANCE, INC., et al.,	§	
	§	
Plaintiffs,	§	
	§	
v.	§	**Civil Action No. 7:16-cv-00108-O**
	§	
ALEX M. AZAR II, Secretary of the United States Department of Health and Human Services; and UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES,	§	
	§	
Defendants.	§	

ORDER

Before the Court is Defendants' Motion to Modify Final Judgment (ECF No. 178), filed November 12, 2019; State Plaintiffs' Response (ECF No. 180), filed November 20, 2019; and Private Plaintiffs' Response (ECF No. 181), filed November 20, 2019.

Defendants state that they "do not believe the Court intended to or, in fact, did vacate the Rule in its entirety, based on the Court's clear statement in the accompanying Memorandum Opinion and Order that it was vacating only 'the *unlawful portions* of the Rule,'" but "out of an abundance of caution, and to remove any doubt," they ask the Court to modify its Final Judgment (ECF No. 176), dated October 15, 2019. Defs.' Mot. 1, ECF No. 178 (emphasis in original) (quoting Mem. Op. & Order 23, ECF No. 175). Defendants ask the Court to specify that the Court vacates "the portion of the definition of '*On the basis of sex'* at 45 C.F.R. § 92.4 that refers to 'termination of pregnancy' and 'gender identity.'" Defs.' [Proposed] Order 1, ECF No. 178-1.

Neither State Plaintiffs nor Private Plaintiffs believe that modification of the Final Judgment is necessary given the Court's severability analysis in its Memorandum Opinion and

Order. *See* State Pls.' Resp. 1–2, ECF No. 180; Private Pls.' Resp. 1, ECF No. 181. However, State Plaintiffs and Private Plaintiffs agree that, "[i]f the Court is inclined to modify its judgment," the modification should clarify that the Court "vacates the Rule 'insofar as the Rule defines "on the basis of sex" to include gender identity or termination of pregnancy.'" State Pls.' Resp. 2, ECF No. 180; *see also* Private Pls.' Resp. 1, ECF No. 181 (agreeing that the State Plaintiffs' "proposed language . . . better captures the conclusion of the Court's summary-judgment order"). State Plaintiffs argue that this language avoids any potential confusion regarding the particular words in the Rule. *See* State Pls.' Resp. 2, ECF No. 180.

Having considered the Defendants' motion and Plaintiffs' responses, the **GRANTS in part** the motion and **MODIFIES** the Final Judgment (ECF No. 176), filed October 15, 2019, to confirm that, consistent with the Court's discussion in the accompanying Memorandum Opinion and Order (ECF No. 175), the Court vacates only the portions of the Rule that Plaintiffs challenged in this litigation. Specifically, the Court **VACATES** the Rule insofar as the Rule defines "*On the basis of sex*" to include gender identity and termination of pregnancy, and the Court **REMANDS** for further consideration. The remainder of 45 C.F.R. § 92 remains in effect.

SO ORDERED on this **21st day** of **November, 2019.**

Reed O'Connor
UNITED STATES DISTRICT JUDGE

EXHIBIT 5

Comments by Lambda Legal Defense and Education Fund, Inc.

August 13, 2019

VIA Electronic Submission

Hon. Alex M. Azar, II, Secretary
U.S. Department of Health and Human Services
Attention: 1557 NPRM, RIN 0945-AA11
Hubert H. Humphrey Building, Room 509F
200 Independence Avenue SW
Washington, DC 20201

Re: **Agency Notice of Proposed Rulemaking; Public Comment Request; Nondiscrimination in Health and Health Education Programs or Activities RIN 0945-AA11**

To Whom It May Concern:

Lambda Legal Defense & Education Fund, Inc. ("Lambda Legal") submits these comments in response to the U.S. Department of Health and Human Services ("HHS" or "Department") and the Center for Medicaid and Medicaid Services ("CMS") Notice of Proposed Rulemaking ("Proposed Rule" or "NPRM") to express our opposition to the proposed rule entitled "Nondiscrimination in Health and Health Education Programs or Activities," published in the Federal Register on July 14, 2019.

Founded in 1973, Lambda Legal is the oldest and largest national legal organization dedicated to achieving full recognition of the civil rights of lesbian, gay, bisexual, transgender and queer ("LGBTQ") people and everyone living with HIV through impact litigation, education, and policy advocacy. The matters addressed in the Proposed Rule are of great concern to Lambda Legal because LGBTQ people and those living with HIV already face widespread discrimination in health care services, and violations of their personal autonomy regarding reproductive decisions, sexual health, gender expression, transition-related care, HIV care and other matters. Lambda Legal has been a leader in the fight against this discrimination and, accordingly, has submitted a series of comments to HHS providing extensive documentation of this discrimination, its serious health effects, the ways that current federal law must be understood as forbidding this mistreatment, and the ways that additional conscience-based exemptions to health standards and federal would wrongfully endanger LGBTQ people and others.[1] Because Lambda Legal remains committed to protecting the rights of LGBTQ people seeking health care and to ensuring that medical professionals and healthcare facilities understand and respect their responsibility to treat LGBTQ patients fairly, Lambda Legal opposes the Proposed Rule for the reasons explained in these comments.[2]

[1] *See, e.g.,* Lambda Legal Public Comment in Response to the Proposed Rule, Protecting Statutory Conscience Rights in Health Care, RIN 0945-ZA03 (submitted March 27, 2018) ("Lambda Legal Religious Exemption Comments"), *available at* https://www.lambdalegal.org/in-court/legal-docs/dc_20180327_comments-hhs; *Lambda Legal Comments on Proposed Rule 1557 Re: Nondiscrimination in Health Programs and Activities, 1557 NPRM (RIN 0945-AA02)* (submitted Nov. 9, 2015) ("Lambda Legal 1557 Comments"), *available at* https://www.lambdalegal.org/in-court/legal-docs/hhs_dc_20151117_letter-re-1557; *Lambda Legal Comments on Request for Information Regarding Nondiscrimination in Certain Health Programs or Activities (RIN 0945-AA02 & 0945-ZA01)* (submitted Sept. 30, 2013) ("Lambda Legal Nondiscrimination Comments"), *available at* https://www.lambdalegal.org/in-court/legal-docs/ltr_hhs_20130930_discrimination-in-health-services.

[2] Lambda Legal also opposes the Proposed Rule for the reasons set forth in the comments submitted by the HIV Health Care Access Working Group – a coalition of over 100 national and community-based HIV service organizations, of which Lambda

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I. Introduction

Lambda Legal vigorously opposes the Proposed Rule. LGBTQ people already experience widespread discrimination in health care settings. Although HHS cannot change the law through the Proposed Rule, the Proposed Rule sends a dangerous message to those who wish to discriminate that they can do so without consequence, which would cause direct harm and literally endanger the lives of LGBTQ people and other marginalized populations. By improperly inviting discrimination contrary to the statute, the Proposed Rule also would cause drastic limitations in access to health care coverage for LGBTQ people, while creating confusion among health care providers about their rights and obligations under the law. The Proposed Rule also would encourage hospitals to deny care to LGBTQ people, and embolden insurance companies to deny transgender people coverage for health care services that they cover for non-transgender people.

It is important to note the context within which the NPRM has been promulgated. HHS issued the Proposed Rule on the heels of two and half years of relentless efforts by this administration to rollback or eliminate equality protections for LGBTQ people in a broad range of contexts. There are too many examples of these efforts to catalogue in this comment, but they are publicly documented.[3] These systematic

Legal is a member, which represents HIV medical providers, public health professionals, advocates, and people living with HIV who are all committed to ensuring access to critical HIV-related health care and support services.

[3] *E.g.*, Human Rights Campaign, *Trump's Timeline of Hate*, *available at* https://www.hrc.org/timelines/trump; National Center for Transgender Equality, *The Discrimination Administration*, *available at* https://transequality.org/the-discrimination-administration; GLAAD, *Trump Accountability Project*, *available at* https://www.glaad.org/trump.

attempts to facilitate discrimination against LGBTQ people have especially marked out and targeted transgender people. The administration, for example, has sought to eliminate information about transgender elders,[4] to exclude transgender students,[5] to deny transgender workers equal opportunity,[6] to ban transgender service members,[7] to bar transgender immigrants,[8] and to leave transgender prisoners without basic personal needs and subject to sexual and other violence.[9] Now, as the NPRM makes clear, the administration proposes to facilitate denials of medically necessary care to transgender patients.

In an administration that seems to find new ways to target LGBTQ people (and transgender people in particular) on a weekly basis, there is no federal agency that has invited more widespread harm to LGBTQ people than HHS, the agency actually charged by Congress with enhancing the health and well-being of all Americans.[10] Instead of advancing the health and well-being of ***all*** Americans, however, under this administration, HHS is attempting the opposite. For example, HHS recently issued a final rule that invites health care providers to deny LGBTQ people, and most explicitly transgender people, health care based on a health provider's religious or personal beliefs, regardless of the medical standard of care.[11] The Department also has repeatedly attempted to erase information about LGBTQ people. For example, the Department altered its website to remove language referencing protections for LGBTQ people and instructed CDC staff not to even use the word "transgender."[12] HHS also has repeatedly rolled back data collection efforts which are critical for understanding and then attempting to meet the needs of LGBTQ people.[13]

[4] Health and Human Services Agency, Administration for Community Living Elimination of data collection survey for transgender elders on the National Survey of Older Americans Act, *available at* https://www.federalregister.gov/documents/2018/02/20/2018-03390/agency-information-collection-activities-submission-for-omb-review-comment-request-redesign-of.

[5] John Riley, *Department of Education Issues New Guidance on Transgender Students*, (June 16, 2017); OCR Instructions to the Field re Complaints Involving Transgender Students, *available at* https://www.documentcloud.org/documents/3866816-OCR-Instructions-to-the-Field-Re-Transgender.html.

[6] Office of the Attorney General Memo to U.S. Attorneys regarding the Revised Treatment of Transgender Discrimination Claims under Title VII of the Civil Rights Act of 1964 (Oct. 4, 2017), *available at* https://www.justice.gov/ag/page/file/1006981/download.

[7] Office of the Deputy Secretary of Defense, Directive Memo with regard to Military Service by Transgender Persons (Mar. 12, 2019), *available at* https://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dtm/DTM-19-004.pdf.

[8] Ben Kesslen, *Dozens of House Members Demand Better Treatment of Transgender Asylum Seekers in ICE Custody* (Aug. 1, 2019), *available at* https://www.nbcnews.com/politics/immigration/dozens-house-members-demand-better-treatment-transgender-asylum-seekers-ice-n1037471.

[9] U.S. Department of Justice, Federal Bureau of Prisons, Change to the Transgender Offender Manual (May 11, 2018), *available at* https://www.bop.gov/policy/progstat/5200-04-cn-1.pdf.

[10] See HHS Mission Statement, *available at* https://www.hhs.gov/about/strategic-plan/introduction/index.html#mission

[11] Protecting Statutory Conscience Rights in Health Care; Delegations of Authority, 84 FR 23170 (May 21, 2019), *available at* https://www.federalregister.gov/documents/2019/05/21/2019-09667/protecting-statutory-conscience-rights-in-health-care-delegations-of-authority (expanding existing conscience protections to include health care treatment for transgender people).

[12] *E.g.*, Lena H. Sun and Juliet Eilperin, *CDC Gets List of Forbidden Words: Fetus, Transgender, Diversity* (Dec. 15, 2017) WASHINGTON POST, *available at* https://www.washingtonpost.com/national/health-science/cdc-gets-list-of-forbidden-words-fetus-transgender-diversity/2017/12/15/f503837a-e1cf-11e7-89e8-edec16379010_story.html?utm_term=.6784cceec03e.

[13] *E.g.*, Department of Health and Human Services, Adoption and Foster Care Analysis and Reporting System NPRM (Apr. 19, 2019), *available at* https://www.federalregister.gov/documents/2019/04/19/2019-07827/adoption-and-foster-care-analysis-and-reporting-system.

Most of the anti-LGBTQ policy changes being attempted by HHS—including the Proposed Rule—arise out of its Office of Civil Rights ("OCR"), headed by its director, Roger Severino. For years Mr. Severino has made no secret of his contempt for LGBTQ people, especially transgender people.[14] For example, before taking the helm of OCR, Mr. Severino was on record that he believes transgender military personnel serving openly "dishonors" the service of other service members.[15] He referred to Gavin Grimm, a male transgender student in a successful Title IX case,[16] as "a gender-dysphoric teen girl."[17] With particular reference to the Proposed Rule, Mr. Severino has referred to the existing health care nondiscrimination protections for transgender people as "special privileges" and propagated the baseless myth that doctors will be forced to enter new fields of medicine against their will.[18]

Consistently with this evident personal antipathy to transgender people as a class, Mr. Severino also has repeatedly disparaged the clinical effectiveness of transition-related health care.[19] Mr. Severino, however, is not a physician and he cites only his opinion and discredited studies that—as with the NPRM—ignore a mountain of both medical and legal authority in order to reach arbitrary, unsupportable and harmful conclusions. Nearly all major medical organizations in the United States have issued position statements confirming based on decades of studies that access to and insurance coverage for transition-related health care is medically necessary for many transgender patients and fully in keeping with contemporary standards of medicine, science, and ethics. For example, the American Medical Association has repeatedly affirmed the propriety of transition-related care in both the civilian and the military context.[20] Likewise, the American Psychiatric Association[21] and the American Psychological Association,[22] as well as a host of other medical organizations, also have issued similar position statements.[23] In fact, no credible major medical organizations have taken a contrary position.

[14] Charles Ornstein, *Heritage Foundation Alum Critical of Transgender Rights to Lead HHS Civil Rights Office* (Mar. 24, 2017), *available at* https://www.propublica.org/article/heritage-foundation-critical-transgender-rights-HHS-civil-rights-office; GLAAD, Trump Accountability Project, Profile of Roger Severino, Director of Office of Civil Rights (at Dept. of HHS), *available at* https://www.glaad.org/tap/roger-severino.

[15] Roger Severino, *Pentagon's Radical New Transgender Policy Defies Common Sense* (July 1, 2016), CNSNEWS.COM, *available at* https://www.cnsnews.com/commentary/roger-severino/pentagons-radical-new-transgender-policy-defies-common-sense.

[16] *Grimm v. Gloucester Cty. Sch. Bd.*, No. 4:15CV54, 2019 WL 3774118 (E.D. Va. Aug. 9, 2019).

[17] Jim DeMint & Roger Severino, *Commentary: Court Should Reject Obama's Radical Social Experiment* (Dec. 14, 2016), *available at* https://www.heritage.org/gender/commentary/court-should-reject-obamas-radical-social-experiment.

[18] Roger Severino, *Why Obamacare Might Force Doctors to Perform Sex-Reassignment Surgeries* (Jan. 13, 2016), *available at* https://www.dailysignal.com/2016/01/13/why-obamacare-might-force-doctors-to-perform-sex-reassignment-surgeries/.

[19] Ryan Anderson & Roger Severino, *Proposed Obamacare Gender Identity Mandate Threatens Freedom of Conscience and the Independence of Physicians*, Heritage Foundation Backgrounder, No. 3089 (Jan. 8, 2016), *available at* https://www.heritage.org/health-care-reform/report/proposed-obamacare-gender-identity-mandate-threatens-freedom-conscience.

[20] American Medical Association House of Delegates Resolution 122, *available at* http://www.imatyfa.org/assets/ama122.pdf; also see AMA Statement on Pentagon's ban on Transgender in the Military (Apr. 11, 2019), *available at* https://www.ama-assn.org/press-center/ama-statements/ama-statement-pentagons-ban-transgender-military.

[21] *See* Professional Organization Statements Supporting Transgender People in Health Care, Lambda Legal (last visited Aug. 13, 2019), *available at* https://www.lambdalegal.org/sites/default/files/publications/downloads/resource_trans-professional-statements_09-18-2018.pdf.

[22] *Id.*

[23] *Id.*

Accordingly, since before the Affordable Care Act was enacted almost a decade ago and increasingly thereafter, health insurance companies have been eliminating their prior, discriminatory exclusions of coverage for transition-related health care. This trend is accelerating both with plans offered through the exchanges and those offered by employers, and insurers have reported no problems with the provision of coverage for this medically-necessary health care. Indeed many states now prohibit insurers from offering plans that discriminate against transgender people.[24]

While equality and a desire to avoid discrimination should drive decisions about benefit coverage, the case for the provision and coverage of transition-related health care is also economically sound. Over and over again, reputable cost studies have shown that the cost of providing this care is less than one-tenth of one percent of an entity's health budget. For example, a study commissioned by the U.S. military concluded that costs associated with providing health care to transgender service members was considered by a former Secretary of the Navy to be "budget dust, hardly even a rounding error."[25] Likewise, research from the Johns Hopkins Bloomberg School of Public Health calculated that the costs would be fewer than two pennies per month for every person with health insurance coverage in the United States.[26] A cost analysis of the City and County of San Francisco's coverage of transition-related surgeries found that costs in the first five years to both insurers and employers were low, averaging between $0.77 and $0.96 per year per enrollee, and resulted in no surcharge or premium increases.[27] Employers who provide health care coverage for their transgender employees likewise report very low costs, if any, from adding transition-related coverage to their health benefits plans or from actual utilization of the benefit after it has been added – with many employers reporting no costs at all.

Contrary to this information readily available to the public, and the information compiled both by HHS when preparing the 2016 Final Rule and by the Armed Forces when preparing to permit open military service by transgender people, this administration has grossly exaggerated the cost of transition-related health care coverage in order to enshrine discrimination.[28] The discriminatory comments by OCR leadership together with this administration's shockingly overt record of anti-transgender bias make plain that this Proposed Rule is the product of biased ideology, not medical or other evidence. Contrary to the statutory responsibility of HHS to enhance the health and well-being of all Americans, this Proposed Rule illegitimately aims instead to embolden those providers and insurers who wish to withhold medically needed heath care from LGBTQ patients.

[24] *See States with health insurance bulletins prohibiting discrimination against transgender people*, Transgender Law Center (last updated May 23, 2016), *available at* https://transgenderlawcenter.org/resources/health/bulletins.

[25] See Declaration of Raymond Edwin Mabus, Jr., former Secretary of the Navy, In support of Plaintiff's Motion for Preliminary Injunction, No. 17-cv-1597 (CKK), *Doe v. Trump* (Aug. 28, 2017), *available at* http://www.nclrights.org/wp-content/uploads/2017/08/Mabus-Declaration-1.pdf..

[26] William V. Padula, Shiona Heru, Jonathan D. Campbell, *Societal Implications of Health Insurance Coverage for Medically Necessary Services in the U.S. Transgender Population: A Cost-Effectiveness Analysis* (Oct. 19, 2015), *available at* https://link.springer.com/article/10.1007%2Fs11606-015-3529-6.

[27] State of California Department of Insurance Economic Impact Assessment (Apr. 13, 2012), *available at* https://transgenderlawcenter.org/wp-content/uploads/2013/04/Economic-Impact-Assessment-Gender-Nondiscrimination-In-Health-Insurance.pdf.

[28] *See, e.g.,* Asher Stockler, *Legal Experts Say Trump's Latest Freewheeling Interview Could Undermine his Transgender Military Ban Case*, NEWSWEEK (June 6, 2019), *available at* https://www.newsweek.com/donald-trump-interview-transgender-military-ban-1442679.

Against this overwhelmingly discriminatory federal policy backdrop, LGBTQ people, and especially transgender people, already have been experiencing serious and persistent barriers to accessing health care coverage,[29] which would only worsen if the Proposed Rule were to be given effect. For example, one in four transgender people report experiencing discrimination, such as being denied coverage for care related to transition, and one-third report verbal harassment or refusal of treatment.[30] As a result of this discrimination, many transgender and nonbinary people avoid seeking health care altogether. According to the 2015 U.S. Transgender Survey, 23% did not seek care when they needed it from fear of being mistreated.[31] These persistent experiences and delays in preventive treatment can lead many people to avoid seeing a doctor altogether, which inevitably leads to serious negative long-term health care outcomes.[32]

In addition to the statistical evidence showing the glaring disparities, the requests for assistance that Lambda Legal receives via our Legal Help Desk and publicly reported examples of refusals of care[33] demonstrate the extreme harm that LGBTQ people already experience, which unavoidably would be exaggerated were the Proposed Rule to be given effect. Below are only a few examples that show the range of harmful discrimination that LGBTQ people regularly experience regarding health care treatment:

- Tyra Hunter, a transgender woman who was seriously injured in a car accident outside Washington D.C who later died from her wounds was jeered at by ambulance workers who refused to her.[34]

- Robert Eads, a transgender man with ovarian cancer whom 20 separate doctors wouldn't treat; one said the diagnosis should make Eads "deal with the fact that he is not a real man."[35]

- K.S., a transgender woman in Dallas who sought help because she had become suicidal, recounted: On several occasions, I was asked about my genitals as well as other inappropriate questions about my transgender status. When I complained…a nurse told me that I should just "expect to be treated like this." On multiple occasions, they made me sleep on the hallway floor rather than in a room, and when I was finally given a room, it was an isolation room…I was also prevented from using the bathroom for hours at a time…[and]denied use of [my electric shaver] for a week, which caused me to grow a beard. The staff of the facility discussed my transgender status loudly…, and as a result, within the first couple of days of my arrival all of the patients around me knew, which caused me to suffer sexual harassment from two male patients. K.S. Statement. Due to this treatment, K.S. attempted suicide twice while at that facility.[36]

[29] See extensive material submitted to HHS in Lambda Legal's prior comments, as referenced *supra* in note 1.

[30] James, S.E., Herman, J.L., Rankin, S., Keisling, M., Mottet, L. & Anafi, M. (2016) (p. 92). *The Report of the 2015 U.S. Transgender Survey*. Washington, DC: National Center for Transgender Equality, *available at* http://www.ustranssurvey.org/reports.

[31] *Id.*

[32] See discussions in Lambda Legal's prior comments, referenced *supra* in note 1.

[33] See examples reported in detail in Lambda Legal's prior comments, referenced *supra* in note 1.

[34] *See* Health Provider Discrimination, Lambda Legal (last visited Aug. 13, 2019), *available at* https://www.lambdalegal.org/know-your-rights/article/trans-health-care-discrimination.

[35] *Id.*

[36] *See* Brief of Amici Curiae Lambda Legal Defense and Education Fund, Inc., Family Equality Council, *et al.*, in Support of Respondents (Oct. 30, 2017), *Masterpiece Cakeshop, Ltd. v. Colorado Civil Rights Commission*, 2017 WL 5127317.

- M.H., a gay man in New York City reported: I was treated roughly physically and emotionally and called a faggot on more than one occasion by a health care aide. At one point, I was dragged down the hall roughly in an office chair, because they said they were short on beds, and I fell out of the chair…I was left on the floor, where I went into convulsions and urinated on myself. I was later told I had a seizure and a cyanotic episode…I could hear the nurse running toward me yelling that she was going to lose her job over this. The health aide responded: "This junky faggot isn't going to make you lose your job."[37]

Despite this persistent, appalling reality for transgender people in particular, the Proposed Rule seeks to roll back and limit the existing rule regarding "Nondiscrimination in Health and Health Education Programs or Activities" (hereinafter "2016 Final Rule"), promulgated on May 18, 2016. The 2016 Final Rule represents the culmination of an extensive process. It was developed over the course of six years and took in two notice and comment periods and received over 25,000 comments which overwhelmingly confirmed both the legal foundation and the practical need to include explicit protections against discrimination based on sex stereotyping and gender identity in the regulations. Since its promulgation, the 2016 Final Rule has successfully led to a dramatic decrease in discriminatory policies and practices.[38] A recent study of 37 states in the federal marketplace showed that 95% of plans did not contain blanket exclusions of transition-related care in 2019.[39] If finalized, the Proposed Rule would undermine this progress in eradicating health care discrimination against LGBTQ people in a broad array of health care programs and entities by inviting insurers and providers once again to discriminate against them, while also discouraging LGBTQ people from seeking health care in the first place.

It must be noted that an agency rule that amends an existing rule is subject to review under the Administrative Procedures Act (APA).[40] Proposed rules must examine the relevant information and articulate a satisfactory explanation for the NPRM, including a "reasoned analysis for the change."[41] The APA analysis of whether an agency action was arbitrary and capricious and therefore unlawful includes an examination of whether the agency's explanation runs counter to the evidence before it.[42] Here, as demonstrated above and in further detail below, HHS has failed utterly to provide a reasoned analysis for its proposed changes and the course it has charted, which runs directly counter to the evidence before the agency and to its statutory mandates.

[37] *Id.*

[38] Sharita Gruberg and Frank J. Bewkes, *The ACA's LGBTQ Nondiscrimination Regulations Prove Crucial*, Center for American Progress (Mar. 7, 2018), *available at* https://www.americanprogress.org/issues/lgbt/reports/2018/03/07/447414/acas-lgbtq-nondiscrimination-regulations-prove-crucial/.

[39] Out2Enroll, Summary of Findings: 2019 Marketplace Plan Compliance with Section 1557, *available at* https://out2enroll.org/out2enroll/wp-content/uploads/2018/11/Report-on-Trans-Exclusions-in-2019-Marketplace-Plans.pdf. This is consistent with summaries from 2017 and 2018, *available at* https://out2enroll.org/out2enroll/wp-content/uploads/2015/10/Report-on-Trans-Exclusions-in-2017-Marketplace-Plans.pdf https://out2enroll.org/out2enroll/wp-content/uploads/2017/11/Overview-of-Trans-Exclusions-in-2018-Marketplace-Plans-1.pdf.

[40] 5 U.S.C. § 706(2)(A); *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29 (1983).

[41] *Id.*

[42] *Id.*

II. The NPRM Fails to Provide a Reasoned Explanation for Repealing the Definition of "On the Basis of Sex."

The 2016 Final Rule explicitly prohibits discrimination on the basis of sex, including discrimination on the basis of pregnancy, false pregnancy, termination of pregnancy, or recovery therefrom, childbirth or related medical conditions, sex stereotyping and gender identity.[43] While Section 1557 remains the law, the NPRM attempts to significantly alter the ACA's sex discrimination protections by eliminating the 2016 Final Rule's definition of sex discrimination altogether, and does not attempt to provide a different definition.[44]

Instead, the NPRM simply announces that interpreting Title IX to prohibit gender identity discrimination was a "novel theory" when HHS promulgated the 2016 Final Rule.[45] In support of this inaccurate generalization, the NPRM points to non-binding language from a five-page district court decision issued in 2017 (a year after the 2016 Final Rule was issued), which noted the lack of controlling U.S. Supreme Court precedent recognizing gender identity discrimination as prohibited under Section 1557.[46] But the dicta referenced in the NPRM was not cited in that case.[47] Even if it were, simply because the U.S. Supreme Court has not explicitly confirmed a legal interpretation does not mean that interpretation is wrong. Equal weight should be given to the Supreme Court's lack of an explicit holding that discrimination based on gender identity or sexual orientation is *not* a prohibited form of discrimination under Section 1557.

More to the point, the NPRM asserts that the 2016 Final Rule exceeded its legal authority under Section 1557 by adopting an interpretation of civil rights law that was "incorrect."[48] But the Department fails to provide a coherent legal analysis that would explain *why* that interpretation was "incorrect." The 2016 Final Rule grounded its interpretation of "sex" on a detailed survey of the extensive existing case law, which has continued to expand with additional supporting case law since the 2016 Final Rule was issued.[49] The NPRM however, offers only two dismissive paragraphs, which fail to address or even acknowledge the substantial body of well-reasoned contrary authority. Instead, the Department relies almost entirely on one preliminary injunction issued by a lone district court,[50] which similarly ignored extensive, contrary legal authority, and which was not appealed and considered at the Circuit Court level.[51]

[43] 45 C.F.R. § 92.4.

[44] 84 FR 27857 ("Because of the likelihood that the Supreme Court will be addressing the issue in the near future, the Department declines, at this time, to propose its own, definition of "sex" for purposes of discrimination on the basis of sex in the regulation.").

[45] The Department refers to discrimination against LGBTQ people as a "novel theory" on nine separate occasions, always without addressing the contrary authority.

[46] 84 FR 27853 (*see, e.g., Baker v. Aetna*, 228 F. Supp. 3d 764, 768-69 ("noting no controlling U.S. Supreme Court legal precedent recognizing gender identity as prohibited discrimination under Section 1557.").

[47] *Baker v. Aetna Life Ins. Co.*, 228 F. Supp. 3d 764, 769 (N.D. Tex. 2017) (the decision simply states that "the Fifth Circuit has not extended *Hopkins'* Title VII reasoning to apply to any statute referenced in § 1557").

[48] 84 FR 27849.

[49] *See* 81 FR 31387-31392 (2016).

[50] *Franciscan Alliance, Inc., et al.* v. *Burwell, et al.,* 227 F. Supp. 3d 660 (N.D. Tex. 2016). Judge O'Connor, who recently gained notoriety for issuing a declaratory judgment striking down the entire Affordable Care Act, has issued nationwide injunctions effecting the rights of LGBTQ people on numerous occasions. In addition to the injunction in this case, Judge O'Connor issued a nationwide injunction in 2015 blocking federal rules that would have provided Family and Medical Leave Act (FMLA) to same-sex couples. *Texas v. United States*, 95 F. Supp. 3d 965 (N.D. Tex. 2015). Judge O'Connor also issued a nationwide preliminary

For example, beyond citing the *Franciscan Alliance* injunction, the NPRM fails to discuss the growing number of authorities that have held that the ACA's prohibition against sex discrimination encompasses protections for transgender people.[52] In addition, the NPRM cites Title VII case law to support its position but ignores the extensive, long-standing countervailing Title VII case law concluding that discrimination on the basis of gender identity *is* prohibited by Title VII.[53] This one-sided presentation is inaccurate at best and gives no indication that the Department has grappled with the existing case law as it is statutorily required to do, much less that its analysis is "reasonable."

There is even less excuse for this inaccurate legal presentation because HSS was on explicit notice about the case law, having been informed by advocacy organizations, including Lambda Legal, during their OMB meetings with the Department.[54] Equally concerning is the failure of the Department to address (and in some cases even to cite) the extensive countervailing appellate case law contradicting the Department's position that the 2016 Final Rule was "incorrect."[55] In addition to the Circuit Courts of Appeal that have held that employment discrimination against transgender people is a form of sex discrimination, three other

injunction enjoining the Title IX student guidance protecting transgender students. *Texas v. United States*, 201 F. Supp. 3d 810 (N.D. Tex. 2016), order clarified, No. 7:16-CV-00054-O, 2016 WL 7852331 (N.D. Tex. Oct. 18, 2016).

[51] 84 FR 27855.

[52] *See*, *e.g.*, *Tovar v. Essentia Health*, 342 F. Supp. 3d 947 (D. Minn. 2018) (D. Minn. Sept. 20, 2018) (holding that a health care plan that excluded health services related to gender dysphoria discriminated against transgender people in violation of the Health Care Rights Law (Section 1557 of the Affordable Care Act), which prohibits discrimination in health care); *Boyden v. Conlin,* 341 F. Supp. 3d 979 (W.D. Wis. 2018) (holding that a state employee health plan refusal to cover transition-related care constitutes sex discrimination in violation of Title VII, Section 1557 of the ACA, and the Equal Protection Clause); *Flack v. Wisconsin Department of Health Services*, 18-cv-309, 2018 WL 3574875 (W.D. Wis. Jul. 25, 2018) (holding that Medicaid exclusion targeting transgender people constitutes sex discrimination under Affordable Care Act and Equal Protection Clause); *Prescott v. Rady Children's Hospital-San Diego*, 265 F. Supp. 3d 1090 (S.D. Cal. Sept. 27, 2017) (holding that discrimination against transgender patients violates the Affordable Care Act); *Cruz v. Zucker*, 195 F. Supp. 3d 554 (S.D.N.Y. 2016) (holding that an exclusion for transition related health care violates the Affordable Care Act); *Rumble v. Fairview Health Servs.*, No. 14–cv–2037, 2015 WL 1197415 (D. Minn. Mar. 16, 2015) (holding that discrimination against hospital patient based on his transgender status constitutes sex discrimination under Section 1557 of the Affordable Care Act).

[53] Federal District Court decisions holding that Title VII's prohibition against sex discrimination encompasses gender identity discrimination include, inter alia: *Boyden v. Conlin*, 341 F. Supp. 3d 979 (W.D. Wis. 2018); *Equal Employment Opportunity Comm'n v. A & E Tire, Inc.*, 325 F. Supp. 3d 1131 (D. Colo. 2018): *Parker v. Strawser Construction*, 307 F. Supp. 3d 744 (S.D. Ohio Apr. 25, 2018); *E.E.O.C. v. Rent-a-Center East, Inc.*, 264 F. Supp. 3d 952 (C.D. Ill. Sept. 8, 2017); *Mickens v. Gen. Elec. Co.*, No. 3:16CV-00603-JHM, 2016 WL 7015665 (W.D. Ky. Nov. 29, 2016); *Roberts v. Clark Cty. Sch. Dist.*, 215 F. Supp. 3d 1005 (D. Nev. 2016); *Fabian v. Hosp. of Cent. Conn.*, 172 F. Supp. 3d 509 (D. Conn. Mar. 18, 2016); *Doe v. State of Arizona*, No. CV-15-02399-PHX-DGC, 2016 WL 1089743 (D. Ariz. Mar. 21, 2016); *United States v. Se. Oklahoma State Univ.*, No. CIV-15-324-C, 2015 WL 4606079 (W.D. Okla. July 10, 2015); *Finkle v. Howard County.*, 12 F. Supp. 3d 780 (D. Md. 2014); *Schroer v. Billington*, 577 F. Supp. 2d 293 (D.D.C. Sept. 19, 2008); *Lopez v. River Oaks Imaging & Diagnostic Group. Inc.*, 542 F. Supp. 2d 653 (S.D. Tex. 2008); *Mitchell v. Axcan Scandipharm, Inc.*, No. CIV.A. 05-243, 2006 WL 456173 (W.D. Pa. Feb. 17, 2006); *Tronetti v. TLC HealthNet Lakeshore Hosp.*, No. 03-CV-0375E (SC), 2003 WL 22757935 (W.D.N.Y. Sept. 26, 2003).

[54] *See* EO 12866 Meetings for RIN 0945-AA11, *available at* https://www.reginfo.gov/public/do/eom12866SearchResults?pubId=201810&rin=0945-AA11&viewRule=true.

[55] *See, e.g., EEOC v. R.G. & G.R. Harris Funeral Homes, Inc.*, 884 F. 3d 560 (6th Cir. 2018); *Glenn v. Brumby*, 663 F.3d 1312 (11th Cir.2011); *Barnes v. City of Cincinnati*, 401 F.3d 729 (6th Cir. March 25, 2005); *Smith v. City of Salem*, 378 F. 3d 566 (6th Cir. Aug. 5, 2004).

federal circuit courts have held that statutes similar to Title VII prohibiting discrimination based on sex also encompass gender identity discrimination.[56]

Moreover, in addition to the five federal circuit courts of appeals and the dozens of district courts that have held that sex discrimination bans cover gender identity discrimination, all of which the Department unreasonably failed to acknowledge, the Department also failed to acknowledge the multiple E.E.O.C. decisions similarly holding that sex discrimination bans cover gender identity discrimination.[57] In sum, despite this nearly overwhelming body of federal case law concluding that Title VII and other federal statutes forbid gender identity discrimination because it is a form of sex discrimination, the Department rests almost entirely upon the lone *Franciscan Alliance* injunction and one circuit court decision, the reasoning of which has been superseded.[58]

The NPRM also fails entirely to provide any justification for its removal of sex-stereotyping as a form of sex discrimination, which also was included in the 2016 Final Rule.[59] In addition to gender identity discrimination being a form of sex discrimination because it is based on sex-based considerations, much of the case law holding that discrimination against LGBTQ people is a form of sex discrimination is based upon Supreme Court case law interpreting "sex" discrimination to include sex-stereotyping. The Department's proposal simply to eliminate that protection is obviously unreasonable. The 2016 Final Rule extensively surveyed and examined existing law and correctly concluded that gender stereotyping is a prohibited form of discrimination based upon Supreme Court and other case law precedent.[60] The Proposed Rule unreasonably ignores this precedent without discussion. This improper approach likely will invite some health providers to believe, mistakenly, that they are at liberty to turn patients away because they do not conform with traditional sex stereotypes and others' perceptions about their sex.

[56] *Whitaker By Whitaker v. Kenosha Unified Sch. Dist. No. 1 Bd. of Educ.*, 858 F.3d 1034 (7th Cir. 2017) (holding that Title IX's prohibition against sex discrimination encompasses discrimination against transgender people), *cert. dismissed sub nom. Kenosha Unified Sch. Dist. No. 1 Bd. of Educ. v. Whitaker ex rel. Whitaker*, 138 S. Ct. 1260415 (2018); *Rosa v. Park West Bank & Trust Co.*, 214 F.3d 213 (1st Cir. June 8, 2000) (holding that the Equal Credit Opportunity Act's prohibition against sex discrimination encompasses discrimination based on gender identity); *Schwenk v. Hartford*, 204 F.3d 1187 (9th Cir. Feb. 29, 2000) (holding that the Gender Motivated Violence Act's prohibition against gender discrimination encompasses gender identity discrimination).

[57] *See Lusardi v. Dep't of the Army*, EEOC Appeal No. 0120133395, 2015 WL 1607756 (April 1, 2015); *Complainant v. Dep't of Veterans Affairs*, EEOC Appeal No. 0120133123, 2014 WL 1653484 (Apr. 16, 2014); *Jameson v. U.S. Postal Service*, EEOC Appeal No. 0120130992, 2013 WL 2368729 (May 21, 2013); *Macy v. Dep't of Justice*, EEOC Appeal No. 0120120821, 2012 WL 1435995 (April 20, 2012).

[58] The Department cites *Etsitty v. Utah Transit. Auth.*, 502 F.2d 1215 (10th Cir. Sept. 20, 2007) as a case supporting its view, but *Etsitty* relied upon a Seventh Circuit decision (*Ulane v. Eastern Airlines, Inc.*, 742 F.2d 1081 (7th Cir. 1984) which has been superseded by the reasoning of *Whitaker v. Kensohsa Unified Sch. Dist. No. 1 Bd. Of Educ.*, 858 F.3d 1034, 1047 (7th Cir. 2017) (clarifying that *Ulane*'s reasoning "cannot and does not foreclose Ash and other transgender students from bringing sex-discrimination claims based upon a theory of sex stereotyping as articulated four years later by the Supreme Court…"); *see also*, *Smith v. Avanti*, 249 F. Supp. 3d 1194, 1200 (D. Colo. 2017) (clarifying that a sex discrimination claim based on gender stereotyping brought by a transgender litigant pursuant to the Fair Housing Act is cognizable in the Tenth Circuit under *Price Waterhouse*).

[59] 45 C.F.R. § 92.4.

[60] 81 FR 31387 ("OCR also believes that its inclusion of gender identity is well grounded in the law and disagrees with those commenters who argued to the contrary. As the Supreme Court made clear in *Price Waterhouse v. Hopkins*, in prohibiting sex discrimination, Congress intended to strike at the entire spectrum of discrimination against men and women resulting from sex stereotypes."); *Price Waterhouse v. Hopkins*, 490 U.S. 228 (1989).

While an erasure of transgender people from Section 1557's protections would certainly send a message to health care providers that it is perfectly acceptable to discriminate against transgender patients, the NPRM is similarly dangerous (and incorrect) in proposing to send a message that it is acceptable to turn patients away because they do not conform with traditional gender stereotypes because they are lesbian, gay, or bisexual. As explained at length in Lambda Legal's prior comments,[61] lesbian, gay, bisexual and queer people already experience significant discrimination in health care. For example, seven percent of LGBQ people report having had a provider use abusive language when treating them and seven percent report experiencing unwanted physical contact from a provider, including fondling, sexual assault or rape.[62] In addition to applying sex-stereotyping analysis to the discrimination claims presented by transgender people, federal courts have also confirmed that sex-based considerations and sex-stereotyping protections also apply to sexual orientation discrimination, which similarly must be recognized as a form of unlawful sex discrimination.[63] The EEOC has also definitively interpreted Title VII to cover sexual orientation-related discrimination as sex discrimination prohibited both as an unavoidably sex-based consideration and as necessarily involving illicit sex stereotyping.[64]

Also, without discussion or analysis, the NPRM proposes to eliminate from the 2016 Final Rule the provision that prohibits a covered entity from discriminating against an individual based on those with whom they are known or believed to have a relationship or to be associated.[65] As with the inclusion of gender identity and sex-stereotype protections, this provision was grounded in an examination and understanding of the existing case law. For example, many courts have recognized an actionable race discrimination claim based on the race of an individual with whom the plaintiff is associated.[66] These cases

[61] *See* note 1, *supra*.

[62] Shabab Ahmed Mirza & Caitlin Rooney, *Discrimination Prevents LGBTQ People from Accessing Health Care*, CTR. FOR AM. PROGRESS (Jan. 18, 2018), *available at* https://www.americanprogress.org/issues/lgbt/news/2018/01/18/445130/discrimination-prevents-lgbtq-people-accessing-health-care/.

[63] *See Zarda v. Altitude Express, Inc.*, 883 F.3d 100, 123 (2d Cir. 2018), *cert. granted sub nom. Altitude Exp., Inc. v. Zarda*, 139 S. Ct. 1599 (2019); *Hively v. Ivy Tech Cmty. Coll. Of Indiana*, 853 F.3d 339 (7th Cir. 2017). Numerous district court decisions have also concluded that sexual orientation discrimination is forbidden sex discrimination. *See, e.g., Boutillier v. Hartford Pub. Schs.*, 2016 WL 6818348 (D. Conn. Nov. 17, 2016); *EEOC v. Scott Med. Health Ctr., P.C.*, 2016 WL 6569233 (W.D. Pa. Nov. 4, 2016); *Winstead v. Lafayette Cty., Bd. Of Cty. Comm'rs,* 197 F. Supp. 3d 1334 (N.D. Fla. 2016); *Videckis v. Pepperdine Univ.*, 150 F. Supp. 3d 1151 (C.D. Cal. 2015); *Isaacs v. Felder Servs., Inc.*, 143 F. Supp. 3d 1190 (M.D. Ala. 2015); *Hall v. BNSF Ry. Co.*, 2014 WL 4719007 (W.D. Wash. Sept. 22, 2014); *Terveer v. Billington*, 34 F. Supp. 3d 100 (D.D.C. 2014); *Koren v. Ohio Bell Tel Co.* 894 F. Supp. 2d 1032 (N.D. Ohio 2012); *Heller v. Columbia Edgewater Country Club*, 195 F. Supp. 2d 1212 (D. Or. 2002); *Centola v. Potter*, 183 F. Supp. 2d 403 (D. Mass. 2002).

[64] *See, e.g., Baldwin v. Foxx*, 2015 WL 4397641 (E.E.O.C. July 16, 2015); *Complainant v. Cordray*, 2014 WL 7398828 (E.E.O.C. Dec. 18, 2014); *Complainant v. Donahoe*, 2014 WL 6853897 (E.E.O.C. Nov. 18, 2014); *Complainant v. Sec'y, Dep't of Veterans Affairs*, 2014 WL 5511315 (E.E.O.C. Oct. 23, 2014); *Complainant v. Johnson*, 2014 WL 4407457 (E.E.O.C. Aug. 20, 2014); *Couch v. Dep't of Energy*, 2013 WL 4499198 (E.E.O.C. Aug. 13, 2013); *Brooker v. U.S. Postal Serv.*, 2011 WL 3555288 (E.E.O.C. May 20, 2013); *Castello v. U.S. Postal Serv.*, 2011 WL 3560150 (E.E.O.C. Dec. 20, 2011); *Veretto v. U.S. Postal Serv.*, 2011 WL 2663401 (E.E.O.C. July 11, 2011).

[65] 81 FR 31472 § 92.209: "A covered entity shall not exclude from participation in, deny the benefits of, or otherwise discriminate against an individual or entity in its health programs or activities on the basis of the race, color, national origin, sex, age, or disability of an individual with whom the individual or entity is known or believed to have a relationship or association."

[66] *E.g.*, *Floyd v. Amite County School Dist.*, 581 F.3d 244, 249 (5th Cir. 2009); *Holcomb v. Iona Coll.*, 521 F.3d 130, 138 (2d Cir. 2008); *McGinest v. GTE Service Corp.*, 360 F. 3d 1103, 1118 (9th Cir. 2004), cert. denied, 552 U.S. 1180 (2008); *Tetro v. Elliot Popham Pontiac, Oldsmobile, Buick & GMC Trucks Inc.*, 173 F.3d 988, 993–96 (6th Cir. 1999); *Parr v. Woodmen of the World Life Ins.*, 791 F.2d 888, 892 (11th Cir. 1986). A number of District Courts have reached similar conclusions when the discrimination was based on association

have recognized that protections apply to both discrimination based on an individual's protected status and discrimination based on a disfavored association involving protected status. This provision is consistent with existing law and should be retained along with the protections concerning gender identity, sex stereotypes and sexual orientation.

The NPRM also argues that that discrimination "because of sex" under Title IX does not include gender identity or sexual orientation discrimination based on a lack of congressional activity in this area. The NPRM asserts that Congress's inaction indicates a policy preference to preclude interpretations of federal law that would protect LGBTQ people from discrimination. This argument is logically specious. First, as former Justice Scalia clarified in a unanimous 1998 Supreme Court decision, although same-sex sexual harassment was not the issue Congress was concerned with when it enacted Title VII, "statutory prohibitions often go beyond the principal evil [they were enacted to combat] … and it is ultimately the provisions of our laws rather than the principal concerns of our legislators by which we are governed." Thus, the *Oncale* case concludes, Title VII's ban on sex discrimination encompasses same-sex sexual harassment.[67] Accordingly, Congressional inaction is irrelevant to whether anti-LGBTQ bias is covered by statutory protections. There are many reasons why legislation does not advance in Congress.[68] But as Justice Scalia explained, it is the words of the statutes that have been enacted, as they are logically understood, that govern absent congressional action to change those words.[69]

The NPRM notes that the Supreme Court will soon be deciding analogous questions in the context of Title VII to help justify the proposed elimination of protections for LGBTQ people, but the proposed action is premature at best.[70] The Supreme Court might well hold, consistently with the enormous and growing case

with persons of a different national origin or sex. *E.g.*, *Montes v. Cicero Pub. Sch. Dist. No. 99*, 141 F. Supp. 3d 885,900 (N.D. Ill. 2015) (national origin); *Morales v. NYS Dep't of Labor*, 865 F. Supp. 2d 220, 242-43 (N.D.N.Y. 2012), aff'd summarily, 530 F. App'x 13 (2d Cir. 2013) (race and national origin); *Kauffman v. Maxim Healthcare Servs., Inc.*, No. 04-CV-2869, 2006 U.S. Dist. LEXIS 47514, 2006 WL 1983196, at *4 (E.D.N.Y. July 13, 2006) (sex and race); *Reiter v. Ctr. Consol. Sch. Dist. No. 26-JT*, 618 F. Supp. 1458, 1460 (D. Colo. 1985) (race and national origin). Courts have also recognized claims of associational discrimination under Section 504 of the Rehabilitation Act. *E.g.*, *Loeffler v. Staten Island Univ. Hosp.*, 582 F.3d 268, 277 (2d Cir. 2009); *Falls v. Prince George's Hosp. Ctr.*, No. Civ. A 97–1545, 1999 U.S. Dist. LEXIS 22551, 1999 WL 33485550 at * 11 (D. Md. Mar. 16, 1999).

[67] *Oncale v. Sundowner Offshore Servs.*, 523 U.S. 79-90, 75 (1998). *See also* Brief of Lambda Legal Defense and Education Fund, Inc. as Amicus Curiae in Support of the Employees, *Bostock v. Clayton County, Georgia*, Supreme Court No. 17-1618, and *Altitude Express, Inc. v. Zarda*, Supreme Court Case No. 17-1623, at page 31 (July 3, 2019), *available at* https://www.supremecourt.gov/DocketPDF/17/17-1618/107176/20190703170952032_190704%20for%20E-Filing.pdf.

[68] *See Solid Waste Agency of N. Cook Ct. v. U.S. Army Corps of Eng'rs*, 531 U.S. 159, 170 (2001) ("A bill can be proposed for any number of reasons, and it can be rejected for just as many others."); *Schroer v. Billington*, 577 F. Supp. 2d 293, 308 (D.D.C. 2008) ("However…another reasonable interpretation of that legislative non-history is that some Members of Congress believe that the *Ulane* court and others have interpreted "sex" in an unduly narrow manner, that Title VII means what it says, and that the statute requires, not amendment, but only correct interpretation. As the Supreme Court has explained, [S]ubsequent legislative history is a hazardous basis for inferring the intent of an earlier Congress. It is a particularly dangerous ground on which to rest an interpretation of a prior statute when it concerns, as it does here, a proposal that does not become law. Congressional inaction lacks persuasive significance because several equally tenable inferences may be drawn from such inaction, including the inference that the existing legislation already incorporated the offered change. *Pension Ben. Guar. Corp. v. LTV Corp.*, 496 U.S. 633, 650, 110 S.Ct. 2668, 110 L.Ed.2d 579 (1990) (internal citations and quotation marks omitted)).

[69] *See further discussion in* Brief of Lambda Legal Defense and Education Fund, Inc., *Bostock v. Clayton County, Georgia*; *Altitude Express v. Zarda*, *supra*, note 67.

[70] 84 FR 27874.

law establishing that discrimination based on gender identity or sexual orientation both are prohibited forms of sex discrimination under Title VII.[71] Even if the Department is confident that the Supreme Court will agree with their contrary reasoning with regard to how sex should be understood under Title VII, many courts have disagreed, as discussed above. Therefore, unless and until the Supreme Court agrees with the Department's view, it clearly would be premature for the Department to act in a manner contrary to the overwhelming body of current case law. Accordingly, we urge the Department immediately to rescind this NPRM and to wait until the Supreme Court has issued a decision. If warranted at that time, the Department can open up another notice and comment period. But for now, if the Proposed Rule is permitted to remain extant, it will only invite harmful discrimination against LGBTQ people (and particularly transgender people), place health care providers in legal jeopardy by falsely signaling to them that it is fine to discriminate, and prompt litigation by those who are injured.

In one especially troubling section of the NPRM, the Department asserts that it considered adding gender identity and sexual orientation discrimination to a definition of sex discrimination or discrimination "on the basis of sex" under Title IX, but concluded doing so was inappropriate (again without any legal analysis) and that state and local entities are better equipped to address issues of gender "dysphoria" and sexual orientation.[72] The NPRM then obliquely refers to potential privacy interests involving "young children" and intimate settings. The notion that health care protections for LGBTQ people are at odds with "young children" in some way is deeply offensive and tellingly reveals the animosity the Department harbors towards LGBTQ people.

The NPRM follows this offensive reference with an equally offensive footnote about cases discussing restrooms and other facilities[73] that is untethered to existing law and outside the scope of Section 1557. The cases cited had nothing to do with what facilities should be available to a patient in a health care setting given the patient's gender identity.[74] In addition, the Department fails once more to acknowledge significant countervailing authority holding that there is no cognizable legal claim for having to share a restroom or

[71] Given the Department's reliance on the Supreme Court's current consideration of TVII's scope of coverage with respect to anti-LGBT discrimination, and the fact that extensive briefing on this issue has been filed very recently with the Supreme Court, the Department's failure to acknowledge the extent of the case law contrary to its interpretation is even more unreasonable, arbitrary and capricious.

[72] 84 FR 27874.

[73] 84 Fed. Reg. 27846, 27874 n.179 ("Policies of covered entities that result in unwelcome exposure to, or by, persons of the opposite biological sex where either party may be in a state of undress – such as in changing rooms, shared living quarters, showers, or other shared intimate facilities – may trigger hostile environment concerns under Title IX. *United States v. Virginia*, 518 U.S. 515, 550 n.19 (1996) ("Admitting women to [an all-male school] would undoubtedly require alterations necessary to afford members of each sex privacy from the other sex in living arrangements"); *Fortner v. Thomas*, 983 F.2d 1024, 1030 (11th Cir. 1993) ("[M]ost people have a special sense of privacy in their genitals, and involuntary exposure of them in the presence of people of the other sex may be especially demeaning or humiliating.").)

[74] The quote from *U.S. v. Virginia* simply noted that Virginia Military Institute would likely need to make accommodations to transition from an all-male school; *Fortner v. Thomas* involved the asserted rights of (presumably cisgender) male inmates not to have their naked bodies and intimate bodily functions intrusively and regularly exposed to (presumably cisgender) female correctional officers.

other single-sex facility with a transgender person.[75] For the Department to suggest otherwise is inconsistent with the rule of law and can hardly be considered a "reasonable" analysis.

We are a nation of laws. Discrimination against transgender people in health care is not only wrong, court after court has held that it is unlawful under the Affordable Care Act. This lawless Proposed Rule invites harm to patients, will spur litigation after that harm is inflicted, and will place health care providers in serious legal jeopardy by falsely signaling to them that it is fine to discriminate against LGBTQ people. We urge the Department immediately to rescind the NPRM.

III. The NPRM Impermissibly Seeks to Eliminate Sexual orientation and Gender Identity Protections in Unrelated Regulations.

The NPRM proposes to allow states and Marketplaces to be able to discriminate against LGBTQ people in all aspects of the Affordable Care Act (nondiscrimination, eligibility determinations, enrollment periods and more). The NPRM purports to allow insurance companies to employ discriminatory benefit designs that could inquire about an applicant's sexual orientation or gender identity and use that information for determining insurability. The NPRM seeks to amend a series of unrelated rules to conform with the NPRM. In other words, the NPRM seeks not only to erase existing protections for LGBTQ people within the 2016 Final Rule, which is consistent with Section 1557 as enacted by Congress, they also seek to eliminate existing protections for LGBTQ people in other regulations—nine of them to be exact.[76] But these rules were not promulgated by OCR and these amendments fall outside OCR's jurisdiction. Rather, they were all advanced by CMS and were promulgated pursuant to the authority granted by several different statutes,[77] including Section 1321(a) and other provisions of the ACA, the Social Security Act and other statutory authority, not Section 1557. As such, OCR lacks the authority to repeal those regulations. It is evident from reliable media reporting that the Department intends to eliminate legal protections for and essentially erase transgender people from federal law, not solely from Section 1557's protections.[78] HHS lacks the authority to do so.

[75] *E.g., Doe v. Boyertown Area Sch. Dist.*, 897 F.3d 518, 526-36 (3d Cir. 2018), cert. denied, 139 S. Ct. 2636 (2019); *Whitaker v. Kenosha Unified Sch. Dist. No. 1 Bd. Of Educ.*, 858 F.3d 1034, 1052-1053 (7th Cir. 2017); *Parents for Privacy v. Dallas Sch. Dist. No. 2*, 326 F. Supp. 3d 1075 (D. Or. 2018); *Adams v. Sch. Bd. of St. Johns Cnty.*, 318 F. Supp. 3d 1293 (M.D. Fla. 2018).

[76] Statutory authority for C.F.R. 155.120(c)(1)(ii), 45 CFR 155.220(j)(2)(requirements of ACA-created health insurance exclusions) provided under: 42 U.S.C. 18021-18024, 18031-18033, 18041-18042, 18051, 18054, 18071, and 18081-18083; statutory authority for 45 C.F.R. 147.104(e) (guaranteed availability of coverage): 42 U.S.C. 300gg through 300gg–63, 300gg–91, and 300gg–92, as amended.; Statutory authority for 45 C.F.R.156.200(e) (QHP issuer participation standards): 42 U.S.C. 18021-18024, 18031-18032, 18041-18042, 18044, 18054, 18061, 18063, 18071, 18082, 26 U.S.C. 36B, and 31 U.S.C. 9701); Statutory authority for 42 C.F.R. 460.98(b)(3), 42 C.F.R. 460.112(a) (Programs of All-Inclusive Care for the Elderly): 42 U.S.C. 1302, 1395, 1395eee(f), and 1396u–4(f), 42 U.S.C. 1302, 1395, 1395eee(f), and 1396u–4(f). Part 460; Statutory authority for 42 C.F.R. 438.3(d)(4): 42 U.S.C. 1302; 42 C.F.R. 438.206(c)(2): 42 U.S.C. 1302; Statutory authority for 42 C.F.R. 440.262 (Standard Medicaid state plans and Medicaid contract requirements): Sec. 1102 of the Social Security Act (42 U.S.C. 1302).

[77] The Affordable Care Act provided the statutory authority for CMS's promulgation of 45 C.F.R. 155.120(c)(1)(ii)(non-interference with Federal law and non-discrimination standards); 45 CFR 155.220(j)(2) (ability to States to permit agents and brokers to assist qualified individuals, qualified employers, or qualified employees enrolling in QHPs); and 45 CFR 156.200(e) (QHP issuer participation standards); 45 CFR 147.104(e) (guaranteed availability of coverage); 42 CFR 438.3(d)(4) (Standard contract requirements); 42 CFR 438.206(c)(2) (Availability of services); and 42 CFR 440.262 (Access and cultural considerations).

[78] Erica L. Green, Katie Benner and Robert Pear, *'Transgender' Could Be Defined Out of Existence Under the Trump Administration* (Oct. 21, 2018), *available at* https://www.nytimes.com/2018/10/21/us/politics/transgender-trump-administration-sex-definition.html

One especially pernicious consequence of proposing to amend these other regulations is that it would allow discrimination against LGBTQ people with regard to marketing or benefit design practices of health issuers under the ACA.[79] Over 133 million people in the U.S. live with at least one chronic condition[80] and over 61 million live with a disability. Before the ACA, people with chronic health conditions were often denied care or paid exorbitant prices for substandard care. The protections against discriminatory benefit design has been lifesaving for many LGBTQ people. The NPRM's proposals, by contrast, would make it more difficult for LGBTQ people to afford health care, contrary to Congress's intentions when enacting the ACA.

For example, the 2016 Final Rule's prohibition on discriminatory plan benefit designs helped LGBTQ people living with HIV get the medications they need. Due to systemic barriers to health care, LGBTQ people have a "higher prevalence and earlier onset of disabilities" and disproportionately experience chronic conditions,[81] including HIV.[82] HIV disproportionately affects gay, bisexual, and queer men of color and transgender women of color.[83] For example, more than 25 percent of Black and Brown transgender women are living with HIV,[84] and 60 percent (10,070) of Black or African American individuals who received an HIV diagnosis in 2017 were gay or bisexual men.[85] Further, 26 percent of gay men, 36 percent of bisexual women, 36 percent of lesbian women, 40 percent of bisexual men experience a form of disability.[86] Additionally, 28 percent of transgender, nonbinary, and gender nonconforming people experience a form of disability.[87] The Proposed Rule unreasonably and unjustifiably would disproportionately impact LGBTQ people, especially LGBTQ people of color living with disabilities and chronic conditions.

The NPRM's proposal to "update" other unrelated regulations to carve out protections for LGBTQ people is not consistent with, and in some cases is unrelated to, the Affordable Care Act and the 2016 Final Rule. The Department has failed provide any explanation or analysis concerning why it proposes to change these unrelated rules or the impact of such an action. There is extensive information to be considered because

("The department argued in its memo that key government agencies needed to adopt an explicit and uniform definition of gender as determined 'on a biological basis that is clear, grounded in science, objective and administrable.' The agency's proposed definition would define sex as either male or female, unchangeable, and determined by the genitals that a person is born with, according to a draft reviewed by The Times. Any dispute about one's sex would have to be clarified using genetic testing.").

[79] The NPRM proposes to update 45 C.F.R. 147.104(e) as a "conforming amendment" in order to eliminate protections for LGBTQ people.

[80] *The Growing Crisis of Chronic Disease in the United States,* Partnership to Fight Chronic Disease, (last visited Aug. 13, 2019), *available at* https://www.fightchronicdisease.org/sites/default/files/docs/GrowingCrisisofChronicDiseaseintheUSfactsheet_81009.pdf.

[81] Intersecting Injustice: A National Call to Action 63 (Lourdes Ashely Hunter, Ashe McGovern & Carla Sutherland eds., 2018), *available at* http://socialjusticesexuality.com/intersecting_injustice/.

[82] *Id.* at 48.

[83] *Id.* at 64-64.

[84] *Id.*

[85] *HIV and African Americans*, Ctrs. for Disease Control & Prevention, *available at* https://www.cdc.gov/hiv/group/racialethnic/africanamericans/index.html (last updated March 19, 2019).

[86] Disabled World, *LGBT and Disability: Information, News and Fact Sheets*, *available at* https://www.disabled-world.com/disability/sexuality/lgbt/ (last updated Feb. 7, 2019).

[87] S.E. James, et al., Nat'l Ctr. for Transgender Equality, *Report Of The 2015 U.S. Transgender Survey* 247 (2016), *available at* https://transequality.org/sites/default/files/docs/usts/USTS-Full-Report-Dec17.pdf.

some of these regulations have been in place for over a decade. Still, the Department fails even to purport to address the impact these regulations have had or the impact that changing these regulations would have.

Because these proposed changes are outside of the OCR's jurisdiction and are insufficiently related to Section 1557, and because the Department offers no legal, policy or cost-benefit analysis about them and their likely impacts on various CMS programs, it is not appropriate for these rulemakings to be combined.

IV. The NPRM's Inclusion of the Title IX Religious Exemption is Not Appropriate in the Health Care Context and Conflicts with the Statutory Text of the ACA.

The 2016 Final Rule provides that covered entities do not have to comply with Section 1557 if having to do so would violate religious exemption laws, but it does not include a categorical Title IX-based religious exemption. The Department rejected the request to include that exemption in the 2016 Final Rule because existing federal law already protects religious beliefs in an appropriate manner.

In addition, the Department explained that the Title IX exemption would be inappropriate in the health care setting because it is framed for educational institutions, which are vastly different from health care settings and the differences "warrant different approaches."[88] The Title IX exemption allows an *educational institution* controlled by a religious organization not to violate its own tenets.[89] Thus, an exemption such as allowing religious schools to only allow men to become ministers serves an important educational and religious function core to those institutions' purpose, which is very different from the purpose served by institutions and insurers that receive federal funding to provide health care to patients or plan members who are members of the general public.

The 2016 Final Rule explains that the education context also is different from the health care context because, for example, while students or parents select schools as matter of choice, individuals needing health care often have limited or no choice, especially patients who live in rural areas or where religious institutions have taken over hospitals that serve people of diverse faiths and no faith.[90] Religiously affiliated hospitals take up a large and growing portion of the health care market.[91] The 2016 Final Rule also clarifies that, unlike the dynamics in educational settings, a blanket religious exemption could result in denial or delay of care or the discouragement of care with serious "life threatening results." [92]

In addition, the inclusion of a new religious exemption, either explicitly or by reference, is contrary to the statutory language in Section 1557, which does not include any exceptions and which incorporated its

[88] 81 FR 31379-80

[89] 20 U.S. C. § 1681(a)(3); 34 C.F.R. § 106.12 (emphasis added).

[90] *Id.* at 31380

[91] *See* Michael Hiltzik, *UC's deal with Catholic Hospitals Threatens the Health of Women and LGBTQ Patients*, LA TIMES (Apr. 12, 2019), *available at* https://www.latimes.com/business/hiltzik/la-fi-hiltzik-uc-dignity-health-discrimination-20190412-story.html; Amy Littlefield, *Meet Another Religious Health System Restricting Reproductive Care* (Jan. 30, 2019) REWIRE.NEWS, *available at* https://rewire.news/article/2019/01/30/meet-another-religious-health-system-restricting-reproductive-health-care/.

[92] 81 FR 31380.

enforcement mechanisms without any such additional exemption.[93] Inserting the Title IX exemption by regulation, contrary to the statute's text, also would create an imbalance in enforcement because the other enforcement statutes (Title VI, the Age Discrimination Act, and Section 504 of the Rehabilitation Act) do not have such exemptions.

Moreover, as Lambda Legal has explained in our prior comments, inserting a new, blanket Title IX religious exemption to Section 1557's protection against sex discrimination likely would have far reaching and serious consequences for patients. It would invite new instances in which health care providers, including insurance companies, hospitals, doctors and nurses, wrongfully would allow their personal beliefs to determine patient care, contrary to medical standards and the current nondiscrimination rules. Also as we previously have explained, religious exemptions disproportionately harm LGBTQ people, who too often are refused health care because of their sexual orientation or gender identity. For example, 8 percent of LGBQ people were refused health care because of their sexual orientation.[94] Similarly, 29% of transgender people were denied care because of their gender identity.[95] When LGBTQ people are denied care, it becomes difficult (and impossible for many) to find another provider, especially for those who live in rural areas and for transgender people. According to a 2018 study, 18% of LGBTQ people said it would be impossible to find the same type of service in another hospital.[96] These rates are dramatically higher for people living outside a metropolitan area, where 41% of respondents stated that, if they were denied treatment, it would be very difficult if not impossible to find the same service at a different location.[97]

For example, in 2017 Lambda Legal filed a federal lawsuit against St. Joseph's Healthcare in Paterson, New Jersey, after the hospital refused to allow a surgeon to perform a medically-necessary hysterectomy for Jionni Conforti as part of his medically necessary treatment for gender dysphoria.[98] In addition to New Jersey's Law Against Discrimination, the case includes a claim under Section 1557 because the Affordable Care Act prohibits discrimination against transgender people as a form of sex discrimination, and publicly funded hospitals must not be permitted to interpose religious beliefs between doctor and patient.

The Proposed Rule's misguided plan to create a new religious exemption ignores Congress's text and is likely to encourage health care providers and institutions to believe religious beliefs are a legitimate basis to limit or deny health care in ways that constitute illegal discrimination. The proposed plan would both harm patients and place health care providers at risk of significant liability. It should be withdrawn.

[93] 42 U.S.C. 18116(a).

[94] Shabab Ahmed Mirza and Caitlin Rooney, *Discrimination Prevents LGBTQ People From Accessing Health Care*, Center for American Progress (Jan. 18, 2018), *available at* https://www.americanprogress.org/issues/lgbt/news/2018/01/18/445130/discrimination-prevents-lgbtq-people-accessing-health-care/.

[95] *Id.*

[96] *Id.*

[97] *Id.*

[98] *See* Complaint for Declaratory, Compensatory, and Injunctive Relief, *Conforti v. St. Josephs Healthcare System, Inc.*, Case No. 17-cv-0050 (D.N.J. January 5, 2017), *available at* https://www.lambdalegal.org/sites/default/files/conforti_nj_20170105_complaint.pdf.

V. The NPRM Improperly Limits the Scope of Application of Section 1557.

It is unclear whether the NPRM seeks to narrow the scope Section 1557 to only programs or activities administered by the Department under Title I, but to the extent that the Department so intends, such an interpretation would be inconsistent with the Affordable Care Act's statutory provisions. Such a narrowing of scope would improperly carve out other HHS programs administered by other agencies.[99] Such a dramatic limiting of scope would be contrary to the statutory requirements of Section 1557, which applies broadly to "any health program or activity, any part of which is receiving federal financial assistance," any program or activity that is administered by an executive agency," and "any entity established under this title."[100] A narrowing of scope also cannot be squared with the court decisions that have found that state Medicaid plans, and other health insurance plans, violate Section 1557's sex discrimination when they exclude coverage of medical procedures for transgender persons.[101] Accordingly the current regulatory provisions regarding Section 1557's applicability to health insurance, and to HHS-administered programs outside the scope of ACA Title I, should be left in place. It is evident that the statutory text of Section 1557 extends to health programs or activities receiving federal financial assistance, including programs not funded directly by HHS, but which are administered by and executive agency.

The NPRM also seeks to improperly limit the scope of Section 1557 with regard to health insurance companies. The NPRM achieves this by redefining "health program or activity" to import a requirement that the health program or activity at issue be "principally engaged in the business of providing health care."[102] The Department's novel argument imports this interpretation from the Civil Rights Restoration Act ("CRRA") in order to allow insurance companies to discriminate without fear of liability under Section 1557 because they are not "principally engaged in the business of providing health care."[103] This legally incorrect.

Congress enacted Section 1557 more than two decades after the CRRA was enacted, and it did so with the clear intent to impose nondiscrimination requirements broadly to any "health programs and activities" receiving federal financial assistance.[104] If Congress intended to limit the scope of liability, it could have easily done so. However, it chose not to include this provision. Furthermore, the CRRA did not address the question of whether health insurance is a "health program or activity."

The proposed narrowing of the scope of Section 1557's protections would allow insurance companies that have to comply with Section 1557 for the plans they sell on an exchange to offer a discriminatory plan in other parts of the insurer's business, such as the sale of non-ACA products or when serving as a third party

[99] *E.g.*, programs administered by the Center for Disease Control and Prevention, the Indian Health Service, and the Substance Abuse and Mental Health Services Administration.

[100] 42 U.S.C. § 18116(a).

[101] *E.g.*, *Flack v. Wisconsin Department of Health Services*, 18-cv-309, 2018 WL 3574875 (W.D. Wis. Jul. 25, 2018) (holding that Medicaid exclusion targeting transgender people constitutes sex discrimination under Affordable Care Act and Equal Protection Clause).

[102] 84 92.3(a)(1), (b)-(c) ("[f]or purposes of this part, and entity principally or otherwise engaged in the business of providing health insurance shall not, by virtue of such provision, be considered to be principally engaged in the business of providing health care.")

[103] 84 FR 27850.

[104] 42 U.S.C. § 18116(a).

beneficiary for group health care plans. Non-ACA-compliant plans often discriminate against patients in various ways prohibited by Section 1557, and giving insurers license to discriminate in this way would defeat the text, context and purpose of Section 1557. The administration has sought to expand the availability of plans that lack consumer protections and the comprehensive design necessary to meet the needs of LGBQ people.[105] Many of these plans discriminate against transgender people and women by simply denying transition-related and reproductive care.[106] This aspect of the Proposed Rule thus is inconsistent with the ACA's text, congressional intent, and the statutory duty of HHS to act in furtherance of the health and well-being of all Americans.

VI. The ACA's Statutory Text Evinces a Clear Intent to Create a Single Legal Standard and Burden of Proof for Any Basis of Prohibited Discrimination Incorporated into Section 1557.

The NPRM repeals the enforcement mechanisms in the 2016 Final Rule and replaces them by limiting the enforcement mechanisms for each protected classification to those of the statute from which it was incorporated, namely those from Title VI, Title IX, the Age Discrimination Act, or Section 504 of the Rehabilitation Act respectively.[107] However, based on Congress's express mandate, Section 92.301 of the 2016 Final Rule clarified that *all* the mechanisms provided for by these statutes apply for purposes of Section 1557 enforcement. For one, Section 1557 creates a private right of action to address claims of discrimination on the basis of race, color, national origin, sex, age, or disability.[108] The ACA's statutory text makes evident that Congress did not intend to import multiple piecemeal legal standards from the multiple statutory contexts into a doctrinal crazy quilt, as the HHS now proposes in the NPRM.

Instead, Congress clearly intended to create a "singular standard, regardless of a plaintiff's protected class status."[109] First, "there is no indication that Congress limited the enforcement mechanisms to apply only to its own protected classes."[110] To the contrary, Congress specified that "[t]he enforcement mechanisms provided for and available under such title VI, title IX, section 504, ***or*** such Age Discrimination Act shall apply for purposes of violations of this subsection."[111] The use of the disjunctive "or" clarifies that the enforcement mechanisms applicable under any of the incorporated statutes are available to every claim of

[105] Jennifer Kates et al, *Health and Access to Care and Coverage for Lesbian, Gay, Bisexual, and Transgender (LGBT) Individuals in the U.S.* (May 3, 2018) Kaiser Family Foundation, available at https://www.kff.org/report-section/health-and-access-to-care-and-coverage-lgbt-individuals-in-the-us-impact-of-changes-in-the-legal-and-policy-landscape-on-coverage-and-access-to-care/.

[106] *See* Karen Pollitz et al., *Understanding Short-Term Limited Duration Health Insurance, Kaiser Family Foundation* (Apr. 23, 2018), *available at* https://www.kff.org/health-reform/issue-brief/understanding-short-term-limited-duration-health-insurance/.

[107] *See* Section 27850 and 27891.

[108] *See Callum v. CVS Health Crop.*, 137 F. Supp. 3d 817, 848 (D.S.C. 2015); *see also S.E. Pennsylvania Transp. Auth. V. Gilead Scis.*, Inc., 102 F. Supp. 3d 688, 698 (E.D. Pa. 2015); *Rumble v. Fairview Health Servs.*, No. 14-CV-2037, 2015 WL 1197415, at *7 n.3 (D. Minn. Mar. 16, 2015); *East v. Blue Cross & Blue Shield of Louisiana,* No. 3:14-CV-00115-BAJ, 2014 WL 8332136, at 2 (M.D. La. Feb. 24, 2014).

[109] See *Rumble*, 2015 WL 1197415, at *10.

[110] *See* Sarah G. Steege, *Finding A Cure in the Courts: A Private Right of Action for Disparate Impact in Health Care*, 16 Mich. J. Race & L. 439, 462 (2011).

[111] 42 U.S.C. § 18116(a) (emphasis added).

discrimination under Section 1557.[112] This is so regardless of the particular type of discrimination triggering the claim. Applying standard rules of statutory construction, all the enforcement mechanisms provided for and available under each of the generally incorporated statutes in Section 1557 are available to every claim of discrimination under Section 1557.

The creation of a single legal standard and burden of proof is also manifest in Congress's interest in avoiding absurd results. Allowing different mechanisms and standards depending on whether the plaintiff's claim is based on race, sex, age or disability discrimination would lead to absurd inconsistencies and would provide "no guidance about what standard to apply for a Section 1557 plaintiff bringing an intersectional discrimination claim."[113] It would be absurd to interpret Section 1557 to not allow people to file complaints of multiple forms of discrimination in one place. Section 1557 recognizes the reality that discrimination "may occur not solely because of the person's race or not solely because of the person's sexual orientation or gender identity, [disability status, or national origin], but because of the combination."[114] Thus, the law aimed to make it easier for people to file complaints of intersectional discrimination. If adopted as a final rule, the proposed changes would only make it harder for people to file reasonably efficient complaints and seek redress in a sensible manner for the discrimination they experience, as Congress has intended.

In addition, we urge the Department to clarify that it has not invented a notice and deliberate indifference standard for claims brought under Section 1557 for purposes of institutional liability. Doing so is appropriate given the text of the statute, and will encourage health care institutions to create grievance procedures and to take steps to discover, address and eliminate discrimination. Requiring health care consumers to identify and notify the official within a health care institution with the requisite authority to address the alleged discrimination would place an unreasonable burden upon them, contrary to the special vulnerability of patients and the goals of Section 1557. Courts have rejected the imposition of an actual notice and deliberate indifference standard under Title IX in cases involving retaliation claims, equal opportunity in athletic programs, employment discrimination and in the athletic programs context.[115] Given Congress's purposes when enacting the ACA, the same result is proper here.

[112] "In its elementary sense, the word 'or,' as used in a statute, is a disjunctive particle indicating that the various members of the sentence are to be taken separately." 73 Am. Jur. 2d Statutes § 147; *see also United States v. Woods*, 134 S. Ct. 557, 567 (2013) ("ordinary use [of the word 'or'] is almost always disjunctive"); *In re Espy*, 80 F.3d 501, 505 (D.C. Cir. 1996) (per curiam) ("Canons of construction ordinarily suggest that terms connected by a disjunctive be given separate meanings and a statute written in the disjunctive is generally construed as setting out separate and distinct alternatives.") (internal citations and quotations omitted.

[113] *Rumble*, 2015 WL 1197415, at *11. "No rule of construction necessitates our acceptance of an interpretation resulting in patently absurd consequences." *United States v. Brown*, 333 U.S. 18, 27 (1948)."

[114] Brief for National LGBTQ Task Force as Amici Curiae Supporting Respondents, *Masterpiece Cakeshop v. Col. C.R. Comm'n*, 137 S.Ct. 2290 (2017), http://www.thetaskforce.org/wp-content/uploads/2017/10/16-111-bsac-LGBTQ-Task-Force.pdf.

[115] See *Jackson v. Birmingham Bd. Of Educ.*, 544 U.S. 167 (2005) (Supreme Court holding that no pre-litigation notice required in the retaliation context); *Pederson v. Louisiana State Univ.*, 213 F.3d 858 (5th Cir. 2000) (athletic programs); *Roberts v. Colo. State Bd. Of Agric.*, 998 F.2d 824, 832 (10th Cir. 1993) (courts have expressly held that Title VII, 42 U.S.C. § 2000e et seq., respondent superior standard is "the most appropriate analogue when defining Title IX's substantive standards" in the employment context).

VII. Notices of Nondiscrimination

Notices informing individuals that an entity cannot discriminate and what to do if they face discrimination, including how to file a complaint with OCR, are essential. The 2016 Final Rule requires covered entities with at least 15 employees to adopt a grievance procedure and designate at least one employee to coordinate its Section 1557 responsibilities.[116] The 2016 Final Rule also requires covered entities to provide notice of nondiscrimination policies in significant communications, in physical locations where the entity interacts with the public, and on the home page of their website. The notice of nondiscrimination must include information about the characteristics protected from discrimination under Section 1557, the availability of and how to access auxiliary aids and services, the availability of and how to access language assistance services, contact information for the designated employee coordinating the entity's Section 1557 responsibilities, the entity's grievance procedures, and complaint procedures for OCR. The Proposed Rule improperly attempts to eliminate these provisions entirely.

The NPRM also proposes to make it more difficult for people with Limited English Proficiency (LEP) to understand their health care rights under federal law by eliminating the requirements outlined in the final rule. As explained already, LGBTQ people experience significant health care disparities. These disparities are multiply compounded when a person is LEP, LGBTQ and a refugee or immigrant. Because of the persecution many LGBTQ people experience in their country of origin, many LGBTQ refugees and immigrants have had limited educational opportunities and often have limited English language facility, which in turn means additional, unwarranted barriers to appropriate health care.[117]

Because many individuals do not know about their rights, how to request language services, or how to file a complaint if they face discrimination, the 2016 Final Rule formulated standards to effectuate Congress's nondiscrimination intentions. By eliminating tagline requirements and notice standards, the Proposed Rule instead will undermine access to health care, health insurance, and legal redress for LGBTQ people and other vulnerable communities, contrary to the statute and without the analysis and evidentiary basis to support the proposed changes.

Moreover, without the regulatory requirements established in the 2016 Final Rule, patients are likely to be placed at risk for serious consequences with regard to privacy and confidentiality where access to language services in a confidential setting are essential in order for information about the patient's health status to be exchanged in a medically competent manner. The NPRM's proposed changes would make the requirement's scope significantly less clear and would cause confusion, discrimination and unjustified health consequences.

[116] MaryBeth Musumeci et al., *HHS's Proposed Changes to Non-discrimination Regulations under ACA Section 1557*, Kaiser Family Foundation (Jul. 1, 2019), *available at* https://www.kff.org/disparities-policy/issue-brief/hhss-proposed-changes-to-non-discrimination-regulations-under-aca-section-1557/.

[117] Sharita Gruberg et al, *Serving LGBTQ Immigrants and Building Welcoming Communities* (Jan. 24, 2018), Center for American Progress, *available at* https://www.americanprogress.org/issues/lgbt/reports/2018/01/24/445308/serving-lgbtq-immigrants-building-welcoming-communities/.

VIII. Private Right of Action

The NPRM asserts that the Department will "no longer assert that a private right of action exists for parties to sue covered entities for any and all alleged violations of the proposed rule … leaving the matter as primarily one for the courts to decide."[118] But this interpretation flouts the will of Congress. When Congress enacted the ACA, including Section 1557, it knowingly and intentionally incorporated the four statutes, each of which provides for both a private right of action as well as compensatory damages. In addition, Congress enacted Section 1557 "against the backdrop of" Supreme Court precedents and regulations making clear that each of the statutes incorporated into Section 1557 provided for a private right of action and compensatory damages.[119] Accordingly, it is beyond clear that Congress intended that there be a private right of action for Section 1557 claims.

IX. Risk Impact Assessment

OCR estimates that 60% (3% of the overall increase) of the originally anticipated increase of 5% of long-term caseload would have been attributable to discrimination claims based on gender identity and sex stereotyping.[120] OCR further estimates that the removal of gender identity and sex stereotyping protection will result in a certain number of covered entities currently at risk of incurring grievance–related costs will no longer face such costs. This analysis is completely unreasonable. First, there is no clarity with regard to the actual number of complaints that have been filed and this cited information thus is highly speculative. Second, because the erasure of gender identity and sex stereotyping protections from the rule is inconsistent with the vast consensus of case law precedent, it will significantly compound the number of grievances and lawsuits as the rule begins to encourage more discrimination and harassment, causing more and more individuals to bring grievances.[121] Lastly, the NPRM fails to account for the human costs associated with LGBTQ people who will be inappropriately denied, discouraged and discriminated against in some cases, with serious health care consequences.

[118] 84 FR 27883-84.

[119] See *McNely v. Ocala Star-Banner Corp.*, 99 F.3d 1068, 1076 (11th Cir. 1996). See *Callum*, 137 F. Supp. 3d at 847 ("Congress intended to create a private right and private remedy for violations of Section 1557 by expressly incorporating the enforcement provisions of the four federal civil rights statutes."; *SEPTA*, 102 F. Supp. 3d at 698; *Rumble*, 2015 WL 1197415, at *7 n.3; see also *Barnes v. Gorman*, 536 U.S. 181, 185 (2002) (finding that although neither Section 202 of the ADA nor Section 504 of the Rehabilitation Act explicitly provides for a private cause of action, they implicitly create one due to their cross-references to each other ant to Title VI of the Civil Rights Act of 1964).

[120] 84 FR 27883.

[121] *See*, e.g., *Tovar v. Essentia Health*, cv-16-100-DWF-LIB (D. Minn. Sept. 20, 2018) (holding that a health care plan that excluded health services related to gender dysphoria discriminated against transgender people in violation of the Health Care Rights Law (Section 1557 of the Affordable Care Act), which prohibits discrimination in health care); *Boyden v. Conlin*, No. 17-cv-264-WMC, 2018 (W.D. Wis. September 18, 2018) (holding that a state employee health plan refusal to cover transition-related care constitutes sex discrimination in violation of Title VII, Section 1557 of the ACA, and the Equal Protection Clause); *Flack v. Wisconsin Department of Health Services*, 18-cv-309, 2018 WL 3574875 (W.D. Wis. Jul. 25, 2018) (holding that Medicaid exclusion targeting transgender people constitutes sex discrimination under Affordable Care Act and Equal Protection Clause); *Prescott v. Rady Children's Hospital-San Diego*, 265 F. Supp. 3d 1090 (S.D. Cal. Sept. 27, 2017) (holding that discrimination against transgender patients violates the Affordable Care Act); *Rumble v. Fairview Health Servs.*, No. 14–cv–2037, 2015 WL 1197415 (D. Minn. Mar. 16, 2015) (holding that discrimination against hospital patient based on his transgender status constitutes sex discrimination under Section 1557 of the Affordable Care Act).

X. Conclusion

Although the NPRM cannot change the law, as interpreted by multiple courts already, it improperly signals to those who wish to discriminate that they are free to do so, promising direct harm to LGBTQ people, and especially transgender people. This lawless Proposed Rule will only spur both mistreatment of patients and resulting lawsuits, placing health care providers in legal jeopardy by falsely signaling to them that it is perfectly fine to discriminate contrary to established federal law. Similarly, all the Proposed Rule will do concerning insurers is to create confusion, foster discrimination against LGBTQ patients, and pointlessly expose insurers to costly lawsuits.

And yet one more serious impact the Proposed Rule will have if left extant for any substantial period – even if not finalized – is to discourage people from seeking the health care they need. Nearly half of the U.S. population already avoids medical appointments when they need them due to cost,[122] and many already avoid care because of fear of discrimination.[123] The combination of these factors, of course, falls hardest on those already marginalized, including people of color, people living with low incomes, and LGBTQ people.

For all the reasons stated above, HHS and CMS should not finalize the NPRM and should instead redirect their efforts to serving the explicit mission of the nation's health care agency by advancing health care access and equity for all. We urge the Department immediately to withdraw the NPRM.

Thank you for the opportunity to submit comments on the Proposed Rule. Please do not hesitate to contact Sasha Buchert at sbuchert@lambdalegal.org if further information would be of assistance.

Most respectfully,

LAMBDA LEGAL DEFENSE AND EDUCATION FUND, INC.

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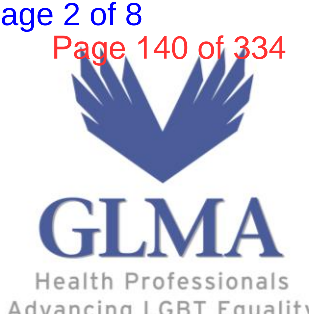
[122] Bruce Jaspen, *Poll: 44% of Americans Skip Doctor Visits Because of Cost*, Forbes (Mar. 26, 2018), *available at* https://www.forbes.com/sites/brucejapsen/2018/03/26/poll-44-of-americans-skip-doctor-visits-due-to-cost/#5feab6ff6f57.

[123] *See, e.g.,* S.E. James, et al., Nat'l Ctr. for Transgender Equality, Report Of The 2015 U.S. Transgender Survey 96-98 (2016), *available at* https://transequality.org/sites/default/files/docs/usts/USTS-Full-Report-Dec17.pdf.

EXHIBIT 6

Comments by GLMA: Health Professionals Advancing LGBTQ Equality



August 13, 2019

Secretary Alex Azar
Department of Health and Human Services
Hubert H. Humphrey Building, Room 509F
200 Independence Avenue SW
Washington, DC 20201

Re: Section 1557 NPRM, RIN 0945-AA11, "Nondiscrimination in Health and Health Education Programs or Activities"

Dear Secretary Azar,

GLMA: Health Professionals Advancing LGBTQ Equality (GLMA) writes today in opposition to Section 1557 NPRM, RIN 0945-AA11, "Nondiscrimination in Health and Health Education Programs or Activities" and strongly urges withdrawal of the proposed rule.

GLMA—previously known as the Gay & Lesbian Medical Association—is a national association of lesbian, gay, bisexual, transgender and queer (LGBTQ) healthcare professionals and their allies whose mission is to ensure health equity for LGBTQ and all sexual and gender minority (SGM) individuals and equality for LGBTQ healthcare professionals. Founded in 1981, GLMA employs the expertise of our medical and health professionals in education, policy and advocacy, patient education and referrals and the promotion of research to improve the health and well-being of LGBTQ people and their families.

Since our founding, GLMA has believed in the critical importance of eliminating health disparities and ensuring that all people, including LGBTQ individuals and their families, do not face discriminatory barriers when seeking quality, affordable healthcare and coverage. We therefore take this opportunity to strongly oppose the changes to the Section 1557 regulation outlined in the proposed rule, in particular the provisions that would eliminate nondiscrimination protections based on gender identity or sex stereotyping in healthcare access and coverage.

As an organization of health professionals who often serve and care for patients from the LGBTQ community, we know that discrimination against LGBTQ individuals in healthcare and coverage remains a pervasive problem. Despite recent advances in legal protections for LGBTQ individuals, LGBTQ people living across the United States continue to regularly encounter discrimination on the basis of sexual orientation and gender identity when seeking health insurance coverage and healthcare. Numerous surveys, studies, and reports have documented the widespread extent of the discrimination experienced by LGBTQ individuals and their families in the health system. *When Health Care Isn't Caring*, a nationwide survey assessing the healthcare experiences of LGBTQ people and people living with HIV, found that the majority of the almost

1100 H St. NW, Suite 540 | Washington, DC 20005 | 202-600-8037 | Fax: 202-478-1500 | info@glma.org | www.glma.org

5,000 respondents reported experiencing at least one of the following types of discrimination when accessing healthcare:[1]

- Health care providers refusing to touch them or using excessive precautions
- Health care providers using harsh or abusive language
- Health care providers being physically rough or abusive
- Health care providers blaming them for their health status

The US Transgender Survey, the largest survey detailing the experiences of transgender people in the United States, further documents the pervasive discrimination faced by transgender and gender nonconforming individuals in healthcare settings. According to the study, "[o]ne-third (33%) of those who saw a health care provider had at least one negative experience related to being transgender, such as being verbally harassed or refused treatment because of their gender identity."[2]

These encounters with discrimination have serious negative consequences for the health and wellbeing of LGBTQ individuals. They also exacerbate the significant health disparities that affect the LGBTQ population at large. Sources such as the National Academy of Medicine[3] (formerly the Institute of Medicine), the Centers for Disease Control and Prevention, and Healthy People 2020 report that discrimination threatens the health of the LGBTQ population in ways that include:[4]

- Increasing risk factors for poor physical and mental health such as smoking and other substance use;[5]
- Driving high rates of HIV among transgender women and gay and bisexual men;[6]
- Barring access to appropriate health insurance coverage, especially for transgender people;[7]
- Obstructing access to preventive screenings;[8] and
- Putting LGBTQ people at risk of poor treatment from health care providers who are unprepared to meet the needs of LGBTQ patients.[9]

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[1] Lambda Legal, *When Health Care Isn't Caring: Lambda Legal's Survey on Discrimination Against LGBT People and People Living with HIV* (2010), *available at* http://www.lambdalegal.org/publications/when-health-care-isnt-caring (hereinafter "When Health Care Isn't Caring").

[2] Nat'l Ctr. for Transgender Equality, *The Report of the 2015 US Transgender Survey* (2016), *available at* http://www.transequality.org/sites/default/files/docs/usts/USTS%20Full%20Report%20-%20FINAL%201.6.17.pdf.

[3] *See, e.g.,* Institute of Medicine, *The Health of Lesbian, Gay, Bisexual, and Transgender People: Building a Foundation for Better Understanding* (2011), *available at* http://www.iom.edu/Reports/2011/The-Health-of-Lesbian-Gay-Bisexual-and-Transgender-People.aspx.

[4] U.S. Dep't of Health and Human Services, *Healthy People 2020: LGBT Health Topic Area* (2015), *available at* http://www.healthypeople.gov/2020/topics-objectives/topic/lesbian-gay-bisexual-and-transgender-health.

[5] Ctr. for Disease Control and Prevention, "Lesbian, Gay, Bisexual, and Transgender Health" (July 2014), *available at* http://www.cdc.gov/lgbthealth/about.htm.

[6] Office of Nat'l AIDS Policy, "National HIV/AIDS Strategy," (2015).

[7] Laura E. Durso, Kellan E. Baker, and Andrew Cray, *LGBT Communities and the Affordable Care Act: Findings from a National Survey* (2013), *available at* http://www.americanprogress.org/wp-content/uploads/2013/10/LGBT-ACAsurvey-brief1.pdf.

[8] Fenway Institute, *Promoting Cervical Cancer Screening Among Lesbians and Bisexual Women* (2013), *available at* http://www.lgbthealtheducation.org/wp-content/uploads/Cahill_PolicyFocus_cervicalcancer_web.pdf.

GLMA members have reported witnessing numerous instances of discrimination in healthcare against LGBTQ people, and in particular transgender individuals, including members who have recently shared:

- "I see patients nearly every day who have been treated poorly by providers with moral and religious objections… Patients with HIV who have been told they somehow deserved this for not adhering to God's law. Patients who are transgender who have been told that 'we don't treat your kind here'. The psychological and physical damage is pervasive."

- "[Some providers in my clinic] do not wish to have contact with transgender patients, mumbling religious incompatibilities when asked why. These people have made our transgender patients feel very uncomfortable and unwelcome at times, making them more potentially more hesitant to use the health services they may need."

- "The impact on my patients who were directly denied care was both psychological and physical. With regard to their mental wellbeing they clearly felt marginalized and disrespected. With regard to their physical wellbeing, they experienced delay in care, and in some cases disruption of their routine medication dosing or diagnostic assessment."

In this context, the Section 1557 nondiscrimination implementing rule adopted in 2016 has played a key role in addressing health disparities faced by vulnerable Americans—including transgender individuals—by protecting these communities from discriminatory practices that impede their access to care and coverage and ensuring access to medically necessary care. The national consensus about the importance of these protections is reflected in the number of leading medical and mental health associations, including the American Medical Association[10] and the American Psychological Association,[11] among many others, who have spoken out in support of maintaining the Section 1557 rule. In fact, in May 2019, GLMA and the American Psychiatric Association helped organize more than 30 associations who joined a letter to you in support of the 1557 nondiscrimination regulation.[12] (See also Attachment A.)

Conclusion

Reducing discrimination and other barriers to accessing health and human services and the accompanying health disparities faced by marginalized communities is core to HHS' mission to "enhance and protect the health and well-being of all Americans." The 1557 nondiscrimination regulation fosters this commitment and ensures that LGBTQ people have access to healthcare and coverage, including equal access to medically necessary care. GLMA supports Section

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[9] "When Health Care Isn't Caring," *supra* note 2.
[10] Am. Medical Assn., *Letter to Director Roger Severino* (Sept. 1, 2017), https://searchlf.ama-assn.org/undefined/documentDownload?uri=%2Funstructured%2Fbinary%2Fletter%2FLETTERS%2F2017-09-01_Letter-to-Severino-re-Section-1557-Identity-Protection.pdf.
[11] Am. Psychological Assn., *Comment on Department of Health and Human Services Request for Information, Docket No. CMS-9928-NC* (July 12, 2017), https://www.regulations.gov/document?D=CMS-2017-0078-2528.
[12] GLMA, *Letter to Sec'y Azar* (May 23, 2019), http://glma.org/index.cfm?fuseaction=document.viewdocument&ID=CEB9FEE4B8DD8B7F4F7575376BD476C3D4D67E05EEFE579F64358A4E67735C28C0731320B03D2F5E1022F1C15602FBEA

1557's nondiscrimination provisions as an essential tool to ensuring the health and well-being of lesbian, gay, bisexual, transgender and queer people in this country. Therefore, GLMA strongly urges HHS to refrain from any action that would eliminate the 1557 nondiscrimination rule and recommends expeditious withdrawal of the proposed rule.

Sincerely,

Hector Vargas, JD
Executive Director

ATTACHMENT A

May 24, 2019

Sent Via Email and Fax

The Honorable Alex Azar
Department of Health and Human Services
200 Independence Ave. SW
Washington, DC 20201

Dear Secretary Azar,

The undersigned health professional associations representing providers of all disciplines and patients across the country are deeply concerned with the Department's announcement today of plans to weaken nondiscrimination protections for lesbian, gay, bisexual, transgender, and questioning (LGBTQ) individuals under Section 1557 of the Affordable Care Act. We oppose these efforts and express our strong support for providing the strongest nondiscrimination protections available for LGBTQ people.

Section 1557's nondiscrimination protections assist some of the populations that have been most vulnerable to discrimination, including LGBTQ people, and help provide those populations equal access to healthcare and health coverage.[1] Federal courts, including in the context of Section 1557, have recognized repeatedly over many years that sex discrimination includes discrimination based on gender identity. The subsequent regulations promulgated under Section 1557 further clarify that discrimination based on gender identity and sex stereotyping is prohibited in healthcare coverage and access.

Despite advances in acceptance for LGBTQ people, stigma and discrimination continue to be the greatest problems facing sexual and gender minorities. In fact, many LGBTQ people develop an internalized shame that can contribute to problems with self-acceptance, anxiety, depression, difficulty forming intimate relationships, and being open about their sexual orientation or gender identity. The literature on the "minority stress model" highlights the impact of social prejudice, isolation and invisibility as the primary factors leading to an increased health burden and greater risk of mental health issues, homelessness and unemployment.[2] LGBTQ patients also have higher rates of suicide with 40 percent of transgender people reporting attempting suicide.[3,4] Additionally, the risk of physical conditions is also exacerbated with increased rates of tobacco use, HIV and AIDS, and weight problems.[2]

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[1] 81 Fed. Reg. 31435 (May 18, 2016).
[2] Hatzenbuehler, M. L., Mclaughlin, K. A., Keyes, K. M., & Hasin, D. S. (2010). The Impact of Institutional Discrimination on Psychiatric Disorders in Lesbian, Gay, and Bisexual Populations: A Prospective Study. American Journal of Public Health, 100(3), 452-459.
[3] Grant et al. (2011). Injustice at every turn: A report of the National Transgender Discrimination Survey. Washington, DC; National Center for Transgender Equality and National Gay and Lesbian Task Force.
http://www.thetaskforce.org/static_html/downloads/reports/reports/ntds_full.pdf
[4] James, S. E., Herman, J. L., Rankin, S., Keisling, M., Mottet, L., & Anafi, M. (2016). The Report of the 2015 U.S. Transgender Survey. Washington, DC: National Center for Transgender Equality.

LGBTQ patients are already more likely to delay getting necessary medical care. In the latest Report of the 2015 U.S. Transgender Survey, nearly one in four respondents reported not seeing a doctor when they needed to for fear of being mistreated. For those that had sought health services in the last year, respondents reported having at least one negative experience, such as refusal of treatment or having to teach the provider about transgender people.[4] Moreover, the lack of data in national surveys and administrative claims make it a challenge to comprehensively study disparities in this population, and more research is needed to enhance clinical care.[5]

The data that we do have indicates that discrimination has detrimental impacts on the physical and mental health of the LGBTQ population.[6] To reduce the cost of health care and achieve our goal of creating a healthier nation, the specific needs of LGBTQ patients must be examined and effectively addressed.

All the undersigned associations have adopted policies or otherwise support addressing the specific health concerns of LGBTQ people, including opposition to discrimination in health care and insurance coverage based on an individual's sexual orientation or gender identity. As part of that commitment, our organizations support public and private health insurance coverage for treatment of gender dysphoria when medically necessary.

In sum, we stand firmly behind Section 1557's gender identity protections and oppose any modifications to the rule that would weaken those protections and thereby jeopardize the health and well-being of LGBTQ populations.

We urge you to reconsider plans to revise the Section 1557 regulations and ensure HHS adopts strategies to focus on better access to health services and improved health outcomes for the millions of LGBTQ people in the United States.

Sincerely,

American Academy of Nursing
American Academy of PAs
American Academy of Pediatrics
American Academy of Psychiatry and The Law
American Association for Geriatric Psychiatry
American College Health Association
American College of Physicians
American Medical Association
American Medical Student Association
American Medical Women's Association
American Nurses Association
American Pediatric Surgical Association

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[5] Reisner et al. (2016). Global Health Burden and Needs of Transgender Populations: A Review. *The Lancet*, 388, 412-436.
[6] Hatzenbuehler ML, McLaughlin, KA, Keyes, KM, Hasin, DS. (2010). The Impact of Institutional Discrimination on Psychiatric Disorders in Lesbian, Gay, and Bisexual Populations: A Prospective Study. American Journal of Public Health, 100(3), 452-459.

American Psychiatric Association
American Psychological Association
American Public Health Association
Association of American Medical Colleges
Association of Nurses in AIDS Care
Doctors for America
Endocrine Society
GLMA: Health Professionals Advancing LGBTQ Equality
HIV Medicine Association
LBGT Physician Assistant Caucus
National Association of Social Workers
National Council for Behavioral Health
National Council of Asian Pacific Islander Physicians
Society for Adolescent Health and Medicine
Society of General Internal Medicine
Society of Physician Assistants in Pediatrics
The Association of Gay and Lesbian Psychiatrists
United States Professional Association for Transgender Health
World Professional Association for Transgender Health

EXHIBIT 7

Comments by the American Psychiatric Association

August 9, 2019

Secretary Alex Azar
U.S. Department of Health and Human Services
Attention: Section 1557 NPRM, RIN 0945-AA11
Hubert H. Humphrey Building, Room 509F
200 Independence Avenue SW
Washington DC 20201

RE: Nondiscrimination in Health and Health Education Programs or Activities – Docket No.: HHS-OCR-2019-0007

Dear Secretary Azar,

On behalf of the American Psychiatric Association (APA), a national medical specialty society representing more than 38,500 physicians specializing in psychiatry, we are writing in response to the Department of Health and Human Services' (HHS or the Agency) proposed rule, *Nondiscrimination in Health and Health Education Programs or Activities*[1], as published in the Federal Register on June 14, 2019. We appreciate the opportunity to comment on this important proposal and focus our comments on the potential negative impacts it may have on health outcomes and patients' mental health.

Background

Franciscan Alliance v. Azar enjoined the implementation of a regulation that would define "on the basis of sex" to include gender identity and termination of pregnancy. The court then granted HHS a remand and stay in order to allow the Agency to correct the problem the court identified. [2] In the proposed rule, HHS deleted the definition of "on the basis of sex," which had included gender identity and termination of pregnancy and altered the definition of covered entities. As a result, the proposed rule will now encourage discrimination in all facets of health care against gender diverse people and women.

The Agency and this Administration do not intend that health care providers should have carte blanche to engage in rank discrimination against entire classes of people

[1] Notice of Proposed Rulemaking, "Nondiscrimination in Health and Health Education Programs or Activities," Federal Register, Vol. 84, No. 115, Friday, June 14, 2019, pgs. 27846-27895.

[2] The issues of whether discrimination "on the basis of sex" includes gender identity and sexual orientation is currently under consideration by the United States Supreme Court in the combined cases *Altitude Express Inc. v. Zarda, Bostock v. Clayton County, GA*, and *R.G. & G.R. Harris Funeral Homes Inc V EEOC.* These cases will consider the issue in the context of Title VII.

with whom they disagree under the cloak of religious freedom. The plaintiffs in *Franciscan Alliance* made it clear that the religious objection was to providing the *service* or *procedure* that is in contrast to their religious beliefs, and **not** to the patient as a person. Thus, plaintiffs challenging provision of gender transition and abortion services recognized the obligation to treat transgender individuals and women who had terminated a pregnancy for "health issues ranging from the common cold to cancer," but stopped short of providing transition related services and abortions. This limit on the claim to religious or conscious objection is a basic and well-understood tenant of our law:

- HHS explicitly recognized a concern "that the proposed regulation could serve as a pretext for health care workers to claim religious beliefs or moral objections….in order to discriminate against certain classes of patients, including illegal immigrants, drug and alcohol users, patients with disabilities or patients with HIV, or on the basis of race or sexual preference." 73 Fed. Reg. at 78,079 -80 (2008). It clarified that the regulation was not intended to permit unlawful discrimination on any basis, for "the health care provider conscience protection provisions have existed in law for many years, and this regulation only implements these existing requirements. As a result, there is nothing in this regulation that newly permits" discrimination against categories of individuals based on their individual characteristics for any reason (including, e.g., on the basis of race, color, national origin, disability, age, sex, religion, or sexual preference). 73 Fed. Reg. at 78,080 (2008).
- In 2011, an HHS action rescinded much of the 2008 Federal Health Care Conscience Rule, at least in part, as a response to litigation that was filed contesting it. The 2011 issuance made clear that the "conscience statutes were intended to protect health care providers from being forced to participate in *medical procedures* that violated their moral and religious beliefs. They were never intended to allow providers to refuse to provide medical care to an individual because the individual engaged in behavior the health care provider found objectionable." 76 Fed. Reg. at 9,973-74 (emphasis added).

Because the proposed rule does not clarify the limitation of the religious and conscience objection to providing the *procedure or service* related to abortion, gender identity or sexual orientation, it may empower providers to refuse **any** health care service or information to entire classes of people even if the health care sought is unrelated to the religiously objectionable procedure. **By eliminating the definitions of terms such as "on the basis of sex" and changing the definition of "covered entity," without making it clear that discrimination against entire classes of individuals for all health services is unlawful, this rule opens to the door to discrimination against vulnerable Lesbian, Gay, Bisexual, Transgender, and Queer (LGBTQ) and female patients, placing them at-risk of serious or life-threatening results in emergency situations.** The Agency cannot mean that people who have had abortions or who are LGBTQ should be lawfully denied access to treatment for cancer, heart disease or mental illness because someone with a religious belief does not think they are worthy of basic health care. Health care providers need clear instruction on what is and is not a permissible refusal to treat a patient under the guise of religious freedom.

Impact on Gender Diverse Patients

As written, the proposed rule would roll back the current definition of sex discrimination, that includes gender identity and sex stereotyping. This policy change would allow providers to refuse to treat LBGTQ patients, further endangering access to care for an already-vulnerable patient population. Additionally, if

implemented, the proposed rule would allow covered entities, such as insurers, to deny, limit, and impose additional cost-sharing for gender-specific services (such as cervical cancer screenings for women) or services related to gender transition (such as hormone therapy, mental health counseling, and surgeries) that a transgender patient may seek. As physician experts, we know that appropriately evaluated transgender and gender diverse individuals can benefit greatly from medical and surgical gender-affirming treatments.[3] It is our official policy to oppose categorical exclusions of coverage for such medically necessary treatment when prescribed by a physician.

We are especially concerned about the rule's potential to exacerbate health disparities among LGBTQ patients. There is ample evidence that patients in protected classes (e.g. LGBTQ patients) are already hesitant to seek medical and mental health care and that discriminatory policies have detrimental mental health and medical impacts on the population subject to discrimination.[4] Despite the need for health services, half of gender minorities educate their own providers about necessary care and 20 percent report being denied care.[5,6] The literature on the "minority stress model" highlights the impact of social prejudice, isolation and invisibility as the primary factors leading to an increased health burden and greater risk of mental health issues, homelessness and unemployment.[7] Research shows that LGBTQ patients have many of the same health concerns as the general population, but they experience some health challenges at higher rates, and face several unique health challenges shaped by a host of social, economic, and structural factors. LGBTQ individuals are two and a half times more likely to experience depression, anxiety, and substance misuse. These patients also experience higher rates of sexual and physical violence against them as compared to their heterosexual counterparts.[8] Like other minority groups, transgender individuals are more likely to experience prejudice and discrimination in multiple areas of their lives (e.g., employment, housing, school, healthcare), which exacerbate these negative health outcomes and makes access to appropriate medical care all the more important. Due to their limited access to care, transgender patients have significantly increased rates of mental disorders, substance use, and suicide,[9] while the risk of physical conditions is also intensified with increased rates of

[3] American Psychiatric Association. Position Statement on Access to Care for Transgender and Gender Diverse Individuals (2018). https://www.psychiatry.org/File%20Library/About-APA/Organization-Documents-Policies/Policies/Position-2018-Access-to-Care-for-Transgender-and-Gender-Diverse-Individuals.pdf
[4] Hatzenbuehler ML, McLaughlin KA, Keyes KM, Hasin DS. 2010. The impact of institutional discrimination on psychiatric disorders in lesbian, gay, and bisexual populations: a prospective study. Am J Public Health. 100(3): 452-459.
[5] Grant JM, Lisa A, Mottet Justin, Tanis Jack, Harrison Jody, Herman L, Keisling Mara. Injustice at every turn: A report of the National Transgender Discrimination Survey. Washington, DC; National Center for Transgender Equality and National Gay and Lesbian Task Force; 2011.
[6] Sandy James et al., 2015 U.S. Transgender Survey 11, 12, 14 (2016), http://www.transequality.org/sites/default/files/docs/USTS-Full-Report- FINAL.PDF
[7] Ilan Meyer. "Prejudice, Social Stress, and Mental Health in Lesbian, Gay, and Bisexual Populations: Conceptual Issues and Research Evidence" Psychological Bulletin. 2003 Sep; 129(5): 674–697.
[8] Jen Kates et al., "Health and Access to Care and Coverage for Lesbian, Gay, Bisexual, and Transgender Individuals in the U.S." August 2017.
[9] Agnes Gereben Schaefer et al., Assessing the Implications of Allowing Transgender Personnel to Serve Openly, RAND Corporation (2016).

tobacco use, HIV and AIDS, and weight problems.[10] **We urge the Administration to remove barriers to care and support evidence-based coverage for medical care, which would help the mental well-being of gender diverse individuals.**

Impact on Women's Access to Care

The proposed rule would expand abortion exemptions by incorporating blanket exemptions from Title IX and including intentionally broad language to incorporate future abortion exemptions. While the existing regulation already includes exemptions derived from federal statutory protections for religious freedom and conscience, broadening the language to include exemptions beyond abortion services could have a dangerous effect on women's access to care. In essence, this language would allow a provider to turn away a patient from any health service if they previously sought an abortion, simply because having an abortion violates the provider's religious beliefs. As the U.S. continues to see rising maternal mortality rates,[11] enabling providers to turn patients away could worsen health outcomes for women and lead to higher health costs. In rural communities, where women experience poorer health outcomes and have even more limited access to health care,[12] these expanded exemptions could be particularly devastating. **APA opposes governmental restrictions on family planning and abortion services[13] and as such, recommends that the Administration not expand abortion exemptions.**

Broader Implications for Health Costs and Mental Health

As the frontline physicians providing treatment for mental illness and substance use disorders, our goal is to ensure that all patients have access to effective treatment and receive care that is compassionate to their individual needs. According to the most recent National Survey on Drug Use and Health, 80.7 percent of people aged 12 or older who needed substance use treatment at a specialty facility did not receive it. In addition, 57.4 percent of adults with any mental illness did not receive mental health care.[14] The indirect cost of untreated mental illness to employers is estimated to be as high as $100 billion a year in the U.S. alone.[15] Ethnic/racial minorities often bear a disproportionately high burden of disability resulting from mental disorders. Lack of cultural understanding by health care providers may contribute to underdiagnosis and/or misdiagnosis of mental illness with language differences between patient and

[10] Sari Reisner et al., Global Health Burden and Needs of Transgender Populations: A Review. The Lancet, 388, 412-436.

[11] MacDorman, M., Declercq, E., Cabral, H., Morton, C., "Is the United States Maternal Mortality Rate Increasing? Disentangling trends from measurement issues: Short title: U.S. Maternal Mortality Trends." Obstet Gynecol. 2016 Sep; 128(3):447-55.

[12] American College of Obstetricians and Gynecologists. "Health Disparities in Rural Women" (2014). https://www.acog.org/-/media/Committee-Opinions/Committee-on-Health-Care-for-Underserved-Women/co586.pdf?dmc=1&ts=20190730T0304131196

[13] American Psychiatric Association. Position Statement on Abortion (2018). https://www.psychiatry.org/File%20Library/About-APA/Organization-Documents-Policies/Policies/Position-2018-Abortion.pdf

[14] Center for Behavioral Health Statistics and Quality. (2018). 2017 National Survey on Drug Use and Health: Detailed Tables. Substance Abuse and Mental Health Services Administration, Rockville, MD.

[15] Finch, R. A. & Phillips, K. (2005). An employer's guide to behavioral health services. Washington, DC: National Business Group on Health/Center for Prevention and Health Services. Available from: www.businessgrouphealth.org/publications/index.cfm

provider being a contributing factor. Lack of coverage, limited access to culturally competent providers, distrust in the health care system, and stigma are additional main barriers to accessing effective care for diverse populations.

For this reason, **we oppose the Agency's proposal to eliminate requirements for covered entities to provide non-discrimination notices and grievances procedures. In addition, we oppose the proposal to eliminate the standards ensuring access to language assistance services, including oral interpretation and written translation, for individuals with limited English proficiency.** As an organization, we train physicians to deliver culturally competent care to serve the needs of evolving, diverse, underrepresented patient populations. Clear communication is essential to delivering quality care and these provisions would undermine necessary efforts to reduce disparities in mental health care.

A rule that would allow health care workers to deny any health care services to transgender individuals or women who have terminated a pregnancy and scales back patient protections for underserved patients will only exacerbate existing problems of access. While the proposal boasts cost savings, the proposed rule will result in higher health care costs and mortality rates, a less productive workforce, and an increased need for already scarce mental health and substance use services. It is important for us to work together to address these challenges to reduce the burden of mental health and substance use issues on patients, their families, communities, and the government. Religious freedoms can be respected without jeopardizing the basic health needs of a substantial portion of the population. We must also ensure that we do not exacerbate the need for services by adding barriers, such as discrimination or fear of discrimination against people in need of treatment. **Thus, we strongly urge the Administration to rescind this proposed rule to ensure that all patients have access to care without fear of discrimination.**

Thank you for the opportunity to offer our expertise. If you have any questions, please contact Kathy Orellana, Associate Director of Practice Management Policy, at korellana@psych.org or at 202-559-3911.

Best,

Saul Levin, MD, MPA

Saul Levin, MD, MPA, FRCP-E
CEO and Medical Director

EXHIBIT 8

Comments by the American College of Obstetricians and Gynecologists

August 13, 2019

Roger Severino
Director, Office for Civil Rights
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Hubert H. Humphrey Building, Room 509F
Washington, D.C. 20201

RE: RIN 0945–AA11: Nondiscrimination in Health and Health Education Programs or Activities

Dear Director Severino:

On behalf of the American College of Obstetricians and Gynecologists (ACOG), I appreciate the opportunity to provide comments on the U.S. Department of Health and Human Services (HHS) Office for Civil Rights (OCR) proposed rule RIN 0945–AA11: "Nondiscrimination in Health and Health Education Programs and Activities" (Proposed Rule). ACOG has more than 58,000 members representing more than 90 percent of all board-certified obstetrician-gynecologists (ob-gyns) in the United States. As the premiere national medical specialty of women's health care physicians, we support the goals of the Patient Protection and Affordable Care Act (ACA) to expand access to continuous and meaningful health insurance coverage and reject discriminatory practices that jeopardize patient care.

Women as well as lesbian, gay, bisexual, transgender, queer and questioning (LGBTQ+) individuals face frequent barriers to health care. For example, women are more likely than men to delay care due to cost concerns.[1] Women who identify as lesbian or bisexual encounter concerns around confidentiality, disclosure, and a limited understanding as to what their health risks may be.[2,3] Moreover, transgender individuals face lack of adequate insurance coverage, mistreatment by health care providers, and health providers' discomfort or inexperience with the transgender population.[4,5,6,7] According to the 2015 U.S. Transgender Survey Report, nearly 25 percent of transgender individuals did not see a doctor when they needed to in the past year because of fear of being mistreated as a transgender person.[8] Thirty-three percent did not see a doctor due to cost.[9]

Prior to the passage of the ACA, women and LGBTQ+ people faced even greater barriers to health care, including higher patient cost-sharing and discriminatory benefit design.[10,11] Notably, Section 1557 of the ACA provides substantial civil rights protections to our patients and prohibits discrimination in health care on the basis of sex. Existing regulations recognize that Section 1557's broad prohibition of discrimination on the basis

of sex includes, but is not limited to, "discrimination on the basis of pregnancy, false pregnancy, termination of pregnancy, or recovery therefrom, childbirth or related medical conditions, sex stereotyping, and gender identity."[12] ACOG recognizes that ensuring women and LGBTQ+ people are able to access health care that is free from discrimination is critical for the health and safety of the patients we serve.[13]

The Proposed Rule seeks to weaken these civil rights protections by eliminating the definition of sex discrimination from the Section 1557 regulation. It also seeks to eliminate prohibitions on discrimination in health insurance products and limit the number of entities and types of insurance products subject to the nondiscrimination requirements. In addition, the Proposed Rule seeks to limit protections for individuals with limited English proficiency and virtually removes an individual's private right of action to sue for discrimination under Section 1557. Each of these proposals will negatively impact access to care for our most vulnerable patients. For these reasons, and those explained in detail below, we urge OCR to withdraw this Proposed Rule in its entirety.

I. The Proposed Rule would eliminate the definition of sex discrimination, weakening protections for LGBTQ+ patients and access to comprehensive women's health care.

Section 1557 broadly prohibits discrimination in health care on the basis of sex. ACOG supports existing regulations that correctly recognize that, among other things, discrimination on the basis of sex for the purposes of Section 1557 includes sex stereotyping, discrimination based on gender identity, and discrimination based on pregnancy status, including termination of pregnancy. The Proposed Rule would eliminate this definition, seeking to undermine the protections of Section 1557 and expose patients to unnecessary harm.

A. The Proposed Rule eliminates recognition that gender identity is a form of prohibited sex discrimination in health care.

ACOG endorses equitable treatment for all patients regardless of gender identity or sexual orientation.[14] OCR's proposal seeks to eliminate recognition of gender identity, which includes gender expression and transgender status, as a form of prohibited sex discrimination. ACOG opposes discrimination on the basis of gender identity and opposes the Proposed Rule's failure to recognize gender identity and sexual orientation as forms of prohibited sex discrimination under Section 1557.[15,16]

Each of OCR's proposed changes related to gender identity are antithetical to Congressional intent and do not align with existing case law which recognizes that sex discrimination includes discrimination based on gender identity.[17,18,19,20] Moreover, failing to recognize gender identity and sex stereotyping as prohibited forms of sex discrimination in health care could put millions of people at significant risk of mistreatment.

Recognition by HHS that gender identity is a prohibited form of sex discrimination under Section 1557 has been a vital tool in our efforts to overcome barriers to health care for transgender patients.[21] Since the implementation of Section 1557, 18 states have implemented affirmative coverage protocols in their respective Medicaid programs to ensure coverage of medically necessary transition-related care.[22] Additionally, a 2019 Marketplace analysis of 622 silver plan options from 129 issuers in 38 states found that 41 percent of plans surveyed had affirmative coverage policies while only six percent had transgender-specific exclusions.[23] This progress – in both Medicaid and the Marketplace – is in jeopardy if OCR's rule is finalized as proposed.

B. The Proposed Rule eliminates recognition of forms of sex discrimination against women.

Existing regulations made clear that sex discrimination under Section 1557 includes discrimination on the basis of pregnancy, false pregnancy, termination of pregnancy, or recovery therefrom, childbirth or related conditions.[24] Under the Proposed Rule, OCR seeks to roll back these protections. Although the preamble of the Proposed Rule acknowledges that the prohibition against sex discrimination includes termination of pregnancy, it refuses to state whether OCR would enforce those protections. Moreover, the Proposed Rule seeks to eliminate the 2016 regulation's clarification that the ban on sex discrimination includes all pregnancy related care. While the scope of protection under Section 1557 is clear, ambiguous implementing regulations and enforcement mean discriminatory practices are likely to flourish.

ACOG believes that health care must be delivered in a way that is respectful of patient autonomy, timely and effective, evidence based, and nondiscriminatory.[25] This includes all care related to pregnancy, false pregnancy, termination of pregnancy, or recovery therefrom, childbirth or related conditions. ACOG opposes OCR's attempt to weaken nondiscrimination protections for women seeking basic medical care.

C. The Proposed Rule codifies overly broad exemptions to anti-discrimination requirements that threaten access to care for women.

ACOG's Code of Professional Ethics states that the "welfare of the patient (beneficence) is central to all considerations in the patient-physician relationship."[26] Moreover, the American Medical Association's Code of Medical Ethics requires medical professionals to act in good faith to protect patient health, even when a patient's health interests conflict with a physician's personal views.[27] As physicians dedicated to providing quality care to women, ACOG supports physician autonomy and the right to practice medicine according to one's conscience, however, ACOG does not support discrimination based on those beliefs.[28]

The Proposed Rule would establish blanket religious exemptions to the prohibition on sex discrimination based on termination of pregnancy. Under the Proposed Rule, a patient in need of abortion services could be denied or discouraged from seeking necessary health care, placing her health or life at risk. Additionally, women who have experienced a prior

termination could be discriminated against if they disclose their prior abortion on a medical history. ACOG believes that safe, legal abortion is a necessary component of women's health care that is essential to women's health and well-being.[29,30] Section 1557 already contains sweeping religious exemptions. ACOG does not support regulatory creation of additional exemptions that go beyond recognized law – especially if they could inhibit patients' ability to achieve full health care equity.

II. The Proposed Rule would eliminate prohibitions on discrimination in health insurance products, allowing issuers to discriminate against certain populations and medical conditions.

ACOG believes that all Americans should be provided with adequate and affordable health coverage.[31] As women's health care physicians, ACOG is determined to stop all efforts to turn back the clock on women's health, including efforts to return to a time before the ACA where health insurance issuers openly discriminated against women and individuals with preexisting conditions.

Section 1557 includes a ban on discriminatory behavior by health insurance issuers. Under the current regulations, covered entities are prohibited from denying, canceling, limiting, or refusing to issue or renew a health insurance policy; denying or limiting coverage of a health insurance claim; imposing additional cost-sharing or other limitations or restrictions on coverage; or using discriminatory marketing practices or insurance benefit designs because of race, color, national origin, sex, age, or disability. These important protections would be eliminated under the Proposed Rule, opening the door for health insurance issuers to discriminate against certain populations and medical conditions.

For example, under the Proposed Rule, insurers could limit access to transition services for transgender individuals. ACOG recognizes that medical and mental health treatments related to gender transition are beneficial and medically necessary for many transgender patients.[32] Further, when access to transgender health care is limited or denied, the results can be dire. According to a recent study published by the American Academy of Pediatrics (AAP), more than 50 percent of transgender male adolescents have attempted suicide.[33] Similarly, 41.8 percent of adolescents who do not identify as exclusively male or female have attempted suicide, followed by nearly 30 percent of transgender female adolescents.[34] ACOG encourages all health plans to cover the various treatments associated with gender identity disorder.[35] This lifesaving care should not be restricted.

The Proposed Rule would also give health insurance issuers the authority to place all drugs for certain diseases or infections – such as HIV – into the highest cost-sharing tier, making them cost prohibitive for many patients. Moreover, the Proposed Rule would allow insurance companies to implement prior authorization or step therapy requirements as well as age restrictions for certain medications, even those that have been found to be clinically effective for all ages.

It is foreseeable that some health plans may target contraceptive methods for prior authorization, step therapy requirements, or age restrictions. ACOG has routinely

discouraged the Centers for Medicare and Medicaid Services (CMS) from allowing entities to require prior authorization and step therapy for family planning services and supplies and for family planning-related services. We believe that medically-appropriate clinical services must be available to patients without costly delays or the imposition of additional barriers.[36]

This is particularly concerning for adolescent access to long-acting reversible contraception (LARC). Notably, ACOG, AAP, the Centers for Disease Control and Prevention, and the Society of Family Planning support the use of LARC by adolescents as these methods have higher efficacy, higher continuation rates, and higher satisfaction rates compared with shorter-acting contraceptives among adolescents who choose to use them.[37] Granting health plans the power to limit access to these critical medications may create barriers for patients to access the method of their choice, potentially leading to inconsistent use of inferior methods and higher rates of unintended pregnancy. Each of these actions by health plans would constitutes sex discrimination under the current Section 1557 regulations, however, these practices would be condoned under the Proposed Rule. ACOG discourages OCR from finalizing these provisions.

III. The Proposed Rule would limit the number of entities and types of insurance products subject to the nondiscrimination requirements.

The Proposed Rule would significantly narrow the applicability of Section 1557 in two ways. First, it would carve out all HHS programs and activities that were not expressly created under Title I of the ACA. This includes programs like the National Health Service Corps and the Indian Health Service, neither of which would need to comply with nondiscrimination protections under the Proposed Rule. Second, while the regulations would still apply to non-health care entities (i.e., health insurance issuers), they would only apply to lines of business that receive federal financial support. Under the current regulations, Section 1557 applies to the insurer itself, meaning any product sold by that insurer cannot discriminate based on race, color, national origin, age, disability, or sex. Under the Proposed Rule, only the lines of business sold by the insurer that receive federal funding would need to comply.

These proposed changes would dramatically limit the scope of nondiscrimination protections across federal programs and health insurance products. Moreover, the Proposed Rule expressly exempts short-term, limited-duration insurance (STLDI) products from complying with Section 1557. STLDI plans often exclude coverage for critically important health care services; vary premium rates by gender, health status, and age; and put individuals and families at significant financial risk. Further exempting these plans from ACA protections via Section 1557 will only harm patients more.

ACOG disagrees with OCR's interpretation of the statute regarding the scope of Section 1557 and the entities covered. To protect patients from discrimination across health programs and insurance types, we urge OCR to keep the 2016 regulations in place.

IV. The Proposed Rule disregards the needs of vulnerable populations.

In addition to provisions that will harm women and LGBTQ+ patients, the Proposed Rule would also undermine protections for individuals with limited English proficiency (LEP) and other vulnerable populations. Under the Proposed Rule, people with LEP could face additional challenges in access to culturally and linguistically appropriate care, including information about accessing services and health insurance. ACOG is concerned that OCR's proposal will result in fewer LEP individuals and families being aware of their health benefits and rights. Additionally, we are concerned that by proposing to eliminate language access plans and other critical protections for LEP individuals seeking care without articulating other, workable solutions, OCR is discouraging entities from taking steps to accommodate the needs of people with LEP.

This change could make health care inaccessible for many marginalized or linguistically isolated communities. According to the U.S. Census Bureau, over 21 percent of the U.S. population, or 66 million people, speak a language other than English at home, with 25 million of them speaking English less than "very well."[38,39] ACOG believes language proficiency should not determine whether people have access to care or the quality of a person's care. Further, ACOG ardently supports the health and well-being of all women and girls, irrespective of immigration status.[40]

In addition to the proposed changes for individuals with LEP, the Proposed Rule seeks to limit an individual's private right of action to sue covered entities for discrimination under Section 1557. Moreover, the Proposed Rule seeks to limit an individual's ability to pursue a disparate impact claim. ACOG supports the civil rights protections enshrined in Section 1557 and discourages OCR from scaling back these critical patient protections.

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Thank you for the opportunity to comment on RIN 0945–AA11: "Nondiscrimination in Health and Health Education Programs and Activities." As articulated above, ACOG believes Section 1557's nondiscrimination protections enshrined in the current regulations are critical to the health and safety of our patients. We urge OCR not to adopt a narrow interpretation of the broad protections afforded by Section 1557 and to instead withdraw this proposal in its entirety. Should you have any questions regarding our comments, please contact Emily Eckert, Health Policy Analyst, at eeckert@acog.org or 202-863-2485.

Sincerely,

Ted L. Anderson, MD, PhD, FACOG
President

[1] Kaiser Family Foundation. Women's coverage, access, and affordability: Key findings from the 2017 Kaiser Women's Health Survey. March 2018. Available at: http://files.kff.org/attachment/Issue-Brief-Womens-Coverage-Access-and-Affordability-Key-Findings-from-the-2017-Kaiser-Womens-Health-Survey
[2] Health care for lesbians and bisexual women. Committee Opinion No. 525. American College of Obstetricians and Gynecologists. *Obstet Gynecol* 2012;119:1077–80.
[3] Legal status: health impact for lesbian couples. ACOG Committee Opinion No. 428. American College of Obstetricians and Gynecologists. *Obstet Gynecol* 2009;113:469–72.
[4] Health care for transgender individuals. Committee Opinion No. 512. American College of Obstetricians and Gynecologists. *Obstet Gynecol* 2011;118:1454–8.
[5] Kosenko K, Rintamaki L, Raney S, Maness K. Transgender patient perceptions of stigma in health care contexts. *Medical Care* 2013;51(9):819–822.
[6] Poteat T, German D, Kerrigan D. Managing uncertainty: A grounded theory of stigma in transgender health encounters. *Social Science & Medicine* 2013;84(1):22–29.
[7] Lambda Legal. When health care isn't caring: Lambda Legal's survey of discrimination against LGBT people and people with HIV. New York, NY: Lambda Legal. 2010.
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[12] 45 CFR §92.4
[13] The limits of conscientious refusal in reproductive medicine. ACOG Committee Opinion No. 385. American College of Obstetricians and Gynecologists. *Obstet Gynecol* 2007;110:1203–8.
[14] Health care for lesbians and bisexual women. Committee Opinion No. 525. American College of Obstetricians and Gynecologists. *Obstet Gynecol* 2012;119:1077–80.
[15] Health care for transgender individuals. Committee Opinion No. 512. American College of Obstetricians and Gynecologists. *Obstet Gynecol* 2011;118:1454–8.
[16] ACOG press release: America's frontline physicians urge Trump Administration to protect transgender patients and women's reproductive health. May 28, 2019. Available at: https://www.acog.org/About-ACOG/News-Room/Statements/2019/Physicians-Urge-Trump-Administration-to-Protect-Transgender-Patients-and-Womens-Health?IsMobileSet=false
[17] *Prescott v Rady Children's Hospital,* 265 F.Supp.3d 1090 (S.D. Cal. Sept. 27, 2017) (holding that discrimination against transgender patients violates the Affordable Care Act)
[18] *Flack v Wisconsin Department of Health Services,* No. 3:18-cv-00309-wmc (W.D. Wis. July 25, 2018) (holding that a Medicaid program's refusal to cover treatments related to gender transition is "text-book discrimination based on sex" in violation of the Affordable Care Act)
[19] *Boyden v Conlin,* No. 17-cv-264-WMC, 2018 (W.D. Wis. September 18, 2018) (holding that a state employee health plan refusal to cover transition-related care constitutes sex discrimination in violation of Title VII, Section 1557 of the ACA, and the Equal Protection Clause)
[20] *Tovar v Essentia Health,* No. 16-cv-00100-DWF-LIB (D. Minn. September 20, 2018) (holding that Section 1557 of the Affordable Care Act prohibits discrimination on the basis of gender identity)
[21] James SE, Herman JL, Rankin S, Keisling M, Mottet L, Anafi M. The report of the 2015 U.S. Transgender Survey. Washington, DC: National Center for Transgender Equality. 2016. Available at: https://transequality.org/sites/default/files/docs/usts/USTS-Full-Report-Dec17.pdf
[22] Movement Advancement Project. Healthcare laws and policies: Medicaid coverage for transition-related care. June 25, 2019. Available at: http://www.lgbtmap.org/img/maps/citations-medicaid.pdf
[23] Out2Enroll. Report on trans exclusions in 2019 Marketplace plans. Available at: https://out2enroll.org/out2enroll/wp-content/uploads/2018/11/Report-on-Trans-Exclusions-in-2019-Marketplace-Plans.pdf

[24] 45 CFR §92.4
[25] The limits of conscientious refusal in reproductive medicine. ACOG Committee Opinion No. 385. American College of Obstetricians and Gynecologists. *Obstet Gynecol* 2007;110:1203–8.
[26] American College of Obstetricians and Gynecologists. Code of professional ethics. December 2018. Available at: https://www.acog.org/-/media/Departments/National-Officer-Nominations-Process/ACOGcode.pdf?dmc=1&ts=20190724T1616133833
[27] American Medical Association. Code of medical ethics: physician exercise of conscience. Available at: https://www.ama-assn.org/delivering-care/ethics/physician-exercise-conscience
[28] The limits of conscientious refusal in reproductive medicine. ACOG Committee Opinion No. 385. American College of Obstetricians and Gynecologists. *Obstet Gynecol* 2007;110:1203–8.
[29] Increasing access to abortion. Committee Opinion No. 613. American College of Obstetricians and Gynecologists. *Obstet Gynecol* 2014;124:1060–5.
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[34] Ibid.
[35] Health care for transgender individuals. Committee Opinion No. 512. American College of Obstetricians and Gynecologists. *Obstet Gynecol* 2011;118:1454–8.
[36] The American College of Obstetricians and Gynecologists. Statement of policy: Access to women's health care. July 2016. Available at: https://www.acog.org/-/media/Statements-of-Policy/Public/64AccesstoWomenHlthCare2016-1.pdf?dmc=1&ts=20190807T1856228994
[37] Adolescents and long-acting reversible contraception: implants and intrauterine devices. ACOG Committee Opinion No. 735. American College of Obstetricians and Gynecologists. *Obstet Gynecol* 2018;131:e130–9.
[38] U.S. Census Bureau. 2017 American Community Survey 1-year estimates: Table S1603 characteristics of people by language spoken at home. Available at: https://factfinder.census.gov/faces/tableservices/jsf/pages/productview.xhtml?pid=ACS_17_1YR_S1603&prodType=table
[39] U.S. Census Bureau. 2017 American Community Survey 1-year estimates: Table S1601 language spoken at home. https://factfinder.census.gov/faces/tableservices/jsf/pages/productview.xhtml?pid=ACS_17_1YR_S1601&prodType=table
[40] American College of Obstetricians and Gynecologists. Statement of Policy: Opposition to Immigration Practices that are Detrimental to the Health and Well-Being of Women and Children. June 2018. Available at: https://www.acog.org/-/media/Statements-of-Policy/Public/94ImmigrationPracticesJune2018.pdf?dmc=1&ts=20190807T1914148938

EXHIBIT 9

Comments by the State Insurance Commissioners of California, Connecticut, Colorado, Delaware, District of Columbia, Illinois, Michigan, Minnesota, Nevada, New Jersey, New Mexico, New York, Oregon, Pennsylvania, Rhode Island, Vermont, Washington, and Wisconsin

5 August 2019

Secretary Alex M. Azar, III
U.S. Department of Health and Human Services
Hubert H. Humphrey Building, Room 509F
200 Independence Avenue, SW
Washington, DC 20201.

Re: Proposed rule RIN 0945-AA11, Docket ID number HHS-OCR-2019-0007

Dear Secretary Azar,

On behalf of the undersigned state insurance commissioners, the primary regulators of insurance markets in the United States, we write to urge the U.S. Department of Health and Human Services to abandon the changes in its recent notice of proposed rulemaking (NPRM) that would amend regulations that implement Section 1557 of the Affordable Care Act (RIN 0945-AA11). The proposed rule, as outlined in the NPRM, would undermine the civil rights protections for millions of consumers, generate confusion and an uneven playing field for regulated entities, and negatively affect state insurance markets.

Many of the undersigned insurance commissioners previously sent a letter to then-Acting Secretary Hargan to express our concern with the Department's plan to change the 2016 rule and eliminate explicit nondiscrimination protections based on sex, including gender identity and sex stereotyping.[1] In that letter, we outlined why these protections are critical to state insurance markets and the consumers we serve.

These protections remain just as important today. We are disappointed that the Department has moved forward in proposing these changes and want to reiterate the importance of these protections for millions of consumers and state insurance markets.

States have long led the way in making clear to regulated entities that discrimination on the basis of gender identity or transgender status is prohibited in our jurisdictions.[2] We implemented these

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[1] A copy of this letter is available at: https://transequality.org/sites/default/files/docs/Insurance%20Commissioners%20Section%201557%20Joint%20Letter%20to%20HHS%20Sec%20%282%29.pdf.

[2] See, for example: 10 Cal. Code Reg. § 2561.2 (2012); Cal. Dep't of Managed Health Care, Letter No. 12-K, Gender Nondiscrimination Requirements (2013); Div. of Ins., Colo. Dep't of Regulatory Agencies, Bull. No. B-4.49, Insurance Unfair Practices Act Prohibitions on Discrimination Based upon Sexual Orientation (2013); Conn. Ins. Dep't, Bulletin No. IC-34, Gender Identity Nondiscrimination Requirements (2013); Hawaii. H.B. 2084 (2016); Md. Maryland Insurance Administration. Bulletin 15-33 (December 10, 2015); Ill. Dep't of Ins., Company Bulletin No. 2014-10, Healthcare for Transgender Individuals (2014) and 50 Ill. Adm. Code 2603 and 50 Ill. Adm. Code 2001.4(e); Mass. Office of Consumer Affairs & Bus. Regulation, Div. of Ins. Bulletin No. 2014-03, Guidance Regarding Prohibited Discrimination on the Basis of Gender Identity or Gender Dysphoria Including Medically Necessary Transgender Surgery and Related Health Care Services (2014); Minn. Dep't of Commerce & Dep't of Health, Administrative Bulletin 2015-5 (November 24, 2015); Montana, Commissioner of Security & Insurance, 2017 Requirements for Health Plan Form Filings and Qualified Health Plan Certification (2016); Nev. Div. of Ins., Bulletin No. 15-002 (June 25, 2015); N.Y. Department of Financial Services, Insurance Circular Letter No. 7 (2014); Or. Div. of Fin. Reg, Bulletin No. DFR 2016-1, Nondiscrimination Related to Transgender Persons in the Transaction of Insurance in Oregon; Chapter 285, 2019 Or. Laws; Penn. The Pennsylvania Bulletin, Notice Regarding Nondiscrimination; Notice 2016-05 (2016); R.I. Health Ins. Comm'n,

protections based on state law, state regulations, and federal law, including Section 1557 and other federal regulations that prohibit discrimination in insurance.[3] States have had to take this action because of an absence of federal guidance on this issue and in response to consumer concerns and complaints.

Transgender people should have equal access to the same health insurance and care as every other insured American. This includes health care related to gender transition, which for years has been recognized by the medical community as medically effective and necessary for many individuals,[4] as well as routine tests and treatment that have sometimes been denied to transgender individuals based on their association with a specific gender (such as pap smears or prostate cancer screenings). Consumer protection is a core part of our mission and responsibility as regulators, and includes ensuring that no person, transgender or not, is treated unfairly or is subject to discrimination.

The proposed changes to the 2016 rule will generate considerable uncertainty for the consumers we serve and the companies we regulate. The vast majority of regulated entities across the country, including those we regulate, have already come into compliance with Section 1557.[5] Undoing the rule and its clarification of federal requirements would impose an additional regulatory burden on these entities and our staff, and the absence of clear and well-understood federal requirements could result in an uneven playing field among insurers. We are also aware that the proposed changes to the rule are inconsistent with several federal court rulings that have explicitly found that the sex nondiscrimination protections in Section 1557 prohibit discrimination based on sex stereotyping or transgender status.[6]

Health Bulletin 2015-3 (Nov. 23, 2015); Dep't of Fin. Regulation, Div. of Ins., Bulletin No. 174, Guidance Regarding Prohibited Discrimination on the Basis of Gender Identity Including Medically Necessary Gender Dysphoria Surgery and Related Health Care (2013); Wash. Comm'r of Ins., Letter to Health Insurance Carriers in Washington State (June 25, 2014); D.C. Dep't of Ins., Sec., & Banking, Bulletin No. 13-IB-01-30/15 (Revised), Prohibition of Discrimination in Health Insurance Based on Gender Identity or Expression (2014); 18 Del. C. § 2304(22) (2013); Delaware Insurance Department, Domestic/Foreign Insurers Bulletin No. 86, the Gender Identity Nondiscrimination Act of 2013 (2016); VT Dep't of Fin. Regulation, Ins. Bulletin No. 174 (Revised), Guidance Regarding Prohibited Discrimination on the Basis of Gender Identity Including Medically Necessary Gender Dysphoria Surgery and Related Health Care (2013); NM Office of Superintendent of Insurance Bulletin 2018-013, Transgender Non-Discrimination in Health Insurance (2018).

[3] Including, for example: 45 C.F.R. §156.200(e), 45 C.F.R. §156.125(b), and 45 C.F.R. §156.125.

[4] *See, e.g.*, Am. Academy of Fam. Physicians, Resolution No. 1004 (2012); Am. Medical Assn., Resolution 122 (A-08), Removing Financial Barriers to Care for Transgender Patients (2008); Am. Psychiatric Assn., Position Statement: Access to Care for Transgender and Gender Variant Individuals (2012); Am. Psychological Assn., Policy on Transgender, Gender Identity & Gender Expression Non-Discrimination (2008); Am. College of Physicians, Lesbian, Gay, Bisexual, and Transgender Health Disparities: A Policy Position Paper, 163 ANN INTERN MED. 135-137 (2015); Am. Coll. of Obstetricians & Gynecologists, Committee Op. 512, 118 OBSTETRICS & GYNECOLOGY 1454 (2011); National Assn. of Social Workers, Transgender and Gender Identity Issues Policy Statement (2008).

[5] *See* Out2Enroll, *Summary of Findings: 2019 Marketplace Plan Compliance with Section 1557*, available at: https://out2enroll.org/out2enroll/wp-content/uploads/2018/11/Report-on-Trans-Exclusions-in-2019-Marketplace-Plans.pdf.

[6] *See, e.g., Rumble v. Fairview Health Servs.*, No. 14–cv–2037, 2015 WL 1197415 (D. Minn. Mar. 16, 2015) (holding that discrimination against hospital patient based on his transgender status constitutes sex discrimination under Section 1557 of the Affordable Care Act); *Flack v. Wis. Dep't of Health Servs.*, No. 3:18-cv-00309-wmc (W.D. Wis. July 25, 2018) (holding that a Medicaid program's refusal to cover treatments related to gender transition is "text-book discrimination based on sex" in violation of the Affordable Care Act and the Equal Protection Clause of the Constitution); *Cruz v. Zucker*, 195 F.Supp.3d 554 (S.D.N.Y. 2016) (holding exclusion invalid under the Medicaid Act and the Affordable Care Act); *Prescott v. Rady Children's Hosp.-San Diego*, 265 F.Supp.3d 1090 (S.D. Cal. Sept. 27, 2017) (holding that discrimination against transgender patients violates the Affordable Care Act); *Tovar v. Essentia Health*, No. 16-cv-00100-DWF-LIB (D. Minn. September 20, 2018) (holding that Section 1557 of the Affordable Care Act prohibits discrimination on the basis of gender identity); *Boyden v. Conlin,* No. 17-cv-264-WMC, 2018 (W.D. Wis. September 18, 2018) (holding that a state employee health plan refusal to cover transition-related care constitutes sex discrimination in violation of Title VII, Section 1557 of the ACA, and the Equal Protection Clause).

Our collective experience in implementing these protections has been that the fiscal and regulatory impact of ensuring nondiscriminatory treatment of insurance claims, including claims for medical care related to gender transition, are negligible. We have been able to consider and resolve the consumer complaints that we have received under Section 1557. In fact, we have found that these historic protections have been nothing short of life changing for people who, prior to the enactment of the Affordable Care Act, were often denied the care that their doctors deemed medically necessary or denied access to insurance altogether.

We are committed to prohibiting discrimination in our states and are deeply concerned about the proposed rule's impact on the companies we regulate and consumers nationwide. For these reasons, we urge you to abandon the proposed rule's changes regarding the unfair treatment of transgender consumers. In its current form, the proposed rule would undermine the civil rights protections for millions of consumers, generate confusion, and negatively affect state insurance markets.

Please do not hesitate to call on us to provide additional information.

Sincerely,

Ricardo Lara, Commissioner
California Department of Insurance

Andrew N. Mais, Commissioner
Insurance Department, State of Connecticut

Michael Conway, Commissioner
Colorado Division of Insurance

Trinidad Navarro, Commissioner
Delaware Department of Insurance

Other federal courts have found that similar federal sex discrimination laws also prohibit anti-transgender discrimination. *See, e.g.*, *Whitaker v. Kenosha Unified School District*, No. 16-3522 (7th Cir. 2017) (Title IX and Equal Protection Clause); *Dodds v. U.S. Dep't of Educ.*, 845 F.3d 217 (6th Cir. 2016) (Title IX and Equal Protection Clause); *Glenn v. Brumby*, 663 F.3d 1312 (11th Cir. 2011) (Equal Protection Clause); *Barnes v. City of Cincinnati*, 401 F.3d 729 (6th Cir. 2005) (Title VII of the 1964 Civil Rights Act); *Smith v. City of Salem*, 378 F.3d 566 (6th Cir. 2004) (Title VII); *Rosa v. Park West Bank & Trust Co.*, 214 F.3d 213 (1st Cir. 2000) (Equal Credit Opportunity Act); *Schwenk v. Hartford*, 204 F.3d 1187 (9th Cir. 2000) (Gender Motivated Violence Act); *Schroer v. Billington*, 577 F. Supp. 2d 293 (D.D.C. 2008) (Title VII); Grimm v. Gloucester County School Board, No. 4:15-cv-54 (E.D. Va. May 22, 2018) (holding that denying a transgender boy access to school restrooms matching his gender violated Title IX and the Equal Protection Clause of the U.S. Constitution); M.A.B. v. Board of Education of Talbot County, 286 F. Supp. 3d 704 (D. Md. March 12, 2018) (holding that prohibiting a transgender boy from boys' locker room based on transgender status is a Title IX sex-discrimination claim as well as a gender-stereotyping claim).

Stephen C. Taylor, Commissioner
District of Columbia Department of Insurance, Securities and Banking

Marlene Caride, Commissioner
New Jersey Department of Banking and Insurance

Robert H. Muriel, Director
Illinois Department of Insurance

Linda A. Lacewell, Superintendent
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Nevada Department of Insurance

Marie L. Ganim, Commissioner
Rhode Island Office of the Health Insurance Commissioner

John G. Franchini, Superintendent
New Mexico Office of Superintendent of Insurance

Michael S. Pieciak, Commissioner
Vermont Department of Financial Regulation

Mike Kreidler, Commissioner
Washington State Office of the Insurance Commissioner

Mark Afable, Commissioner
Wisconsin Office of the Commissioner of Insurance

EXHIBIT 10

Comments by the Cities of New York, Chicago, Baltimore, Bloomington, Los Angeles, Portland, Providence, and Seattle

August 13, 2019

U.S. Department of Health and Human Services
Office for Civil Rights
Hubert H. Humphrey Building, Room 509F
200 Independence Avenue SW
Washington, DC 20201

RE: Nondiscrimination in Health and Health Education Programs or Activities, RIN 0945-AA11, Proposed Rule, Fed. Reg. Vol. 84, No. 115, HHS Docket No. HHS-OCR-2019-0007.

The Cities of New York and Chicago, joined by the Cities of Baltimore, Bloomington, Los Angeles, Portland, Providence and Seattle, and the Town of Carrboro (together, the "Signatories") submit this Comment in opposition to Proposed Rule published by the Department of Health and Human Service ("HHS") on June 14, 2019.

THE PROPOSED RULE VIOLATES THE ADMINISTRATIVE PROCEDURE ACT

The APA requires courts to "hold unlawful and set aside agency action, findings, and conclusions that are, among other things, "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A); *see also Motor Vehicle Mfrs. Ass'n of United States v. State Farm Mut. Automobile Ins. Co*., 463 U.S. 29, 41 (1983).

I. <u>The Proposed Rule Is Not In Accordance With Governing Law</u>.

An agency "does not have the power to adopt a policy that directly conflicts with its governing statute." *Maislin Indus., U.S. v. Primary Steel, Inc.*, 497 U.S. 116, 134-35 (1990); *see also United States v. Mead*, 533 U.S. 218, 228-29 (2001) (agency action cannot be "manifestly contrary to the statute"); *Chevron, U.S.A., Inc. v. Natural Resources Defense Council, Inc.,* 467 U.S. 837, 843 n.9 (1984) (courts "must reject administrative constructions which are contrary to clear congressional intent"). Thus, agency action is "not in accordance with law" where it "ignores the plain language of the statute," renders statutory language "superfluous," or "frustrate[s] the policy Congress sought to implement" in the statute. *Pacific Northwest Generating Coop v. Department of Energy*, 580 F.3d 792, 806 (9th Cir. 2009).

The Proposed Rule is in direct conflict with Section 1557 of the ACA in many ways. It conflicts with Section 1557 because it eliminates protections for discrimination based on gender identity and sex stereotyping. It conflicts with Section 1557 because it allows other forms of sex discrimination, such as discrimination based on termination of pregnancy. It conflicts with Section 1557's prohibitions on discrimination based on national origin, as incorporated into Section 1557 through Title VI, by weakening language notice and access requirements. It conflicts with Section 1557 by unlawfully limiting the scope and reach of Section 1557. And it

conflicts with Section 1557's explicit inclusion of enforcement mechanisms available under numerous civil rights laws. As such, the Proposed Rule is "not in accordance with law" and therefore invalid under the APA.

A. The Proposed Rule's Removal of Protections against Discrimination Based on Sex Stereotyping and Gender Identity Conflicts with Section 1557.

Section 1557 provides that "an individual shall not … 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," on the grounds prohibited by Title IX of the Education Amendments of 1972, 20 U.S.C. § 1681 ("Title IX") (sex); Title VI of the Civil Rights Act of 1964, 42 U.S.C. § 2000d ("Title VI") (race, color, national origin); the Age Discrimination Act of 1975, 42 U.S.C. § 6101; and Section 794 of Title 29 (Rehab Act)(disability). *See* 42 U.S.C. § 18116. Thus, by its plain terms, Section 1557 was enacted to prevent discrimination in healthcare on any of the grounds recognized by federal civil rights and other statutes.

1. The Proposed Rule Conflicts with Congressional Intent to Protect Transgender and Gender Non-Conforming Individuals from Discrimination in Healthcare.

The ACA was enacted in 2010 "to increase the number of Americans covered by health insurance and decrease the cost of health care." *National Federation of Independent Business v. Sebelius*, 567 U.S. 519, 539 (2012); *see also King v. Burwell*, 135 S. Ct. 2480, 2485 (2015) (the ACA "adopts a series of interlocking reforms designed to expand coverage in the individual health insurance market."); *Morris v. California Physicians' Service*, 918 F.3d 1011, 1016 (9th Cir. 2019) (the purpose of ACA "as demonstrated by the content of its provisions and the implementing regulations, as well as its history, is to broaden access to health care."). One of the ways Congress sought to achieve this goal was through enactment of Section 1557, which aimed to decrease or eliminate many of the barriers felt by classes of individuals who routinely experienced discrimination in health care services, such as higher insurance premiums, denial of coverage for medically necessary procedures, or substandard care. By incorporating the non-discrimination provisions of other civil rights laws into the health care field, Congress sought to prevent discrimination and expand health care to all Americans, regardless of race, color, national origin, sex, age, and disability. As self- implementing, Section 1557 did not require regulations in order to take effect. 42 U.S.C. § 18116(c).

Importantly, by incorporating Title IX's provisions into Section 1557, Congress kept in place exemptions from compliance with the general prohibition against discrimination for covered entities that objected to providing coverage based on religious beliefs, or funding for

abortion services. Thus, Section 1557 struck a balance between protecting health care access for all, including reproductive and sexual health care, and religious liberty.

By allowing blanket discrimination against whole classes of individuals, however, the Proposed Rule tips the balance against health care access and in favor of discrimination, which frustrates the primary and essential purpose of the ACA. *See, e.g.*, *Sebelious*, 567 U.S. at 539. The Supreme Court has held that, under ordinary principles of statutory construction, distinct sections of the ACA must be interpreted in harmony with its overall purpose. *See King*, 135 S. Ct. at 2496 (looking at whole context of statute, Court found that Congress could not have possibly intended to eliminate one of its overarching reforms in a single provision); *see also Morris*, 918 F.3d at 1016 (purpose of ACA "strongly indicates" that provisions must be interpreted and applied in accord with this purpose). The Proposed Rule impermissibly conflicts with the very purpose of Section 1557—to prevent discrimination—and the ACA generally—to expand healthcare access to all Americans.

In 2012, the Department of Health and Human Service's Office of Civil Rights (OCR), the agency responsible for enforcing Section 1557, specifically held that gender identity and gender non-conformance was protected under Section 1557. OCR issued an opinion letter on July 12, 2012, stating that "[w]e agree that Section 1557's sex discrimination prohibition extends to claims of discrimination based on gender identity or failure to conform to stereotypical notions of masculinity or femininity and will accept such complaints for investigation." *See* Letter from Leon Rodriguez, Director, Office of Civil Rights, to Maya Rupert, Federal Policy Director, National Center for Lesbian Rights.[1] The letter also provided that "Section 1557 also prohibits sexual harassment or discrimination regardless of the actual or perceived sexual orientation or gender identity of the individual involved." *Id*.

Further advancing this purpose, and after an extensive due diligence period that included a request for information on August 1, 2013, proposed rules issued on September 8, 2015, and a thorough evaluation and response to nearly 25,000 comments, HHS promulgated regulations (the "2016 Regulations), which comprehensively set forth definitions, procedures, notice requirements, and enforcement mechanisms, for the implementation of Section 1557. *See* 45 C.F.R. § 92.1 *et seq*. (May 18, 2016).

The 2016 Regulations defined "on the basis of sex" to include "discrimination on the basis of pregnancy, false pregnancy, termination of pregnancy, or recovery therefrom, childbirth or related medical conditions, sex stereotyping, and gender identity." *Id*. at § 92.4. Gender identity was defined as "an individual's internal sense of gender, which may be male, female,

[1] Available at https://www.washingtonblade.com/2012/08/07/hhs-affirms-trans-protections-in-health-care-reform.

neither, or a combination of male and female, and which may be different from an individual's sex assigned at birth." In turn, "sex stereotyping" was defined as "stereotypical notions of masculinity or femininity, including expectations of how individuals represent or communicate their gender to others, such as behavior, clothing, hairstyles, activities, voice, mannerisms, or body characteristics" *Id.* While HHS noted that it supported banning discrimination on the basis of sexual orientation as policy, it did not expressly include it in the definition (noting that the law was mixed on this issue), but it did state that discrimination on the basis of sexual orientation was prohibited if it were based on sex stereotyping. 81 Fed. Reg. at 31389-90.

The 2016 Regulations also included a nondiscrimination provisions, stating that "[e]xcept as provided in Title I of the ACA, an individual shall not, on the basis of race, color, national origin, sex, age, or disability, be excluded from participation in, be denied the benefits of, or otherwise be subjected to discrimination under any health program or activity to which this part applies." 45 C.F.R. § 92.101(a)(1). In addition, the 2016 Regulations provided that covered entities "shall treat individuals consistent with their gender identity," except that they cannot "deny or limit health services that are ordinarily or exclusively available to individuals of one sex, to a transgender individual based on the fact that the individual's sex assigned at birth, gender identity, or gender otherwise recorded is different from the one to which such health services are ordinarily or exclusively available." *Id.* at § 96.206. In other words, the 2016 Regulations made clear that, for example, a transgender male could not be denied service or coverage for ovarian cancer due to the fact that he did not present as a woman. Thus, beyond the incorporation of Title IX, the 2016 Regulations affirmatively prohibited discrimination on the basis of gender identity and transgender status.

The 2016 Regulations emphasized, however, that "[i]nsofar as the application of any requirement under this part would violate applicable Federal statutory protections for religious freedom and conscience, such application shall not be required." *Id.* at § 92.2(b)(2). Accordingly, the 2016 Regulations continued to recognize that religious and moral objections to providing health care coverage and services could be legitimate bases for exemption from Section 1557.

HHS explained that the 2016 Regulations were written to "adopt formally this well-accepted interpretation of discrimination 'on the basis of sex.'" 81 Fed. Reg. 31387-88. HHS looked to other federal agencies, who had previously interpreted sex discrimination to include discrimination on the basis of gender identity, citing opinions from the Department of Labor, Department of Education, Department of Housing and Urban Development, and the Department of Justice. *Id.* at 31387 and note 56. HHS also noted that around the same time that Congress passed the ACA, it also passed two statutes that protected against discrimination on the basis of gender identity. *See* 18 U.S.C 249(a)(2)(A), the Matthew Shepard and James Byrd, Jr. Hate Crimes Prevention Act (HCPA) (criminalizing actions that cause harms based on persons' actual

or perceived sexual orientation, or gender identity, which in turn is defined as "actual or perceived gender-related characteristics"); 34 U.S.C. 12291(b)(13)(A) (2013), the Violence Against Women Reauthorization Act (adding "gender identity" as a protected characteristic in discrimination provision.). Perhaps most importantly, HHS emphasized that, at the time the ACA was enacted in 2010, federal courts had already interpreted sex discrimination to cover transgender people, and that, since that time, courts had interpreted Section 1557 specifically to cover such discrimination. *Id*. at 31387-90.

In removing these protections, through elimination of the definitions and antidiscrimination provisions, the Proposed Rule is—unlawfully—in direct conflict with Section 1557. The statutory purpose of the ACA generally, and Section 1557 in particular, as further reflected in the thoughtful and comprehensive 2016 Regulations, make clear that Congress intended to include gender identity and transgender status under the definition of "on the basis of sex." Congress did not intend to permit discrimination on the basis of sex for an entire class of individuals, those who are transgender, gender non-conforming, or otherwise non-binary (TGNCBN). Yet that is what the Proposed Rule allows. HHS now claims that Congress intended "sex" to refer solely to a person's biological sex assigned at birth,[2] but it offers no reasonable evidence to support this sudden turn-around, nor adequately explain its decision to reverse course in the face of the exhaustive record before HHS two years ago, when the 2016 Regulations were written.

Moreover, HHS's recent interpretation of Congress's meaning of term "sex," is too narrow in light of the ACA's goal to prohibit discrimination and provide equal access to health care and insurance and the statutory context of Section 1557. This narrow reading contravenes the U.S. Supreme Court's view that the interpretation of statutes "must not negate their own stated purposes," *New York State Dept. of Social Servs. v. Dublino*, 413 U.S. 405, 419–420 (1973) and "must not be guided by a single sentence or member of a sentence, but look to the provisions of the whole law, and to its object and policy." *Pilot Life Ins. Co. v. Dedeaux*, 481 U.S. 41, 51 (1987); *see also Util. Air Regulatory Grp. v. E.P.A.*, 134 S. Ct. 2427, 2441 (2014) (noting the "fundamental canon of statutory construction that the words of a statute must be read in their context and with a view to their place in the overall statutory scheme."). The ACA does, and must, protect all people from discrimination in healthcare, and the Proposed Rule conflicts with this plain Congressional intent.

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[2] This position likewise ignores the ever-growing body of scientific data showing that sex is not always accurately assigned at birth. Sex assignment at birth, typically based on reproductive anatomy, often ignores the complexity of factors that determine a person's sex, including "genetic or chromosomal sex, gonadal sex, internal morphological sex, genitalia, hormonal sex, phenotypic sex, assigned sex/gender of rearing, and self-identified sex." Derek Waller, Recognizing Transgender, Intersex, and Nonbinary People in Healthcare Antidiscrimination Law, 103 Minn. L. Rev. 467, 472-79 (2018) (internal citations omitted).

2. The Proposed Rule Conflicts with Precedent Under Title IX and Similar Civil Rights Statutes Holding that Discrimination on the Basis of Sex Includes Gender Identity.

As discussed, Section 1557 incorporates the protections of Title IX, which prohibits discrimination on the basis of sex in federally-funded education programs and activities. *See* 20 U.S.C. § 1681. While Title IX does not contain an explicit definition of discrimination "on the basis of sex" in its text or regulations, courts have commonly interpreted the phrase to include discrimination on the basis of sex stereotyping and gender identity. Notably, Section 1557 explicitly prohibits an interpretation of the statute that would invalidate or limit the rights, remedies, procedures, or legal standards to individuals aggrieved under Title IX, Title VII and other civil rights statutes. The Proposed Rule is an abrupt and unlawful departure from this body of law.

In determining the scope of Title IX's protections against sex discrimination, courts traditionally looked to case law developed under Title VII, which prohibits discrimination "because of sex" in the employment context. *See* 20 U.S.C. §§ 2000e *et seq*. In 1989, the Supreme Court recognized that discrimination "because of sex" under Title VII included sex stereotyping, such that a woman who was denied a promotion because she did not exhibit feminine qualities typically associated with being female, had stated a Title VII discrimination claim. *Price Waterhouse v. Hopkins*, 490 U.S. 228, 251 (1989) ("[I]n forbidding employers to discriminate against individuals because of their sex, Congress intended to strike at the entire spectrum of disparate treatment of men and women resulting from sex stereotypes."), *superseded by statute*, Civil Rights Act of 1991, Pub. L. No. 102-166, 105 Stat. 1071. In so doing, the Court essentially rejected the reasoning, "and vitiate[d] the precedential value, of earlier Federal appellate court decisions that limited Title VII's coverage of 'sex' discrimination to the anatomical and biological characteristics of sex." 2016 Regulations, 81 Fed. Reg. at 31388.

A majority of appellate courts have held that the sex stereotyping recognized by *Price Waterhouse* extends to transgender individuals or discrimination based on sexual orientation. *See, e.g.*, *EEOC v. R.G. & G.R. Harris Funeral Homes, Inc*., 884 F.3d 560, 576 (6th Cir. 2018) (employer violated Title VII when it fired employee for being transgender; "[d]iscrimination on the basis of transgender and transitioning status is necessarily discrimination on the basis of sex"); *Zarda v. Altitude Express, Inc.*, 883 F.3d 100, 132 (2d Cir. 2018) (rehearing en banc) (Title VII prohibits discrimination based on sexual orientation), *cert. granted*, 139 S. Ct. 1599 (2019); *Hively v. Ivy Tech Cmty. Coll. of Ind.*, 853 F.3d 339, 350-52 (7th Cir. 2017) (describing plaintiff's sexual orientation as "the ultimate case of failure to conform to the female stereotype" and holding that sexual orientation discrimination is *per se* sex discrimination under Title VII); *Glenn v. Brumby*, 663 F.3d 1312, 1316-17 (11th Cir. 2011) ("[D]iscrimination against a transgender individual because of her gender-nonconformity is sex discrimination, whether it's described as being on the basis of sex or gender."); *Smith v. City of Salem*, 378 F.3d 566, 572-73

(6th Cir. 2004) (recognizing discrimination based on gender identity or gender non-conformity as actionable sex discrimination under Title VII); *Schwenk v. Hartford*, 204 F.3d 1187, 1202 (9th Cir. 2000) (holding that sex discrimination under Title VII encompasses both biological differences between men and women, and gender identity). *But see Bostock v. Clayton Cty. Bd. of Comm'rs*, 723 F. App'x 964, 965 (11th Cir. 2018) (denying employee's Title VII discrimination claim based on sexual orientation, citing earlier circuit precedent that "forecloses" employee's claim "regardless of whether we think it was wrong"), *cert. granted*, 139 S. Ct. 1599 (2019); *Etsitty v. Utah Transit Auth.*, 502 F.3d 1215, 1220-21 (10th Cir. 2007) (discrimination based on person's status as transsexual was not discrimination "because of sex" under Title VII).[3]

Relying in large part on these Title VII cases, appellate courts have consistently held that Title IX must be construed to include gender identity discrimination. For example, in *Whitaker v. Kenosha Unified School District No. 1*, 858 F.3d 1034, 1039-1047 (7th Cir. 2017), the Seventh Circuit held that discrimination against someone for being transgender is sex discrimination under the sex-stereotyping theory recognized in *Price Waterhouse*, and affirmed a preliminary injunction enjoining a school district from enforcing its policy barring transgender students from using school restrooms matching their gender identities against the plaintiff, a transgender boy. *Id*. at 1039, 1049-50 (policy that subjects transgender person to differential treatment because they are transgender "punishes that individual for his or her gender non-conformance" and is, therefore, form of sex discrimination prohibited by Title IX).

The three other federal appellate courts that have considered this issue under Title IX have likewise held that it protects against gender identity discrimination. *See Doe by & through Doe v. Boyertown Area Sch. Dist.*, 897 F.3d 518, 533-34 (3d Cir. 2018) (concluding that school district's sex-neutral bathroom policy allowing students to use bathrooms that align with gender identity did not discriminate against cisgender students on basis of sex, and further finding that "barring transgender students from restrooms that align with their gender identity would itself pose a potential Title IX violation"), *cert. denied*, 2019 U.S. App. LEXIS 3666; *Dodds v. U.S. Dep't of Educ*., 845 F.3d 217, 221(6th Cir. 2016) (affirming preliminary injunction that required school to allow transgender girl to use girl's bathroom); *G.G. ex rel. Grimm v. Gloucester Cty. Sch. Bd*., 822 F.3d 709, 720-23 (4th Cir. 2016) (Title IX's regulations protected transgender student from discrimination on basis of sex), *vacated and remanded*, 137 S. Ct. 1239 (2017), *dismissed as moot*, 2017 WL 9882602 (Dec. 12, 2017).

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[3] On April 22, 2019, the Supreme Court granted certiorari to three of these cases—*Harris*, *Zarda*, and *Bostock*—to address whether Title VII's protections apply to transgender status and sexual orientation. *See* 139 Sp. Ct. 1599.

Against this landscape of Title VII and IX cases, HHS's position that "'sex' under Title IX does not include sexual orientation or gender," 84 Fed. Reg. at 27853, is flat out wrong, and cannot be used as a legitimate basis for writing these protections out of the Proposed Rule. And the hollow arguments put forth by HHS in an attempt to support its position reveal as much.

First, HHS dishonestly asserts that "Congressional activity" in this area "suggests" that sex under Title IX does not include sexual orientation or gender. *Id*. at 853. HHS cites the syllabus in *FDA v. Brown & Williamson Tobacco Corp*., 529 U.S. 120, 122 (2000), for the proposition that when "Congress several times considered and rejected bills" that would have granted the agency authority, "[it] evidenced a clear intent to [reject such authority]." 84 Fed. Reg. at 27853. Then, as evidence of Congress's intent here, HHS cites to: (1) a gender equity bill introduced in 2016 to amend Title IX, which never made it out of committee; and (2) proposed amendments to the Civil Rights Act over the last thirty years that likewise did not proceed past committee (except the Equality Act, which actually passed the House of Representatives in 2019). *Id*. & n. 38, 39.

The examples HHS relies on fail to support its version of Congressional intent. Unlike in *Brown & Williamson*, Congress has not repeatedly "considered and rejected" bills defining sex to include gender identity and sexual orientation; such bills either stalled in committee, or passed. *See also* 18 U.S.C. § 249(a)(2)(A) (the Hate Crimes Prevention Act) and 34 U.S.C. § 12291(b)(13)(A) (the Violence Against Women Reauthorization Act). And the Supreme Court has made clear that mere inaction by Congress is virtually meaningless. *See Whitaker*, 858 F.3d at 1049 ("Congressional inaction is not determinative" since it "'lacks persuasive significance because several equally tenable inferences may be drawn from such inaction, including the inference that the existing legislation already incorporated the offered change.'") (internal citation omitted). Thus, Congressional inaction could just as easily mean that Congress believed that "sex" under Title IX already included gender identity and sexual orientation. Furthermore, had HHS read the actual case and not just the syllabus, it would have known that *Brown & Williamson* actually states that "[w]e do not rely on Congress' failure to act—its consideration and rejection of bills that would have given the FDA this authority—in reaching this conclusion." 529 U.S. at 155. Rather, the Court stressed that its holding was based on the fact that "Congress has enacted several statutes addressing the particular subject of tobacco and health, creating a distinct regulatory scheme," while at the same time "Congress has persistently acted to preclude a meaningful role for *any* administrative agency in making policy on the subject of tobacco and health." *Id*. at 156.

Second, HHS misleadingly exaggerates the existence of a conflict of law, while wrongly implying that the weight of judicial authority aligns with its new interpretation. HHS states that "[w]hile four appellate courts have addressed the issue, a large volume of district court opinions have been inconsistent on the issue." 84 Fed. Reg. at 27855. HHS fails to mention that those

"four appellate courts" all recognized gender identity as a basis for discrimination under Title IX; indeed, it relegates them to a dismissive footnote only. While it is true that several district courts have ruled inconsistently on the issue, HHS impermissibly elevates the value and importance of these cases above the appellate court decisions.

Finally, HHS states that it is repealing the definitions for consistency's sake and to prevent "public confusion," citing the fact that DOJ's current position, as stated in *Franciscan Alliance* and other recent cases, conflicts with the 2016 Regulations. *Id.* at 27854-55, 856. This is nothing more than circular logic: Despite years of "sex" being interpreted to include gender identity and sexual orientation by DOJ, HHS, and the courts, DOJ decides unexpectedly last year to change its position, and HHS now relies on this new position as justification for its actions. This nonsensical explanation does not and cannot save the fact that the new position conflicts with Section 1557 itself. And if consistency were the true goal, it could have easily left untouched HHS and DOJ's prior interpretation. In fact, HHS goes on to say that it is not proposing its own definition of sex "because of the likelihood that the Supreme Court will be addressing the issue in the near future." *Id.* at 27857. Better then, HHS could have avoided even further confusion and litigation by holding off on issuing the Proposed Rule after the Supreme Court granted certiorari on April 22, 2019.

3. The Proposed Rule Conflicts with Case Law Interpreting Section 1557.

Finally, the Proposed Rule conflicts with every court—save one—that has directly considered whether Section 1557 prohibits discrimination based on gender identity and transgender status.

In the first case to address the issue, *Rumble v. Fairview Health Services*, 2015 WL 1197415 (D. Minn. Mar. 16, 2015), a transgender man claimed the local hospital and physicians violated Section 1557, alleging discriminatory treatment due to his transgender status. *Id.* at *3. Since HHS had not yet promulgated the 2016 Regulations, the court looked at the plain statutory language of Section 1557 and its incorporation of the four nondiscrimination statutes. *Id.* The court found that Section 1557 was ambiguous "insofar as each of the four statutes utilizes different standards for determining liability, causation, and a plaintiff's burden of proof." *Id.* at *9. Although it did not expressly find that Section 1557 was ambiguous with regard to the definition of sex, the court looked to agency interpretation—OCR's 2012 Opinion Letter—for guidance. *Id.* at *10. The court found that the OCR letter, while not controlling, was persuasive in "the thoroughness evident in its consideration, the validity of its reasoning, its consistency with earlier and later pronouncements." *Id.* Accordingly, it concluded that discrimination on the basis of sex under Section 1557 included transgender status. *Id.*

Next, in *Prescott v. Rady Children's Hospital*, 265 F. Supp. 3d 1090 (S.D. Cal. 2017), the court found that Section 1557 applied to protect transgender individuals in a lawsuit brought by a mother against a hospital, on behalf of her deceased minor transgender son. *Id.* at 1097. The defendant argued that the claim must be dismissed because the alleged conduct occurred before the 2016 Regulations (defining sex discrimination as including gender identity) had been promulgated, though they were in effect at the time the lawsuit was brought. *Id*. at *1098. The court rejected this claim, finding that Section 1557 affords protection against discrimination on the basis of gender identity "solely on the language of section 1557 itself," and not the 2016 Regulations. To support its finding, the court relied on Title VII and Title IX cases, *supra* at 6-9.

Two cases decided in 2018 from the district court in Wisconsin followed. In *Flack v. Wisconsin Department of Health Services*, 328 F. Supp. 3d 931 (W.D. Wis. 2018), the court granted a preliminary injunction to two plaintiffs who challenged the State of Wisconsin's Medicaid plan, which contained a categorical exclusion from coverage for all "[t]ranssexual surgery" and related procedures and medications. The Court found that the blanket exclusion, which prevented the two plaintiffs from getting medically necessary treatments, did so on the basis of both their assigned sex at birth and their transgender status, holding that "[e]ven accepting defendants' [narrow] definition of sex," the Wisconsin exclusion nevertheless denied plaintiffs coverage because of their natal sex," because the same procedure would be allowed for those seeking if gender matched natal sex, while not if it did not match gender identity. *Id*. at 947. The court concluded that the case was a "straightforward case of sex discrimination." *Id.* at 948.

Shortly thereafter, the same court also upheld a claim under Section 1557 brought by transgender women employees of the State of Wisconsin, wherein the state had excluded procedures and services related to gender reassignment from its health insurance coverage provided to employees. *See Boyden v. Conlin*, 341 F. Supp. 3d 979 (W.D. Wis. 2018). Following the reasoning in *Flack*, the court concluded holding that denying coverage for transsexual surgery fell within the ambit of the ACA's prohibition on "sex discrimination." *Id*. at 995.

Most recently, in *Tovar v. Essentia Health*, 342 F. Supp. 3d 947 (D. Minn. 2018), the Minnesota district court held that the plain language of Section 1557 prohibited discrimination on the basis of gender identity. There, plaintiff alleged that her transgender son was denied coverage for medically necessary care by defendant's health care plan, which categorically excluded all health services related to gender transition. *Id*. at 950-51. Following the Supreme Court's "expansive view" of sex discrimination in *Price Waterhouse v. Hopkins*, 490 U.S. 228, 251 (1989), as well as the decisions of "numerous courts" on the "precise question at issue here" under Section 1557, the court concluded based "solely on the plain, unambiguous language of the statute" that the plaintiff had stated a claim for sex discrimination under the ACA based on gender identity. *Id.* at 953, 957.

Thus, five out of the six cases that have interpreted sex discrimination under Section 1557 have held that it includes discrimination based on gender identity and transgender status.[4] Nevertheless, HHS claims that the Proposed Rule is "necessary," because the 2016 Regulation "is likely not constitutional." 84 Fed. Reg. at 27849. HHS supports this conclusion by relying entirely on *Franciscan Alliance,* despite the fact that it is an outlier and contrary to all of the other court decisions. Indeed, as it did with the Title IX cases that it disagrees with, HHS recognizes only that "other Federal courts have gender identity discrimination cases . . . pending on their dockets," *id*. at 27855, yet fails completely to acknowledge their holdings. HHS cannot escape the legal import of these cases by simply burying its head in the sand and ignoring them, while placing undue importance on a one-off decision it happens to agree with. Such wishful thinking does not eliminate the clear conflict between the Proposed Rule and the body of law interpreting Section 1557.

Furthermore, HHS's position conflates the 2016 Regulations with the statute itself. While *Franciscan Alliance* held that the definition of "on the basis of sex" in the 2016 Regulations went too far, the cases holding that Section 1557 extends to gender identity and transgender status did so on the basis of Section 1557 itself, and not the 2016 Regulations. Therefore, the Proposed Rule does not (and cannot) change the protections against discrimination that are part of Section 1557 as conferred by Congress, and act only to directly conflict with it.

In sum, HHS's attempt to rewrite Section 1557 by removing explicit protections under the 2016 Regulations is not only in direct contrast with existing law, but also marks an unlawful attempt to omit from discrimination protection an entire class of individuals. Congress directed HHS to bar sex discrimination in health care on the basis of sex; and it did so with clear intent to protect all individuals, including those who would encounter discrimination due to their transgender or gender non-conforming status. HHS's Proposed Rule, therefore, is in direct conflict with governing law, plainly violates the APA, *see Maislin Indus. v. Primary Steel, Inc.*, 497 U.S. 116, 134-35 (1990), and is an unlawful attempt to circumvent Congressional intent and well-established legal precedents through rule making.

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[4] HHS also cites two consolidated cases from the North Dakota district court alleging that the 2016 Regulations were unlawful, but those cases were stayed in light of the injunction issued in *Franciscan Alliance*. *See Religious Sisters of Mercy v. Burwell*, No. 3:16-cv-386 (D.N.D. Nov. 7, 2016); *Catholic Benefits Ass'n v. Burwell,* No. 3:16-cv-432 (D.N.D. Dec. 28, 2016). HHS cites only to their dockets, however, because there are no published opinions or decisions in these cases.

B. The Proposed Rule's Blanket Removal of Protections For Persons Who Have Terminated a Pregnancy, Are Recovering Therefrom, or Suffering From Resulting Medical Conditions Conflicts With Section 1557.

The Proposed Rule would allow health care providers and other covered entities to invoke blanket abortion and religious objection exemptions from the 2016 Regulations' general prohibition on sex discrimination. Specifically, the Proposed Rule would allow for blanket denials of health care and insurance for persons based upon their termination of a pregnancy, recovery therefrom, or resulting medical conditions, irrespective of competing interests, including the health of people who may require emergency treatments. HHS notes that the statute will not apply if any part of it would "violate, depart from, or contradict definitions, exemptions, affirmative rights, or protections" under a wide range of provider conscience provisions set forth in HHS's recent rule "Statutory Conscience Rights in Health Care."

Essentially, under the Proposed Rule, people in need of abortion or other health care services that violate a provider's religious beliefs could be denied, delayed, or discouraged from seeking necessary care, placing them at risk of serious or life-threatening results in emergencies and other circumstances where the individual's choice of health care provider is limited. Should this lead to restrictions in abortion coverage by health insurers or abortion and related service provision by healthcare providers, the resulting gap in healthcare access would almost certainly disproportionately affect poor and low-income women who are unable to pay out-of-pocket for abortion services.

These proposed changes conflict with Section 1557 for numerous reasons. First, the text of Section 1557 is unambiguously clear as to the exemptions that apply to its antidiscrimination mandates. The statute explicitly extends nondiscrimination protections "except as otherwise provided for in [the] title (or an amendment made by [the] title)." 42 U.S.C. § 18116(a). Second, the Proposed Rule considers an overbroad universe of "conscience protections" separately established by HHS and not sanctioned by any federal laws or regulations. The expanded "conscience protections" would allow anyone "with an articulable connection to a procedure, health service, health program or research activity" to raise these alleged conscience objections. Meaning, the myriad participants in a health care encounter—from intake and billing staff to pharmacists, translators, radiology technicians, and insurance companies—could refuse to participate in service delivery to or provide coverage for patients, even under emergency circumstances. These expanded "conscience protections" would themselves amount to a violation of Section 1557 and the incorporated federal civil rights laws as they are nothing more than a new standard of selective and discriminatory treatment for many of the most vulnerable populations. HHS's rule seeking to expand "conscience protections" is currently being challenged in a California federal court by the city and county of San Francisco, and in a New

York federal court by a coalition of 23 states and municipalities, including signatories of this comment.[5]

Third, while debating the language of Section 1557, Congress considered and rejected broader exemptions similar to those now proposed by HHS. Congress refused to expand the federal conscience clause to prohibit "requir[ing] an individual or institutional health care provider to provide, participate in, or refer for an item or service to which such provider has a moral or religious objection, or require such conduct as a condition of contracting with a qualified health plan. *See, e.g.,* 155 CONG. REC. S13193-01 (2009). Congress also considered and rejected broader religious and moral exemptions in the context of the Women's Health Amendment. *See, e.g.,* 155 CONG. REC. S13193-01 (2009).

Finally, Congress has already included protections in the ACA to address religious concerns. Specifically, Title I of the ACA, in which Section 1557 is found, clearly incorporates existing federal conscience protections. *See e.g.,* 42 U.S.C. § 18023(c)(2)(a)(i) (2010) ("Nothing in this Act shall be construed to have any effect on Federal laws regarding . . . conscience protection."); 42 U.S.C.A. § 18113 (2010) (exemptions for objections to assisted suicide); 42 U.S.C.A. § 18023 (2010) (allowing states to prohibit abortion coverage in the state exchanges); 42 U.S.C. § 18023(c)(1)-(2) (the ACA shall not "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").

Additionally, the ACA is already subject to the Religious Freedom Restoration Act (RFRA), and the 2016 Regulations allow for a case-by-case assessment of burdens on a provider's religion pursuant to the RFRA. The 2016 Regulations rejected incorporating Title IX's blanket religious exemption because Title IX is limited to educational institutions, which is significantly different from the health care context. While students and parents typically have a choice about whether to select a religiously affiliated educational institution, individuals' choice of health care provider or health care plan may be limited, especially in cases of emergency and in areas where hospitals are run by religious institutions. Notably, Congress has recognized the importance of ensuring the provision of emergency care to all persons without exception, and mandated that such care must be made available without exception. *See* 42 U.S.C. § 1395dd (hospitals that have an emergency room or department must provide to anyone requesting treatment an appropriate medical screening to determine whether an emergency medical condition exists, and to stabilize the condition or, if medically warranted, to transfer the person to another facility).

[5] *State of New York v. U.S. Dep't of Health and Human Srvcs*, Case 1:19-cv-04676 at https://ag.ny.gov/sites/default/files/state_of_new_york_v_hhs_complaint.pdf; *City and County of San Francisco v. Azar*, Case No. 3:19-cv-2405 at https://www.sfcityattorney.org/wp-content/uploads/2019/05/1_Complaint.pdf.

Thus, HHS previously and more appropriately relied upon the RFRA to make individual case-by-base determinations about "whether a particular application of Section 1557 substantially burdened a covered entity's exercise of religion, and if so, whether there were less restrictive alternatives available." This means that, under the 2016 Regulations, there may be some instances in which a provider's religious beliefs will exempt it from providing services to which it objects to an individual, but other instances, based on the facts of a particular case, in which an individual must receive services despite a provider's religious objection.

The RFRA approach better balances the rights of all stakeholders and adheres to the ACA's purpose to provide equal access to health care and insurance; rather than prioritizing the purported religious and moral objections of providers and insurance companies over the rights of patients in need of critical medical care for time-sensitive health conditions. Indeed, the denials, delays, and inadequate medical care that individuals would face due to the assertion of overbroad "conscience objections could inflict significant and in some cases life threatening harm in the healthcare context.

C. The Proposed Rule's Weakening and Elimination of Language Assistance Conflicts with Section 1557.

(1) The Proposed Rule Makes Existing Language Access Mandates Discretionary

The Proposed Rule waters down existing requirements to ensure that low English proficiency ("LEP") individuals have access to translations and interpretation services. Specifically, the Proposed Rule would replace required steps to provide meaningful access "to each LEP individual eligible to be served or likely to be encountered" with a broader test that an "entity" apply a four-factor analysis to determine an organization's obligations to provide language assistance services. Using such a metric in the healthcare context would shift a healthcare entity's focus from providing language access to each individual – consistent with the established standards of patient-centered care – to a looser consideration of language access exclusively on an institutional level.

Section 1557's protections for LEP individuals builds upon pre-existing civil rights law, such as Title VI, which prohibits discrimination on the basis of race, color and national origin in programs and activities receiving federal financial assistance. Under governing U.S. Supreme Court case law, Title VI obligates recipients of Federal financial assistance to provide LEP individuals with meaningful access to Federally funded programs or activities. Section 1557 extends this protection to federally administered programs, and requires that healthcare institutions implement some of the basic standards and practices that are necessary for ensuring equal access to healthcare, regardless of the language patients and their families speak.

The Proposed Rule weakens language access because it will allow increased justifications for institutions to deny individuals language services, even when that information may be critical

to a patient's health and wellbeing. Health care entities will more likely discount LEP individuals when determining whether language access must be provided, and already vulnerable families and communities may experience disruptions and delays in the provision of their health care. Indeed, already marginalized communities are most likely to be neglected under the proposed changes—those who typically have less access to resources in their languages, and are often vulnerable due to their immigration and socio-economic status. Language access discrimination often overlaps with pre-existing barriers to access to health care, such as national origin, race, and color discrimination Thus, the Proposed Rule will put more vulnerable people at risk by making healthcare services more difficult to access or understand.

(2) The Proposed Rule Eliminates Notice and Taglines Requirements

The 2016 Regulations require covered entities to take reasonable steps to provide meaningful access to each LEP individual eligible to be served or likely to be encountered. Requirements also include posting a visibly-sized notice of non-discrimination and the availability of language access services in physical locations where the entity interacts with the public, on the entity's website, as well as in significant publications. The 2016 Regulations also require taglines on such publications, which must be translated into top 15 non-English languages for large-sized publications and top two languages for small-sized publications.

The Proposed Rule would eliminate notice requirements about one's rights to translation services, protections from discrimination, and directions concerning how to file a complaint. These proposed changes would result in a failure to provide meaningful access to language services for LEP individuals. These changes will also deprive persons with communication disabilities, such as individuals who are deaf or hard of hearing and use a foreign sign language as their preferred mode of communication of meaningful access to language services. Under governing U.S. Supreme Court case law, Section 794 of Title 29 (the Rehab Act) obligates recipients of Federal financial assistance to provide persons with disabilities with meaningful access to Federally funded programs or activities.

Ultimately, the Proposed Rule will undoubtedly weaken language access. In fact, in the Proposed Rule, HHS admits that repealing the requirements for taglines may "[decrease] access to, and utilization of, health care for non-English speakers by reducing their awareness of available translation services." 84 Fed. Reg. at 27855. When linguistically appropriate care is not available to people who speak English "less than well," patients, providers, and healthcare providers alike are put at risk. Studies have shown that language barriers impede access to health insurance, hinder utilization of health care services, compromise quality of care, and increase the risk of adverse health outcomes among LEP individuals. Cite? LEP individuals are more likely than others to report being in fair or poor health, defer needed medical care, or misunderstand medication instructions.

Essentially, when patients do not know they have the right to an interpreter, do not know how to request an interpreter, or cannot read important notices about their care or insurance, it is much more likely that they will not receive care or service in a language that they can understand. When communication between patients and providers is compromised, healthcare providers are unable to provide adequate patient care, and patients' health is put at risk. Simply put: If individuals do not know they can access language services, they will not access them, and their health will suffer. Thus, because the proposed elimination of the notice and tagline requirements will impede the ability of LEP individuals and persons with communication disabilities to meaningfully access health care and coverage programs and services, these proposed changes violate Section 1557 and the incorporated federal civil rights laws— Title VI and Section 794 of Title 29.

D. The Proposed Rule's Exemption of Numerous Health Care Insurance Entities Conflicts With the Scope of Section 1557.

Adding to protections against discrimination within the U.S. Constitution and federal civil rights laws, Section 1557 is the first civil rights statute to explicitly target discrimination in healthcare, including private insurance. Congress sought to advance the ACA's mission to expand coverage and to increase access to care through Section 1557, which broadly applies to "any health program or activity, any part of which is receiving Federal financial assistance," "any program or activity that is administered by an executive agency," and "any entity established under this title," and specifically enumerates "contracts of insurance" as a form of Federal financial assistance.

A previous regulatory analysis estimated that the 2016 Regulations would cover about 900,000 physicians, 133,343 facilities (such as hospitals and nursing homes), 445,657 clinical laboratories; 1,300 community health centers; 40 health professional training programs; Medicaid and public health agencies in each state and the territories; and at least 180 insurers.

The Proposed Rule severely limits the application of Section 1557 in health insurance by (1) entirely eliminating the definitions section of the 2016 Regulations and no longer defining "covered entity" and "health program or activity;" and (2) interpreting Section 1557 to apply only to an insurer's fully federally-funded or supported operations and those principally engaged in the business of providing healthcare.

Within this narrow scope, the Proposed Rule would entirely exempt Medicare Part B, group health plans established under ERISA, short-term plans, the Federal Employees Health Benefits Program, off-exchange products, and certain non-ACA health care programs administered by HHS from compliance with Section 1557.

The proposed exemptions run directly counter to the underlying statute that explicitly covers all health programs and activities if any part of them is receiving federal funding. The

plain text of Section 1557 includes any and all federal financial assistance by the terms "any health program or activity, . . . that is administered by an Executive Agency or any entity established under this title." Moreover, according to HHS' 2003 LEP guidance, which HHS claims it intends to follow, "coverage extends to a recipient's entire program or activity, *i.e.*, to all parts of a recipient's operations. This is true even if only one part of the recipient receives the federal assistance."[6]

More specifically, the Proposed Rule erroneously excludes ERISA plans from the scope of Section 1557 on the grounds that "such programs do not receive federal financial assistance from HHS and/or the entities operating them are not principally engaged in the business of providing health care." However, Section 1557 explicitly refers to "contracts of insurance," and thereby removes previous uncertainty about when civil rights law protections apply to health insurance coverage. The statute also makes it clear that all health insurers, so long as any part of their program or activity receives federal financial assistance, must not discriminate against individuals on the grounds of race, color, national origin, sex, or disability. Further, employer-sponsored plans, including self-funded group plans, heavily rely on federal financial assistance. In fact, as noted by the Commonwealth Fund, the government's largest expenditure in healthcare coverage outside of Medicare and Medicaid, is its subsidy of employer-sponsored coverage through the favorable tax treatment given to employer-sponsored plans, worth an estimated $146 billion in fiscal year 2018.[7] Health insurance companies, and employer-sponsored plans, also rely on government tax benefits.

HHS's proposal to exclude entities that are "principally or otherwise engaged in the business of providing health insurance," except for their specific operations that receive federal financial assistance, is similarly flawed. HHS seeks to justify this proposal by pointing to the Civil Rights Restoration Act of 1987 (CRRA), which did not explicitly refer to health insurance. However, even if that is true, Section 1557 expands the reach of the CRRA to "insurance contracts." And this was fully within Congress' authority to do so. The federal government has legal authority to regulate all health insurers and insurance plans, relying on the Commerce Clause or setting condition on the expenditure of federal funds. The condition does not have to be limited to activities specifically funded by the federal government so long as it is in pursuit of "the general welfare," related to a national concern, and done unambiguously.[8] Indeed, the federal government has regulated and continues to regulate the health insurance industry,

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[6] Federal Register, Vol. 68, No. 153, "Guidance to Federal Financial Assistance Recipients Regarding Title VI Prohibition Against National Origin Discrimination Affecting Limited English Proficient Persons," August 8, 2003 p. 47313. https://www.govinfo.gov/content/pkg/FR-2003-08-08/pdf/03-20179.pdf
[7] The Joint Committee on Taxation, 2018. "Estimates of Federal Tax Expenditures for Fiscal Years 2018-2022," JCX-81-18. Washington, DC; Congress of the United States, available at https://www.jct.gov/publications.html?func=startdown&id=5148
[8] *South Dakota v. Dole*, 483 U.S. 203, 207 (1987).

including ERISA plans, in numerous aspects. For example, the Health Insurance Portability and Accountability Act of 1996 limits the ability of employer-sponsored health plans to engage in certain risk selection practices, including discriminating on the basis of pre-existing health conditions in determining eligibility for enrollment or level of premiums for plan members. Finally, as explained below in Section II(A)(1), the exemptions are irrational and are contradicted by significant evidence. *See, supra*, at pp. 19-21.

E. The Proposed Rule's Elimination of Mandated Enforcement Mechanisms Conflicts With Section 1557.

The Proposed Rule would eliminate the enforcement mechanisms available to HHS's OCR and protected individuals. However, Section 1557 unambiguously mandates that "the enforcement mechanisms provided for and available under such Title VI, Title IX, section 794, or such Age Discrimination Act shall apply for violations of [Section 1557]." 42 U.S.C. §18816(a). This statutory mandate provides OCR with centralized authority to monitor and enforce civil rights laws in the health care sector.

The Proposed Rule removes most provisions supporting OCR's enforcement authority under the statute, including its power to request information from a covered entity, access the books, records, and facilities of HHS to evaluate compliance of the agency's own programs, order remedial action, ban retaliatory action against an individual making a complaint, and/or take legally permissible disciplinary actions for those in non-compliance, including suspension or termination of funds.

These proposed changes run counter to both the statute and the very purpose of OCR. Indeed, OCR was created to provide the area-specific knowledge and expertise for effective government oversight and civil rights law enforcement in the health sector, which is a specialized industry requiring specialized knowledge. Removing enforcement authorities delegated to OCR under the 2016 Regulations would essentially eliminate the OCR's primary means to serve the mission of the office.

The Proposed Rule would also repeal mandates within the 2016 Regulations that require covered entities to hold themselves accountable under Section 1557, including requirements to designate an employee responsible for coordinating the responsibilities under the 2016 Regulations and to establish grievance procedures that allow individuals to allege discrimination. It would also eliminate a provision explicitly providing a private right of action to individuals who allege discrimination in violation of Section 1557, and a provision that requires covered entities to notify individuals of their rights under Section 1557 and the 2016 Regulations.

In other words, under the Proposed Rule, an individual being discriminated against would no longer be informed of whether and how they can file their grievances or lawsuits. A covered entity would no longer need to take concrete actions to address such grievances.

Combined with removal of much of OCR's enforcement authority, the Proposed Rule would virtually eliminate all avenues that allow the individuals' voices to be heard and enable OCR to hold stakeholders accountable.

Additionally, removing the institutionalized enforcement mechanism that makes it easier for individuals to raise their voices when they believe that their civil rights have been violated will impact populations that have been historically marginalized, already experience significant barriers to health care, and have disproportionately poor health outcomes, including people of color and immigrants. These are the individuals who are least likely to know their rights or how to exercise their rights, and whose limited resources make it difficult to file a lawsuit under the underlying statute or utilize other means to file their grievances and challenge the discrimination they experience.

This proposed regulatory rollback runs directly counter to the clear goal of Section 1557 to provide equal access to health care and insurance and essentially renders the statute meaningless.

II. The Proposed Rule is Arbitrary and Capricious

An agency rule is arbitrary and capricious if the agency has: relied on factors that Congress did not intend it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise. *See Motor Vehicle Mfrs. Ass'n*, 463 U.S. at 43-44.

Under the "arbitrary and capricious" standard, HHS is required to examine relevant data and articulate a satisfactory explanation for its action, including a "rational connection between the facts found and the choice made," based upon relevant factors. *See Motor Vehicle Mfrs. Ass'n*, 463 U.S. 29 at 43; *Burlington Truck Lines, Inc. v. United States*, 371 U.S. 156, 168 (1962). Applying these standards demonstrates that, if finalized, the Proposed Rule would violate the APA.

A. HHS's Explanations for the Proposed Rule Are Not Rational and Run Counter to Significant Evidence.

(1) Arbitrary Exemptions of Certain Health Care Insurance From Section 1557

As previously noted, the Proposed Rule would dramatically limit the scope of the ACA non-discrimination protections, by effectively removing many of the currently covered health care insurance programs from the statute's reach. For the reasons below, HHS's justifications for these exemptions are irrational and unsupported by evidence.

As an initial matter, determining the civil rights obligations of insurers and employers based on whether the federal government provides financial assistance directly through subsidies or indirectly through tax benefits is illogical, especially since disparities for racial minorities[9] and foreign-born individuals[10] in obtaining employer-sponsored insurance continue to exist. The ACA was instrumental in reducing racial, ethnic, sex, and disability-based disparities in health insurance coverage. Indeed, studies have found that after the implementation of the ACA: people of color experienced large coverage gains, with an 11 percentage point decline in the uninsured rates for Hispanics and Asians and 8 percentage point decline for Blacks and American Indians, compared to Whites (5 percentage points);[11] the number of uninsured women fell from 19 million in 2010 to 11 million in 2016[12] -- notably the uninsurance rate for Latinas, decreased by more than 10 percentage points from 30.4% in 2013 to 19.9% in 2017 (4.8% for White women during the same period).[13] However, this progress would not have been possible without the robust non-discrimination protections in Section 1557. It is imperative that such protection continue to be extended to all types of health insurance plans. The Proposed Rule's reduced scope of application would violate the goal of ACA broadly and Section 1557 to expand equal access to health care.

HHS arbitrarily limits which entities should be considered "covered entities" and subject to non-discrimination mandates based on the reasoning that "[h]ealth insurance is distinct from health care." This flawed judgment ignores two important facts. First, a person's access to health care is often dramatically limited by their access to, or lack of access to, adequate health insurance coverage. Prior to the enactment of the ACA, health insurers could effectively restrict coverage for certain classes of people through decisions about issuance, cost-sharing, and benefit-design—tactics that the ACA was designed to prevent by requiring guaranteed issue, renewability, and coverage of essential health benefits, and by prohibiting pre-existing condition exclusions.

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[9] Waidmann, T. A., Garrett, B., & Hadley, J. (2004). Explaining Differences in Employer Sponsored Insurance Coverage by Race, Ethnicity, and Immigrant Status. Economic Research Initiative on the Uninsured Working Paper, 42.

[10] Buchmueller, T. C., Lo Sasso, A. T., Lurie, I., & Dolfin, S. (2007). Immigrants and employer-sponsored health insurance. Health Services Research, 42(1p1), 286-310.

[11] Artiga S., Orgera K., Damico A (2019). Changes in Health Coverage by Race and Ethnicity since Implementation of the ACA, 2013-2017. Kaiser Family Foundation Issue Brief, available at https://www.kff.org/disparities-policy/issue-brief/changes-in-health-coverage-by-race-and-ethnicity-since-implementation-of-the-aca-2013-2017/

[12] Gunja M.Z., Collins S.R., Doty M.M., Beutel S. (2017). How the Affordable Care Act Has Helped Women Gain Insurance and Improved Their Ability to Get Health Care. The Commonwealth Fund Issue Brief, available at https://www.commonwealthfund.org/publications/issue-briefs/2017/aug/how-affordable-care-act-has-helped-women-gain-insurance-and

[13] National Partnership for Women & Families Fact Sheet, 2018. "Women's Health Coverage: Stalled Progress," analysis based on the U.S. Census Bureau's 2018 Current Population Survey Annual Social and Economic Supplement. http://www.nationalpartnership.org/our-work/resources/health-care/womens-health-coverage-sources-and-rates-of-insurance.pdf

Next, depending upon life, work, economic and social circumstances, individuals can move fluidly across health insurance markets, being insured for some period through the public programs such as Medicaid, then getting employer sponsored coverage and later becoming self-employed. According to a Health Affairs study, one in four Americans changed their health insurance coverage at least once in 2015. After omitting the newly insured, the three most common reasons for churning were job-related insurance changes, loss of eligibility for Medicaid or ACA marketplace subsidies, and inability to afford a previous plan.[14] Given the frequency of insurance "churning," meaningful civil rights protections for individuals accessing health insurance cannot be achieved without granting the same protections regardless of their insurance types or products. Under the Proposed Rule, the same person protected from discrimination if insured through Medicaid might not receive comparable protections through employer-sponsored coverage. Section 1557's protections were not designed to be subject to the "luck of the draw" of selecting coverage in the "right" insurance market. Thus, it is vital that Section 1557 continue to apply to all health programs and activities that interact with individuals at various points in their overall pursuit of health insurance and health care services.

(2) Arbitrary Removal of Termination of Pregnancy, Recovery Therefrom and Related Medical Conditions as Forms of Sex Discrimination

As noted above, HHS now claims that, under Section 1557, Congress intended "sex" to refer solely to a person's biological sex assigned at birth, but offers no reasonable evidence to support this this policy shift nor adequately explains its decision to reverse course in the face of the exhaustive record previously before HHS, when the 2016 Regulations were written. In addition to running counter to governing law, this policy reversal conflicts with the interpretation of Title IX by other federal agencies. In fact, since 2012, the Department of Education has recognized and enforced discrimination against students and employees based upon termination of pregnancy, recovery therefrom and resulting medical conditions as sex discrimination under Title IX in the education settings.[15]

This conflict is notable because, within the same Proposed Rule, HHS justifies removing gender identity as a form of sex discrimination because such a reading it is inconsistent with those of other federal agencies. *See* Proposed Rule at p. 27856. Using HHS's erroneous logic,

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[14] Sommers, B. D., Gourevitch, R., Maylone, B., Blendon, R. J., & Epstein, A. M. (2016). Insurance churning rates for low-income adults under health reform: lower than expected but still harmful for many. Health Affairs, 35(10), 1816-1824.

[15] 34 C.F.R. § 106.40(b) (defining sex discrimination to reach discrimination against students on "the basis of such student's termination of pregnancy or recovery therefrom."); § 106.51(b)(6) (barring employment discrimination with respect to "[g]ranting and return from leaves of absences for termination of pregnancy); § 106.57(b)(prohibiting illicit discrimination against employees or prospective employees "on the basis of termination of pregnancy or recovery therefrom."); *see generally,* Office for Civil Rights, Pregnant or Parenting? Title IX Protects You from Discrimination at School, U.S. Dep't of Educ. http://www2.ed.gov/about/offices/list/ocr/docs/dclknow-rights-201306-title-ix.html.

termination of pregnancy, recovery therefrom and resulting medical conditions should continue to be considered sex discrimination in the health care and insurance context under Section 1557 to align with the regulations of another federal agency governing the provision of education and employment in education settings. HHS's conflicting justifications for the removal of various forms of sex discrimination from the 2016 Regulations are clearly not rational.

(3) Arbitrary Elimination of Language Access Requirements

HHS contends that the 2016 Regulations concerning language access must be eliminated in their entirety because the notice and tagline requirements were inconsistent with those required by other components of HHS, and provided relatively minimal benefit to LEP individuals.[16] For the reasons set forth below, HHS's explanation is irrational and runs counter to significant evidence.

There is a Need for Robust Language Access Regulations in Healthcare

The importance of addressing the language needs of LEP individuals is prevalent throughout the United States. The Migration Policy Institute estimates that 25.1 million people in the U.S. are considered LEP, and nearly 20% of them are U.S.-born citizens.[17] The ACA has proven to be instrumental in supporting LEP individuals in obtaining health insurance coverage. In fact, the insurance coverage rate among LEP individuals has increased from 61.7% in 2010 to 74.8% in 2017, with a noticeable jump in 2014, when various ACA insurance expansion provisions went into effect.[18] However, a disproportionately large percentage of LEP individuals remain uninsured (25.2% vs. 7.5% according to the 2017 ACS data), and targeted outreach and assistance are crucial in closing the coverage gap within this population. Given the high need, the government has a duty to ensure that LEP individuals receive appropriate language assistance services when they seek insurance coverage, utilize benefits, or receive health care services.[19]

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[16] Proposed Rule at p. 27852

[17] Migration Policy Institute (MPI) tabulations from the U.S. Census Bureau's 1990 and 2000 Decennial Censuses and 2010 and 2013 American Community Surveys (ACS), Migration Policy Institute, July 2015. https://www.migrationpolicy.org/article/limited-english-proficient-population-united-states (Between 1990 and 2013, the LEP population in the U.S. grew 80% from nearly 14 million (6% of the total U.S. population) to 25.1 million (8%)).

[18] SHADAC analysis of the American Community Survey (ACS) Public Use Microdata Sample (PUMS) files, State Health Compare, SHADAC, University of Minnesota, accessed on June 28, 2019, available at http://statehealthcompare.shadac.org/table/15/health-insurance-coverage-type-by-limited-english-proficiency#1/5,4,1,10,86,9,8,6,18,19/24/29,30

[19] NY State of Health: The Official Health Plan Marketplace, 2019 Open Enrollment Report, May 2019. https://info.nystateofhealth.ny.gov/sites/default/files/NYSOH%202019%20Open%20Enrollment%20Report_0.pdf

The Proposed Rule Runs Contrary To Long-Standing Federal Guidance To Ensure Meaningful Access

Notice and Taglines Requirements

HHS contends that the notice and tagline requirements in the 2016 Regulations must be eliminated entirely because they are inconsistent with those required by other components of HHS, and provided relatively minimal benefit to LEP individuals. However, in HHS's own Language Access Plan, the agency notes that the taglines in non-English languages are used to inform LEP clients of their right to free language services and the nondiscrimination practices of the relevant agency. Further, the Department of Justice's guidance for federally conducted or assisted programs explicitly recognizes that "[w]hen…an LEP individual does not know about the availability of language assistance services, [they] will be less likely to participate in or benefit from an agency's programs and services," that notices and taglines serve as a temporary measure to promote better language access when documents deemed "vital" have yet to be translated, and that "agencies should provide notice about its language assistance services in languages LEP persons will understand."

Language Access Plans

The Proposed Rule also would eliminate the provision that allows HHS to consider whether the covered entity has an effective written language access plan. However, developing and implementing an effective written language access plan is an important factor in evaluating a covered entity's compliance under the 2016 Regulations, and is crucial to providing effective language access services in a sustainable manner.

Removing the consideration of whether an entity has an effective written language access plan evaluating a covered entity's compliance means that entities will be disincentivized from devising systematic plans to guarantee access, which provide the architecture necessary to evaluate and apply a systematically equal delivery of service across an institution and its service population. Ad hoc provision of language services results in inequality and a reduction in the quality of language access available, which negatively affects both patients with LEP and healthcare systems.

Moreover, similar to Section 1557, Federal Executive Order 13166 (EO13166) requires federal agencies to implement a system and plan to ensure improved access to services for LEP individuals, and New York State Executive Order 26 (EO26) requires state agencies to appoint a Language Access Coordinator and publish a language access plan. A recent independent analysis of the EO26 concluded that such mandates would benefit both NYS LEP residents and government agencies and improve access to and quality of services provided by state agencies. In addition, the report concluded that the EO would reduce health disparities among LEP

populations, without materially affecting the operations of the covered entities.[20] The 2016 Regulations encourage health insurers, researchers, and health care providers to take similar action to accommodate LEP individuals' language needs. The proposal to remove this consideration could discourage use of an important planning tool that helps entities better comply with the law and ensure that language access services are implemented in a cost-efficient manner to benefit both LEP individuals and covered entities themselves.

The Proposed Rule Eliminates or Weakens Major Tools that Facilitate Language Access, Which Will Result in Negative Health Outcomes.

HHS also proposes eliminating the current remote video interpreting standards and instead includes standards only for remote audio interpreting services. However, because healthcare institutions are increasingly relying on remote video interpretation services, it is vital that there are high standards for any language service provider that provides medical interpretation. The removal of standards for remote video interpretation means that healthcare institutions will have a compromised ability to budget for high quality video remote interpretation. Indeed, the rapid development and integration of new technologies into the delivery of interpretation continue to expand the availability and lower costs for video remote interpretation.

The proposed change further eliminates "qualified" from the proposed description of interpreters and translators that can provide language services under the law, and eliminates "above average familiarity with" from the definition. This weakens the qualifications required of language service providers that provide interpretation and translations for healthcare institutions, thereby jeopardizing the quality of communication possible between providers and LEP patients. Also, the use of underqualified language service providers can result in negative patient outcomes and miscommunications that can result in liability for the institution and increased costs due to inefficiencies such as unnecessary tests and procedures. In short, by undermining this valuable tool for effective communication, the Proposed Rule undermines access to quality healthcare for individuals with LEP.

B. HHS Failed to Consider Important Aspects of the Problem Underlying the Proposed Rule.

(1) HHS Failed To Account For The Need to Address Existing Discrimination in Health Care And The Resulting Negative Impact on Health Care Outcomes

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[20] New York Lawyers for the Public Interest, Letter to U.S. Department of Health and Human Services Office for Civil Rights, RE: Request for Information Regarding Nondiscrimination in Certain Health Programs or Activities, October 1, 2013. https://nylpi.org/wp-content/uploads/bsk-pdf-manager/33_NYLPI_section_1557_comments_final_hardcopy.pdf

Section 1557 will have a detrimental and far-reaching impact on the health of LGBQ and TGNCNB people, women, and our communities. Indeed, HHS' futile distinction between health insurance and health care ignores the direct role of insurers in care access and health outcomes. HHS also disregards the deleterious impact of discrimination on care access and health, particularly where, as here, the discrimination is state-sanctioned.

For patients across the United States who lack state and local protections against discrimination based on gender identity and termination of pregnancy, the Proposed Rule poses a significant threat to their dignity and general and emergency health care needs. In short, the Proposed Rule would permit health care providers and insurance companies— who are not being asked to cover or participate in abortion procedures or gender affirming care or transitions— to refuse to provide treatment or coverage for basic and essential medical care which is, without exception, made available to other persons. HHS essentially contends that such refusal of care is warranted and lawful if a health care provider or insurance company takes issue with a person's gender identity or the fact that they have undergone an abortion procedure.

In fact, an analysis of HHS complaints before the nationwide preliminary injunction issued in *Franciscan Alliance* found that the majority of complaints filed with HHS's OCR under the 2016 Regulations addressed denials of medical care or insurance coverage for generally available healthcare services— and unrelated to gender affirming care or gender transition. For example, a health care provider could refuse to treat a patient for the flu solely based on the person's gender identity or refuse to accept a new transgender patient in favor of a person who is not transgender. Furthermore, under the Proposed Rule, women could be denied preventative and emergency care medical care or insurance coverage solely because they have terminated a pregnancy, are recovering therefrom or are suffering from a medical condition related to an abortion. Even survivors of sexual assault, particularly women of color who already experience difficulty in accessing reproductive health care, would experience less support in accessing pregnancy termination related to their assault.

In addition, the Proposed Rule would eliminate the prohibition on categorical denials, automatic exclusions, and limited coverage for gender-affirming care. Gender-affirming care is medically necessary and, in many cases, life-saving for TGNCNB people.[21] It includes a range of treatments, such as hormone replacement therapy, breast augmentation/reconstruction, mastectomy, facial feminization, voice training, or genital surgery,[22] and mental health care for

[21] World Professional Association for Transgender Health (WPATH), *Position Statement on Medical Necessity of Treatment, Sex Reassignment, and Insurance Coverage in the U.S.A.* ("Position Statement") (Dec. 21, 2016) ("The medical procedures attendant to gender affirming/confirming surgeries are not 'cosmetic' or 'elective' or 'for the mere convenience of the patient.' These reconstructive procedures are not optional in any meaningful sense, but are understood to be medically necessary for the treatment of the diagnosed condition.")
[22] WPATH, The Standards of Care, 9-10 (2012).

gender dysphoria. The country's leading medical associations have affirmed almost uniformly that access to these services leads to better overall health outcomes and should be deemed medically necessary.[23]

The protections afforded by Section 1557 to LGBQ and TGNCNB people have served as a critical tool in closing the healthcare gap facing many members of these communities. However, under the Proposed Rule, health care providers could roll back their protections or discontinue their compliance efforts that are already underway under the 2016 Regulations, leading to further deleterious healthcare outcomes for this population.

Even with protections under other federal laws and robust legal protections in place in states and localities, discrimination in the healthcare setting remains an unfortunate reality for transgender residents of our localities. The inability to obtain such medical care under the Proposed Rule will further marginalize LGBQ and TGNCNB communities that already experience rampant discrimination in health care settings, inhibiting care-seeking and reducing the availability of culturally competent and affirming health care.[24] Studies consistently show that transgender people face high rates of discrimination when seeking health care. According to the Report of the 2015 U.S. Transgender Survey, which included 27,715 participants, 25% of respondents reported experiencing a problem with their insurance in the past year that was directly related to their gender identity, including being denied health care coverage; and 23% of respondents did not see a doctor when they needed care because of fear of being mistreated.[25]

The risk of adverse health outcomes is compounded by the likelihood that some TGNCNB persons unable to obtain gender-affirming care through their insurance will engage in risky behaviors in order to meet their health needs. For example, sharing used needles for hormone injections place TGNCNB people at greater risk for HIV.[26] Other risky behaviors may include taking a higher hormone dosage than prescribed, purchasing hormones through unsafe underground markets, or injecting dangerous substances, like silicone, to bring one's body in line with the one's innate sense of their gender.[27]

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[23] https://transcendlegal.org/medical-organization-statements

[24] Jaime M. Grant, Lisa A. Mottet, Justin Tanis, National Gay and Lesbian Task Force & National Center for Transgender Equality, *Injustice at Every Turn: A Report of the National Transgender Discrimination Survey*, 6 (2011) https://transequality.org/sites/default/files/docs/resources/NTDS_Report.pdf.

[25] James, S. E., Herman, J. L., Rankin, S., Keisling, M., Mottet, L., & Anafi, M. (2016). *The Report of the 2015 U.S. Transgender Survey*. Washington, DC: National Center for Transgender Equality.

[26] Neumann, M. S., PhD., Finlayson, T. J., PhD., Pitts, N. L., B.S., & Keatley, J., M.S.W. (2017). Comprehensive HIV prevention for transgender persons. *American Journal of Public Health, 107*(2), 207-212.

[27] Sevelius, J. M. (2013). Gender affirmation: A framework for conceptualizing risk behavior among transgender women of color. *Sex Roles, 68*(11-12), 675-689.

Reduced access to mental health services for TGNCNB people resulting from the rule is also concerning given astounding rates of mental health issues among TGNCNB persons that result from interpersonal and systemic discrimination. According to the 2015 U.S. Transgender Survey, 40% of those surveyed had attempted suicide in their lifetime, compared to an estimated 4.6% of the general U.S. population. Thirty-nine percent of respondents experienced serious psychological distress in the month prior to completing the survey (based on the Kessler 6 Psychological Distress Scale) compared to an estimated five percent of the U.S. population.[28] A meta-synthesis of 42 studies of suicidality among transgender populations similarly found lifetime suicidal ideation among 56% of participants, with 29% attempting suicide.[29] In addition, LGBTQ youth disproportionately experience mental and behavioral health challenges compared to their heterosexual/cisgender peers. According to the NYC data, they are more likely to feel sad or hopeless (50% vs. 25%), more likely to attempt suicide (20% vs. 6%), more likely to drink alcohol (35% vs. 20%) and twice as likely to misuse both prescription and illicit drugs (16% vs. 8%).[30] By rolling back civil rights protections of the population already reluctant to seek care, the Proposed Rule could further exacerbate mental health disparities between LGBTQ youth and their heterosexual/cisgender peers as they may face additional barriers in accessing care without meaningful anti-discrimination protections in place.

Ultimately, by eliminating rigorous rules that require federally assisted health programs to respect and promote rights of the individuals that our civil rights laws were intended to support, the Proposed Rule will likely increase these individuals' social isolation and lead to poorer health outcomes. In contrast, a recent study found that state-level policies providing protections to transgender people from discrimination in schools and the ability to change name and gender on identifying documents led to better mental health, less alcohol consumption, and more recent health care utilization among transgender individuals.[31] In addition, gender-affirming care has been shown to improve mental health disorders, including depression, anxiety, and gender dysphoria, and promote overall patient well-being.[32]

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[28] James SE, Herman JL, Rankin S, Keisling M, Mottet L, Anafi M. The Report of the 2015 U.S. Transgender Survey. Washington, DC: National Center for Transgender Equality. 2016. https://www.transequality.org/sites/default/files/docs/USTS-Full-Report-FINAL.PDF.

[29] Adams N, Hitomi M, Moody C. Varied reports of adult transgender suicidality: synthesizing and describing the peer-reviewed and gray literature. *Transgend Health*. 2017; 2(1):60-75.

[30] June 19, 2019 testimony to New York City Council Committees on Youth Services and Mental Health, Addiction and Disabilities, Oversight – Mental Health Services for LGBTQ Youth. Testimony delivered by: Ashe McGovern, J.D. Executive Director, NYC Unity Project, Senior Policy Advisor, LGBTQ Initiatives; Hillary Kunins, MD, MPH, MS, Executive Deputy Commissioner, Division of Mental Hygiene, New York City Department of Health and Mental Hygiene

[31] Steve N. Du Bois et al., *Examining Associations Between State-Level Transgender Policies and Transgender Health*, 3:1 TRANSGENDER HEALTH 220-224 (2018).

[32] *See*, *e.g.*, WPATH, Position Statement (Dec. 21, 2016).

(2) HHS Failed To Account For Population Health Implications

Reduced health care access flowing from the Proposed Rule also has significant population health implications, including in compromising HIV prevention efforts. In 2017, approximately 38,700 people living in the U.S. were diagnosed with HIV, and transgender people received an HIV diagnosis at a rate three times higher than the national average.[33] People at risk for HIV must have access to pre-exposure prophylaxis (PrEP), which reduces the risk of sexual transmission of HIV by well over 90%. For persons with HIV, retention in care not only enables them to live healthy lives, but is a necessary component of ending the epidemic, as persons with an undetectable viral load for six months or longer who remain on treatment cannot transmit HIV through sex. Secretary Azar himself said ensuring PrEP access was "a major step" in the administration's promise to end the HIV epidemic in America by 2030.[34]

Crucial to ensuring everyone's access to HIV prevention and treatment tools, however, is not only the affordability and availability of drugs and healthcare services but also an inclusive care environment. Research has established a negative association between the impact of perceived discrimination and adherence to HIV antiretroviral therapy,[35] underscoring the importance to individual and community health of culturally competent and gender-affirming health care services to persons living with, or at risk of, HIV.

Similarly, delays in accessing testing and treatment for sexually transmitted infections (STIs)—for which many transgender persons are at higher risk as compared to the general population—will compound the already alarming rates of STIs nationally and locally. There were 2.3 million recorded cases of chlamydia, gonorrhea, and syphilis in the U.S. in 2017—the highest number ever on record.[36] Research has shown that STI rates are often highest among populations whose access to health services are the most limited.[37] In a recent study of HIV and STIs among transgender youth ages 15-24, respondents who reported having a provider knowledgeable on transgender health were significantly more likely to report being tested for

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[33]CDC. HIV among transgender people. 2019. Available at www.cdc.gov/hiv/group/gender/transgender/index.html Accessed July 1, 2019.

[34] HHS Press Office, "Trump Administration Secures Historic Donation of Billions of Dollars in HIV Prevention Drugs", May 9, 2019. https://www.hhs.gov/about/news/2019/05/09/trump-administration-secures-historic-donation-of-billions-of-dollars-in-hiv-prevention-drugs.html

[35] Turan, B., Rogers, A. J., Rice, W. S., Atkins, G. C., Cohen, M. H., Wilson, T. E., . . . Weiser, S. D. (2017). Association between perceived discrimination in health care settings and HIV medication adherence: Mediating psychosocial mechanisms. *AIDS and Behavior, 21*(12), 3431-3439.

[36] Centers for Disease Control and Prevention. NCHHSTP Newsroom: 2018 STD Prevention Conference. https://www.cdc.gov/nchhstp/newsroom/2018/2018-std-prevention-conference.html. Published August 28, 2018.

[37] Geisler WM, Chyu L, Kusunoki Y, et al. Health insurance coverage, health-care-seeking behaviors, and genital chlamydia infection prevalence in sexually active young adults. Sex Transm Dis. 2006 Jun;33(6):389-96.

HIV and STIs.[38] Protecting against gender discrimination is thus integral to protecting and promoting community health. Thus, HHS's proposal to reduce health care access by TGNCNB individuals—a group known to have high rates and risk factors for HIV—is irresponsible and entirely counter to the federal initiative to end the HIV epidemic, which would not be possible without prompt diagnosis, use of PrEP, viral suppression, and community support to achieve plan goals. In addition, if people of color are denied or dissuaded from receiving necessary prophylaxis, screening, and treatment for HIV and other STIs, existing disparities will widen—once again, undermining the federal administration's plan to end the HIV epidemic.

(3) HHS Failed To Account For The Cost Savings Attributable to the 2016 Regulations

HHS's cost assessment fails to account for cost-savings attendant to persons receiving timely and appropriate health care and averting the downstream costs of untreated health conditions. With respect to language access mandates, while it is true that a significant investment of resources is required, the failure to do so can be extremely costly to a healthcare system and to the people it serves. Furthermore, it has been shown that medically necessary health care for transgender individuals is cost-saving by reducing the risk of negative "end points," such as depression, suicidality, substance abuse, drug abuse, and HIV.[39] Averted HIV infections from appropriate prophylaxis, testing, and treatment can save tens of millions of dollars in medical costs attendant to HIV, including costs for daily medication and treatment of opportunistic infection, with the medical costs saved by avoiding just one HIV infection in the U.S. being conservatively estimated at $229,800 (2015 USD).[40] And each new HIV infection is a step backwards in the federal plan to end the epidemic.

Moreover, gender-affirming care is cost-effective and, when averaged with a pool of insured people, is typically less expensive than routine procedures, like those connected with childbirth.[41] Employers report very low costs from including coverage for gender-affirming care,

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[38] Sharma, A., Kahle, E., Todd, K., Peitzmeier, S., & Stephenson, R. (2019). Variations in testing for HIV and other sexually transmitted infections across gender identity among transgender youth. *Transgender Health, 4*(1), 46-57.
[39] Padula WV, Heru S, Campbell JD. Societal implications of health insurance coverage for medically necessary services in the U.S. transgender population: a cost-effectiveness analysis. *J Gen Intern Med*. 2016;31(4):394-401.
[40] Oh P, Pascopella L, Barry P, Flood J. A system synthesis of direct costs to treat and manage tuberculosis disease applied to California, 2015. *BMC Research Notes*. 2017;10(434):1-7.
[41] *See* Letter from WPATH to Roger Severino, Director, Office of Civil Rights (OCR), U.S. Department of Health and Human Services (HHS) (Aug. 15, 2017).

with many employers reporting no costs at all.[42] For example, a study on San Francisco's coverage of gender affirming care found that the cost was negligible.[43]

However, public and private health insurance companies exclude transition-related health care from coverage, even in cases when a physician determines them medically necessary for a patient.[44] In the 2015 LGBT Health and Human Services Needs Assessment Survey ("2015 survey"), which examined the nexus between economic insecurity and health for TGNCNB New Yorkers, 61.3% of nearly 4000 respondents reported that their insurance does not cover transition-related care.[45] Based upon multiple studies, Lambda Legal has noted that denials of insurance coverage for medically necessary care can cause serious harm to TGNCNB people, including depression, suicide, or potentially harmful self-surgery or self-medication.[46]

Covering care improves people's life opportunities and capacity for self-sufficiency. Without access to these vital surgical, hormonal or other treatments, fewer TGNCNB individuals will be able to change their identity documents. This inability to have identity documents that match one's gender identity and expression will make employment, travel, housing and other social needs much harder to navigate for TGNCNB individuals.[47] These barriers also contribute to longer term economic instability for a population that experiences poverty at a much higher rate than non-TGNCNB populations. According to the 2015 Survey, TGNCNB respondents were twice as likely to be in poverty than non-transgender respondents.[48]

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[42] Jody L. Herman, Williams Institute, *Costs and Benefits of Providing Transition-Related Health Care Coverage in Employee Health Benefits Plans* (Sept. 2013) https://williamsinstitute.law.ucla.edu/wp-content/uploads/Herman-Cost-Benefit-of-Trans-Health-Benefits-Sept-2013.pdf.

[43] Economic Impact Assessment, Gender Nondiscrimination in Health Insurance, State of California (2012), available at https://transgenderlawcenter.org/wp-content/uploads/2013/04/Economic-Impact-Assessment-Gender-Nondiscrimination-In-Health-Insurance.pdf.

[44] Lambda Legal, "Creating Equal Access to Quality Health Care for Transgender Patients: Transgender Affirming Hospital Policies," Revised May 2016. https://www.lambdalegal.org/sites/default/files/publications/downloads/fs_20160525_transgender-affirming-hospital-policies.pdf May 2016

[45] Somjen Frazer and Erin Howe, "Transgender Health and Economic Insecurity: A report from the 2015 LGBT Health and Human Services Needs Assessment Survey," Empire State Pride Agenda: New York, NY. http://strengthinnumbersconsulting.com/wp-content/uploads/2017/06/TG-health-and-economic-insecurity-report-FINAL.pdf

[46] Lambda Legal, "Creating Equal Access to Quality Health Care for Transgender Patients: Transgender Affirming Hospital Policies," Revised May 2016. https://www.lambdalegal.org/sites/default/files/publications/downloads/fs_20160525_transgender-affirming-hospital-policies.pdf May 2016

[47] Somjen Frazer and Erin Howe, "Transgender Health and Economic Insecurity: A report from the 2015 LGBT Health and Human Services Needs Assessment Survey," Empire State Pride Agenda: New York, NY, p. 8. http://strengthinnumbersconsulting.com/wp-content/uploads/2017/06/TG-health-and-economic-insecurity-report-FINAL.pdf

[48] Somjen Frazer and Erin Howe, "Transgender Health and Economic Insecurity: A report from the 2015 LGBT Health and Human Services Needs Assessment Survey," Empire State Pride Agenda: New York,

Ultimately, improving access to medically necessary treatment of gender dysphoria, including the wide range of services to bring a transgender person's body into congruence with their gender, will improve an array of health and economic outcomes for TGNCNB persons.

(4) HHS Failed To Account For The Administrative Burdens And Significant The Proposed Rule Will Impose On States And Cities

HHS is silent regarding the negative financial impact the Proposed Rule will have on state and local health departments. In fact, additional human and financial resources will be needed for community outreach and other programming to combat increases in LGBQ and TGNCNB-related stigma and discrimination. Moreover, public health clinics may have increases in patient volume and in uncompensated care. And this is to say nothing of the resources required to counter any increases in HIV, STIs, or other diseases resulting from the Proposed Rule.

HHS HAS NOT COMPLIED WITH EXECUTIVE ORDER 13132, THE TREASURY GENERAL APPROPRIATIONS ACT, OR EXECUTIVE ORDER 12866.

Executive Order 13132

As explained above, HHS's failure to consider all aspects of the problem – specifically, the significant costs that the Proposed Rule would shift to state and local governments – violates the APA. In addition, HHS has violated the APA by failing to consider and evaluate the federal implications. The requirement that HHS consider the costs to state and local governments and federalism implications associated with the Proposed Rule violates not only the APA but also Section 6 of Executive Order 13132, which mandates that:

> no agency shall promulgate any regulation that has federalism implications, that imposes substantial direct compliance costs on State and local governments, . . . unless (1) funds necessary to pay the direct costs incurred by the State and local governments in complying with the regulation are provided by the Federal Government; or (2) the agency, prior to the formal promulgation of the regulation, (a) consulted with State and local officials early in the process of developing the proposed regulation; (b) in a separately identified portion of the preamble to the regulation as it is to be issued in the Federal Register, provides to the Director of the Office of Management and Budget (OMB) a federalism summary impact statement, which consists of a description of the extent of the agency's prior consultation with State and local officials, a summary of the nature of their concerns and the agency's position supporting the need to issue the regulation,

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NY. http://strengthinnumbersconsulting.com/wp-content/uploads/2017/06/TG-health-and-economic-insecurity-report-FINAL.pdf

and a statement of the extent to which the concerns of State and local officials have been met; and (c) makes available to the [OMB] Director any written communications submitted to the agency by State and local officials.

Exec. Order No. 13,132, 64 Fed. Reg. 43,255 (Aug. 10, 1999)

HHS ignores this requirement, stating in conclusory fashion and without data, analysis or any other evidentiary support, that the Proposed Rule "does not have federalism implication and does not impose substantial direct compliance costs on State and local governments."[49] HHS is incorrect.

As explained above, the Proposed Rule will require states and local governments to expend additional human and financial resources for community outreach and other programming to combat increases in LGBQ and TGNCNB-related stigma and discrimination. Moreover, public health clinics may have increases in patient volume and in uncompensated care, and resources would be required to counter any increases in HIV, STIs, or other diseases resulting from the Proposed Rule. This could force state and local governments to make significant expenditures to protect the health and well-being of their residents. *See id.*

Moreover, the Proposed Rule has federalism implications. Policies and regulations that have federal implications include those that have substantial direct effects on States and local governments, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.[50]

In addition to violating the federal civil rights laws incorporated into Section 1557, the Proposed Rule also runs counter to the U.S. Constitution and other federal laws. Specifically, the proposal to permit health care insurance companies and providers to deprive persons of health care coverage and services due to their race, national origin, color, sex and disability status is a violation of the Equal Protection Clause of the Fourteenth Amendment. Further, the proposal to remove enforcement mechanisms through which persons may challenge a discriminatory denial of health care services and insurance is a violation the Due Process Clause of the Fifth and Fourteenth Amendments. Finally, HHS's proposal to allow providers to deprive certain persons of medical care, despite the existence of emergency circumstances, is a direct violation of the Emergency Medical Treatment & Labor Act.[51]

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[49] Proposed Rule at p. 20592
[50] Exec. Order No. 13,132, 64 Fed. Reg. 43,255 (Aug. 10, 1999).
[51] 42 U.S.C. § 1395dd (requiring hospitals that have an emergency room or department to provide to anyone requesting treatment an appropriate medical screening to determine whether an emergency medical condition exists, and to stabilize the condition or, if medically warranted, to transfer the person to another facility).

Notably, pursuant to Section 1557, Congress explicitly specified that the statute may not be construed to invalidate or limit the rights, remedies, procedures, or legal standards available to individuals aggrieved under Title VI, Title VII, or Title IX, in part, or to supersede State laws that provide additional protections against discrimination on any basis set forth in Section 1557.[52] However, as set forth above, the Proposed Rule seeks to set new regulations implementing Section 1557 that would ignore the very mandates within the statute. In addition, the protections under Section 1557 are similar to those available in other states and localities, including New York State Human Rights Law, New York City Human Rights Law, and Chicago Human Rights Law.

For example, both New York State and New York City have a Human Rights Law prohibiting discrimination on the basis of gender identity and gender expression.[53] Chicago's Human Rights Ordinance likewise prohibits discrimination on the basis of gender identity and gender expression. *See* Chicago Mun.Code § 2-160-010 *et seq*. And in 2016, the NYC Commission on Human Rights published legal enforcement guidance explicitly prohibiting employers from offering employee benefits that discriminate on the basis of gender identity, and NYC laws prohibit discrimination in public accommodations, health care, and other settings.[54]

The Signatories are committed to prohibiting unlawful discrimination in all of our local programs, including the administration of health insurance which serves the fundamental purpose of ensuring that vital health care services are broadly available to all individuals throughout the country. In addition, NYC upholds a sexual and reproductive justice framework in city programs and services. We recognize that sexual and reproductive justice exists only when all people have the power and resources to make healthy decisions about their bodies, sexuality, and reproduction. This framework includes the right to: choose to have or not have children; choose the conditions under which to give birth or create a family; care for one's children with necessary social support in a safe and healthy environment; and control one's own body and self-expression, free from any form of sexual, reproductive, or gender based oppression.

The Proposed Rule poses a serious impediment to these protections by giving license to health insurers and providers to discriminate against our residents by excluding coverage of medically necessary care in violation of Section 1557 and federal civil rights laws. Due to the compliance costs and federalism concerns implicated by the Proposed Rule, a federalism summary impact statement should be provided.

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[52] 42 U.S.C. 18116(b).
[53] NYS Human Rights Law § 296(2)(a) (prohibiting health care entities and providers from withholding or denying health care services to any person because of their sexual orientation, gender identity or expression, or the marital status of any person); N.Y.C. Admin. Code § 8-107.
[54] 10 N.Y.C.R.R. § 405.7 (c)(2) (prohibiting discrimination against patients in NYC health care facilities based on sexual orientation, gender, gender identity, and marital status).

The Treasury General Appropriations Act of 1999

HHS does not address the affirmative obligations imposed on it by the Treasury General Appropriations Act of 1999. That Act provides that:

> before implementing policies and regulations that may affect family well-being, an agency shall assess whether the action — (1) strengthens or erodes the stability or safety of the family and, particularly, the marital commitment; (2) strengthens or erodes the authority and rights of parents in the education, nurture, and supervision of their children; (3) helps the family perform its functions, or substitutes governmental activity for the function; (4) increases or decreases disposable income or poverty of families and children; (5) is warranted because the proposed benefits justify the financial impact on the family; (6) may be carried out by State or local government or by the family; and (7) establishes an implicit or explicit policy concerning the relationship between the behavior and personal responsibility of youth, and the norms of society.

Pub. L. No. 105–277, §654(c)(1-7), 112 Stat. 2681- 528-30 (1998).

Because HHS has not assessed the impact of the Proposed Rule on family well-being in any fashion, the Proposed Rule should not be finalized.

Executive Order 12866

Finally, HHS's assertion that the Proposed Rule is compliant with the Regulatory Flexibility Act is incorrect and incomplete. For the reasons discussed above, contrary to HHS's analysis, implementation of the Proposed Rule would impose an administrative and financial burden on states and localities. *See, supra*, at p. 31.

For all of the reasons set forth above, the Signatories object to the Proposed Rule and call on HHS to withdraw it.

Sincerely,

City of New York, NY

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EXHIBIT 11

Comments by the National Center for Transgender Equality

August 13, 2019

U.S. Department of Health and Human Services
Office for Civil Rights
Hubert H. Humphrey Building, Room 509F
200 Independence Avenue SW
Washington, DC 20201

Submitted via www.regulations.gov

RE: Nondiscrimination in Health and Health Education Programs or Activities (RIN 0945-AA11)

To Whom It May Concern:

The National Center for Transgender Equality (NCTE) submits the following comments to express our strong opposition to the Department of Health and Human Services' proposal to roll back life-saving nondiscrimination protection under Section 1557.

Founded in 2003, NCTE is one of the nation's leading social justice organizations working for life-saving change for the nearly two million transgender people in the United States and their families. Over our years of advocacy, we have time and again seen the devastating impact that discrimination in health care settings has on transgender people and their loved ones. Our experience has shown us that discrimination against transgender people in health care is a pervasive problem that has prevented many transgender people from accessing the care they need—whether it comes in the form of being turned away from a doctor's office or emergency room, being denied coverage for necessary preventive screenings or treatments that are covered for other individuals, or being harassed and degraded simply because of being transgender. The section 1557 implementing rule that the Department adopted in 2016 ("2016 Rule") provides vitally important clarifications of the law that have been widely embraced by many covered entities and have helped ensure access to lifesaving care. The Proposed Rule, in contrast, runs directly counter to the law it aims to implement, fails to provide a reasoned justification for numerous regulatory rescissions and threatens to exacerbate the health disparities that transgender people and other patient populations face. As this comment explains, the Department has failed to consider the potential costs of the Proposed Rule to the health, lives, and dignity of patients, as well as economic costs that could run into the hundreds of millions or billions of dollars from excess morbidity and mortality alone. The Department should not finalize the Proposed Rule.

Our comment is presented in the following sections:

- Part 1: Health care discrimination against transgender people
- Part 2: The proposed changes are not supported by a reasoned analysis
- Part 3: Improper addition of exemptions into Section 1557
- Part 4: Flawed analysis of the regulation's impact

PART 1: HEALTH CARE DISCRIMINATION AGAINST TRANSGENDER PEOPLE

I. The Proposed Rule will exacerbate the health disparities that transgender people face.

a. Like anyone else, transgender people need access to medically necessary care.

An estimated 0.6% of the U.S. adult population is transgender, representing nearly 2 million Americans.[1] The medical and scientific community overwhelmingly recognizes that a person's innate experience of gender is an inherent aspect of the human experience for all people, including transgender people.[2] For example, the American Psychological Association states that having "deeply felt, inherent" gender identity that is different from the gender one was thought to be at birth is part of "healthy and normative" range of variation in human development found across cultures and across history.[3] The Department has previously recognized that "variations in gender identity and expression are part of the normal spectrum of human diversity."[4] Many, though not all, transgender people experience a medical condition known as gender dysphoria. Gender dysphoria is a serious medical condition that is codified in the American Psychiatric Association's *Diagnostic and Statistical Manual of Mental Disorders* (DSM 5), which defines it as clinically significant distress or impairment related to an incongruence between one's experienced gender and the gender one was thought to be at birth.[5]

Like anyone else, transgender people need preventive care to stay healthy and acute care when they become sick or injured. Some may also need medical care to treat gender dysphoria. Under the treatment protocol widely accepted by the medical community, medically necessary treatment for gender dysphoria may require steps to help an individual transition from living as one gender to another.[6] This treatment, sometimes referred to as "transition-related care," may include

[1] Andrew R. Flores et al., *How Many Adults Identify as Transgender in the United States?* (2016), http://williamsinstitute.law.ucla.edu/wp-content/uploads/How-Many-Adults-Identify-as-Transgender-in-the-United-States.pdf. *See also* Jody L. Herman et al. *Age of Individuals who Identify as Transgender in the United States* (2017), https://williamsinstitute.law.ucla.edu/wp-content/uploads/TransAgeReport.pdf (estimating that 0.7% of people in the United States between the ages of 13 and 17, or 150,000 adolescents, are transgender).

[2] *See, e.g.*, Am. Psychological Ass'n, *Guidelines for Psychological Practice with Transgender and Gender Nonconforming People*, 70 AMERICAN PSYCHOLOGIST 832, 834-35 (2015), https://www.apa.org/practice/guidelines/transgender.pdf; Brief of American Academy of Pediatrics, American Psychiatric Association, American College of Physicians, and 17 Additional Medical and Mental Health Organizations in Support of Respondent, *G. G. v. Gloucester County Sch. Bd.*, No. 16-274 8–9 (Sup. Ct. *filed* March 2, 2017) (affirming that "[e]veryone—whether they are transgender or cisgender—develops awareness of their gender identity along a 'pathway'" with typical stages and that transgender identity is a normal variation of this development); Am. Acad. of Pediatrics, *Ensuring Comprehensive Care and Support for Transgender and Gender-Diverse Children and Adolescents*, PEDIATRICS Oct 2018, 142 (4) e20182162; World Prof. Ass'n for Transgender Health, *Standards of Care for the Health of Transsexual, Transgender, and Gender Nonconforming People* 16 (7th ed. 2011), https://www.wpath.org/publications/soc.

[3] Am. Psychological Ass'n, Guidelines for Psychological Practice with Transgender and Gender Nonconforming People, *e*, 70(9):832, 834-35 (2015).

[4] Substance Abuse & Mental Health Servs., *Ending Conversion Therapy: Supporting and Affirming LGBTQ Youth* 1 (2015), https://store.samhsa.gov/shin/content/SMA15-4928/SMA15-4928.pdf.

[5] Am. Psychiatric Ass'n, *Diagnostic and Statistical Manual of Mental Disorders* 452 (5th ed. 2013).

[6] *See generally* World Prof. Ass'n for Transgender Health, *supra* note 2; Wylie C. Hembree et al., *Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline*, 102

counseling, hormone therapy, and/or a variety of possible surgical treatments, depending on the individualized needs of each patient.[7] It is the overwhelming consensus among major medical organizations—including the American Medical Association,[8] the American College of Physicians,[9] the American Psychological Association,[10] the American Psychiatric Association,[11] the American Academy of Family Physicians,[12] the Endocrine Society,[13] the American College of Obstetricians and Gynecologists,[14] the American Academy of Pediatrics,[15] and the World Professional Association for Transgender Health[16]—that transition-related treatments are medically necessary, effective, and safe when clinically indicated to alleviate gender dysphoria. For example, the American Psychiatric Association "[a]dvocates for removal of barriers to care…for gender transition treatment," emphasizing that "[s]ignificant and long-standing medical and psychiatric literature exists that demonstrates clear benefits of medical and surgical interventions to gender variant individuals seeking transition" and "[a]ccess to medical care (both medical and surgical) positively impacts the mental health of transgender and gender variant individuals."[17] Numerous studies and meta-analyses have demonstrated the significant benefits of

THE JOURNAL OF CLINICAL ENDOCRINOLOGY & METABOLISM 3869 (2017). *See also* Am. Medical Ass'n, *AMA Policies on GLBT Issues, Patient-Centered Policy H-185.950, Removing Financial Barriers to Care for Transgender Patients* (2008), http://www.imatyfa.org/assets/ama122.pdf (recognizing WPATH *Standards* as "internationally accepted"); Am. Psychiatric Ass'n, *Position Statement on Discrimination Against Transgender and Gender Variant Individuals* (2012), http://www.dhcs.ca.gov/services/MH/Documents/2013_04_AC_06d_APA_ps2012_Transgen_Disc.pdf (citing WPATH *Standards*); Am. Psychological Ass'n, *Policy on Transgender, Gender Identity & Gender Expression Non-Discrimination* (2008), http://www.apa.org/about/policy/transgender.aspx (same).

[7] *See* World Prof. Ass'n for Transgender Health, *supra* note 2 at 16.

[8] Am. Medical Ass'n, *supra* note 6.

[9] Am. College of Physicians, *Lesbian, Gay, Bisexual and Transgender Health Disparities: A Policy Position Paper from the American College of Physicians*, 163 ANNALS OF INTERNAL MEDICINE 135, 140 (2015).

[10] Am. Psychological Ass'n, *supra* note 6.

[11] Am. Psychiatric Ass'n, *supra* note 6.

[12] Am. Acad. of Family Physicians, *Resolution No. 1004: Transgender Care* (2012), https://www.aafp.org/dam/AAFP/documents/about_us/special_constituencies/2012RCAR_Advocacy.pdf.

[13] Hembree et al., *supra* note 6.

[14] Am. College of Obstetricians & Gynecologists, *Committee Opinion No. 512: Health Care for Transgender Individuals*, 118 OBSTETRICS & GYNECOLOGY 1454 (2011), https://www.acog.org/Clinical-Guidance-and-Publications/Committee-Opinions/Committee-on-Health-Care-for-Underserved-Women/Health-Care-for-Transgender-Individuals.

[15] Am. Acad. of Pediatrics, *supra* note 2.

[16] World Prof. Ass'n for Transgender Health, *supra* note 2.

[17] Am. Psychiatric Ass'n, *supra* note 6.

transition-related care in the treatment of gender dysphoria.[18] Indeed, transition-related treatments are the only treatments that have been demonstrated to be effective in treating gender dysphoria.[19]

b. Transgender people face widespread and pervasive discrimination in health care.

Due to longstanding and pervasive social stigma, many transgender people have struggled to get access to medically necessary care—including care recommended to treat gender dysphoria, as well as medical care for unrelated conditions. Numerous studies have documented the widespread and pervasive discrimination experienced by transgender people and their families in the health care system. For example, the 2015 U.S. Transgender Survey (USTS), a national study of nearly 28,000 transgender adults in the United States, found that:

- Just in the year prior to taking the survey, one-third (33%) of respondents who saw *any health care provider* during that year were turned away because of being transgender, denied treatment, physically or sexually assaulted in a health care setting, or faced another form of mistreatment or discrimination due to being transgender.[20]
- In the year prior to taking the survey, nearly one-quarter (22%) of respondents who visited a *drug or alcohol treatment program* where staff thought or knew they were transgender were denied equal treatment or service, verbally harassed, or physically assaulted there due to being transgender.[21]
- In the year prior to taking the survey, 14% of respondents who visited a *nursing home or extended care facility* where staff thought or knew they were transgender were denied equal treatment or service, verbally harassed, or physically assaulted there due to being transgender.[22]
- In the year prior to taking the survey, one-quarter (25%) of respondents *experienced a problem with their health insurance* related to being transgender. This included being

[18] *See, e.g.*, Ashli A. Owen-Smith, et al., *Association Between Gender Confirmation Treatments and Perceived Gender Congruence, Body Image Satisfaction, and Mental Health in a Cohort of Transgender Individuals*. J SEXUAL MEDICINE (Jan. 17 2018); Gemma L. Witcomb et al., *Levels of Depression in Transgender People and its Predictors: Results of a Large Matched Control Study with Transgender People Accessing Clinical Services*, J. AFFECTIVE DISORDERS (Feb. 2018) Cecilia Dhejne et al., *Mental Health and Gender Dysphoria: A Review of the Literature*, 28 INT'L REV. PSYCHIATRY 44 (2016); William Byne et al., *Report of the American Psychiatric Association Task Force on Treatment of Gender Identity Disorder*, 41 ARCHIVES OF SEXUAL BEHAVIOR 759 (2012); Marco Colizzi, Rosalia Costa, & Orlando Todarello, *Transsexual Patients' Psychiatric Comorbidity and Positive Effect of Cross-Sex Hormonal Treatment on Mental Health: Results from a Longitudinal Study*, 39 PSYCHONEUROENDOCRINOLOGY 65 (2014); Audrey Gorin-Lazard et al., *Hormonal Therapy is Associated with Better Self-Esteem, Mood, and Quality of Life in Transsexuals*, 201 J. NERVOUS & MENTAL DISORDERS 996 (2013); M. Hussan Murad et al., *Hormonal Therapy and Sex Reassignment: A Systematic Review and Meta-Analysis of Quality of Life and Psychosocial Outcomes*, 72 CLINICAL ENDOCRINOLOGY 214 (2010); Griet De Cuypere et al., *Sexual and Physical Health After Sex Reassignment Surgery*, 34 ARCHIVES OF SEXUAL BEHAVIOR 679 (2005); Giuloio Garaffa, Nim A. Christopher, & David J. Ralph, *Total Phallic Reconstruction in Female-to-Male Transsexuals*, 57 EUROPEAN UROLOGY 715 (2010); Caroline Klein & Boris B. Gorzalka, *Sexual Functioning in Transsexuals Following Hormone Therapy and Genital Surgery: A Review*, 6 J. SEXUAL MEDICINE 2922 (2009).
[19] *See, e.g.,* Substance Abuse & Mental Health Servs., *supra* note 4.
[20] Sandy E. James et al., *The Report of the 2015 U.S. Transgender Survey* 96–97 (2016), www.ustranssurvey.org/report.
[21] *Id.* at 216.
[22] *Id.* at 219.

denied coverage for treatments for gender dysphoria as well as being denied coverage for a range of unrelated conditions simply because they are transgender.[23]

The 2015 USTS also revealed patterns of marked health disparities affecting respondents. Respondents were approximately five times more likely than the general population to have been diagnosed with HIV, with elevated rates among people of color and in particular among Black transgender women, who were over 60 times more likely to be living with HIV than the general population.[24] Standard questions based on the K-6 Kessler Psychological Distress Scale revealed that transgender respondents were approximately eight times more likely than the general population to have experienced serious psychological distress in the month prior to taking the survey.[25] Further, respondents were nearly twelve times more likely to have attempted suicide in the previous year than the general population.[26] Rates of suicide attempts and psychological distress were particularly high among respondents who had faced barriers to accessing medical care and anti-transgender discrimination in health care and other settings.

Similarly, a nationally representative 2017 study found that transgender respondents faced high rates of discrimination in health care settings.[27] Out of those who had visited a doctor or health care provider **in the previous year**:

- Nearly one-third (29%) reported that a health care provider refused to see them because of their actual or perceived gender identity.
- One in eight (12%) said that a health care provider refused to provide them with care related to gender dysphoria.
- More than one in five (21%) said that a health care provider used harsh or abusive language when treating them.
- Nearly one-third (29%) experienced unwanted physical contact or sexual assault by a health care provider.

Other studies have also found widespread discrimination against transgender people in public settings, including health care.[28]

[23] *Id.* at 95.
[24] *Id.* at 122.
[25] *Id.* at 105.
[26] *Id.* at 112.
[27] Shabab Ahmed Mirza & Caitlin Rooney, *Discrimination Prevents LGBTQ People from Accessing Health Care* (2016), https://www.americanprogress.org/issues/lgbt/news/2018/01/18/445130/discrimination-prevents-lgbtq-people-accessing-health-care.
[28] *See, e.g.*, Jessica Xavier et al., *Transgender Health Care Access in Virginia: A Qualitative Study*, 14 INT'L J. OF TRANSGENDERISM, 3 (2013), https://www.tandfonline.com/doi/abs/10.1080/15532739.2013.689513; Jessica Xavier et al., *The Health, Health-Related Needs, and Lifecourse Experiences of Transgender Virginians: Virginia Transgender Health Initiative Study Statewide Survey Report* (2017), http://www.vdh.state.va.us/epidemiology/DiseasePrevention/documents/pdf/THISFINALREPORTVol1.pdf.

II. Personal experiences of transgender people further illustrate the extent of discrimination.

Quantitative data regarding discrimination against transgender people in health care is supplemented by numerous personal stories of transgender people and their loved ones. These include stories included as part of the record in the Department's rulemaking for the 2016 Rule, as well as stories that have been submitted in comments for the current Proposed Rule.

a. The record for the 2015 Proposed Rule includes numerous stories of discrimination.

Approximately 25,000 public comments, including stories from many transgender people and their loved ones, informed the 2016 Rule.[29] The following are only a sample of stories collected and submitted by the National Center for Transgender Equality.[30]

A transgender man hospitalized in a gynecological unit for treatment uterine cancer was met with hostility and disrespect:

> Even though I was not there for anything trans related, several nurses repeatedly asked me about my "sex change operation." They went out of their way to remind me that I was a man on the gynecological unit and my pages for nurses often went answered last. I had one nurse ask me incredibly personal questions related to being trans hours after I was wheeled out of surgery. It was degrading, triggering, and wholly unwelcomed. I had to deal with this all while recovering from cancer. No one could see me as a person; they saw me as an intruder.

Another transgender man described being exploited by an endocrinologist while recovering from a traumatic brain injury:

> [The endocrinologist] massaged my breasts…for a long time—not for any medical reason, but because he was curious to feel how testosterone and binding had changed my chest. He did not ask consent for this. Then, he asked me to describe my clitoris to him in great detail. After I did…he asked me to remove my pants and underwear so that he could inspect my clitoris and see my vagina.

Some commenters described how discrimination led to delayed and substandard care:

> [Discrimination has] resulted in repeated medical errors that would have been fatal if I hadn't halted them and asked what was in the syringe or reminded doctors about what I was there for. I've had unrelated conditions misdiagnosed because they were too distracted by my trans issues…. The quality of care I had when I did manage to

[29] Nondiscrimination in Health Programs and Activities, 81 Fed. Reg. 31376, 31376 (May 18, 2016) [hereinafter 2016 Rule].

[30] A few of the following stores were included in the comment submitted by and on behalf of NCTE itself. Nat'l Ctr. for Transgender Equality Comment on Nondiscrimination in Health Programs and Activities (Nov. 9, 2015). The remainder were shared with NCTE specifically for the 2013 and 2015 public comment periods and submitted as individual comments. Personal stories have been edited lightly for grammar and punctuation only.

> get care at all was abysmal…. I should not have had to wait for a tumor that almost killed me to get the treatment I needed all along.

Many commenters described being repeatedly turned away by primary care providers:

> I found it very difficult to find doctors that would treat me; they claimed religious reason[s]. When they did they were hateful and mean in their treatment even to [the] extent of embarrassing me in front of others or the staff.

At least one commenter reported that barriers related to health care discrimination led them to move across the country, causing significant personal and financial hardship:

> I had to move 2,000 miles to have access to trans-related healthcare. That should be completely unacceptable in the 21st century.

In some cases, commenters reported providers abruptly refusing treatment in the middle of an appointment:

> I have been refused health care by transphobic physicians, and had a nurse practitioner literally rush out of the room and leave me alone in the office until I eventually understood she wasn't coming back and had to leave.

Some reported being turned away when seeking urgent or emergency care:

> I was once denied entry to a hospital after an accident because I "didn't look like the gender on my ID, and they thought I'd stolen it." I'm transgendered, living in stealth for the past eleven years. Think about that.

Many transgender people shared accounts of health providers who mocked, dismissed, and invalidated their gender identity. For example, one transgender man said:

> While at the emergency room, I was made fun of by staff and nurses after telling them I was on testosterone. I heard them in the hallway laughing at me for having [breasts] and calling me a 'girl/boy.'"

Commenters described how discrimination in care led to serious medical complications:

> As a transgender individual, I have personally experienced discrimination at the hands of medical professionals that has resulted in permanent damage being done to my heart. Due to entrenched bigotry in the field of urology I was not able to get proper medical care for intense testicle pain until that pain, which was a symptom of a serious issue in need of treatment, had gone untreated to the point that [it] caused numerous blood clots to form in [my heart]. I kept having the very same experience with urologists over and over again. As soon as they perceived that I was gender variant, they would rush me out of their offices and ask me to never return…. The suffering that I endured was completely unnecessary and resulted in

> my having become permanently disabled, forced to lose the only job I had been able to get after graduating from college and having to endure painful angina for the rest of my life, so that the "philosophical beliefs" of some conservative physicians could be shielded from the impact of having to cut away diseased tissue from a transgender woman…. There is never a good excuse for discrimination in health care. Not when said discrimination results both in needless suffering and permanent health care issues that amount to wasted lives and resources. Please outlaw the practice of discrimination against not only members of the transgender community, but against everyone. Personal beliefs are sacred, but a life is even more so.

Some commenters reported experiencing multiple forms of discrimination in both primary and hospital care:

> It took me almost 6 years to find a primary care physician who would even treat me…. Even though I am now legally female, during my last hospital stay in 2010, I was shuffled out of a normal room and put in isolation all the way at the end of the ward. I was also consistently and inappropriately gendered with the wrong pronouns and treated with disdain and contempt by the hospital staff, from doctors to the food service employees. Frankly, I would rather die than go into a hospital again.

Another commenter similarly reported:

> As a transgender person in a rural and poor region of the US, I have struggled my entire life to attain basic healthcare…and am forced to import and monitor my own medication. Doctors I speak to will…sometimes outright deny all care completely when I disclose my gender. In addition, it is far too common for healthcare workers to misgender, use incorrect names and inappropriate language, and violate patient privacy when dealing with trans patients – something I have witnessed as both a patient and a healthcare worker.

Another individual illustrates how discriminatory treatment leads many transgender people to avoid seeking necessary care:

> Multiple medical professionals have misgendered me, denied to me that I was transgender or tried to persuade me that my trans identity was just a misdiagnosis of something else, have made jokes at my expense in front of me and behind my back, and have made me feel physically unsafe. I no longer see male medical professionals due to concerns for my physical safety. I often do not seek medical attention when it is needed because I'm afraid of what harassment or discrimination I may experience in a hospital, clinic, or office.

One commenter described how they had been delaying seeking care for a medical concern for months because of their fears because on past experiences of bias:

> I need to go to the hospital right now. Actually, I needed to go several months ago… My specialist recently decided to stop treating me without giving an explanation. Each day I assess how bad it's gotten. Is my life at risk today? How can I decrease the likelihood of fatality? ... You would think I would just bite the bullet and go to the hospital if it were that bad, right? Well, what if going to the hospital can actually make you worse than you are before. Malpractice, negligence, and harassment that trans people experience from bigoted staff, nurses, and doctors can make every trip to the doctor a nightmare. If you're trans, you know that sometimes going to the doctor can be just as deadly as staying home. … I desperately need treatment…. will I get a judgmental doctor who withholds vital information, an angry nurse who gives the wrong instructions, an assistant who "accidentally" mixes up medical doses? Will I become the freak show of the ER, paraded in front of medical students and visited by any number of staff who aren't on my medical team, while my actual medical care takes a backseat to irrelevant question about my genitals? Without access to nondiscriminatory health care my life will be much shorter and much more painful.

Another commenter described how repeated negative experiences made them reluctant to seek care for an eating disorder:

> Being transgender and trying to go into treatment while being treated unfairly and discriminated against made the experience very traumatic to me. I have relapsed countless time because they never actually focused on my anorexia…it makes me afraid to try and seek help again in fear of discrimination.

Intersex individuals also described similar experiences of discrimination:

> I was born intersexed….I am not a freak, I am not sub-human, but a person who struggles daily to live a normal healthy life. Even though I have medical insurance from the market place, it does me no good. It won't cover my health related care I need.... I fear going to the doctor for many reasons. Mostly cost, and the way I am treated, such as a lab rat to be toyed with. This IS MY health, and my life. I hurt no one by being me. I ask for our government to make these changes and make them soon. This country needs to revise how it thinks in terms of transgender health care. Medical care shouldn't be available to a select few, it SHOULD AND NEEDS TO BE AVAILABLE TO ALL!

Some commenters reporting being denied discrimination from providers based on sex coding:

> I am a transgender woman…Despite all my ID and presentation now being female, I have been denied a blood test at a lab as being inappropriate for my gender. Despite having my [medical history] in his hand, a dermatologist asked me to my face if I was "a man, or a woman?" A dentist recently referred to me as "him." I went to an emergency room recently and despite my ID, etc. [listing me as female] they admitted me as male.

Transgender people also shared stories about the impact of discriminatory insurance practices:

> I have been trying to get top surgery for over two years now. I applied for my current job in part because it had an insurance provider that said it covered trans-related surgery. After talking to my surgeon, and waiting 5 months for a response from my insurance company, I was told that they did not cover "sex change surgery" under any circumstances. I then picked up overtime at my job and a second, part-time job to try and save money for my surgery, working 60 hours a week on average. I finally have enough money for my top surgery, but I now have to delay my wedding ceremony for another year. The money I saved could have been used for that if my insurance company had not had "trans-related care" as a specific exclusion on my policy.

For many transgender people, lack of insurance coverage means that they need to forgo medically necessary care, often leading to avoidable consequences to their health:

> I bind my chest every day. Everyone will tell you that binding more than 8 hour a day is bad for you and can lead to many health problems, but since I work 12 hours a day 5 days a week and my chest is a DD I have to keep the binder on. If surgery were more affordable or covered by insurance I would have had top surgery by now instead of suffering from degenerative disc disease in my upper spine, arthritis in my shoulders, nerve damage, and a disc that occasionally herniates in my lower back- causing my sciatic nerve on the left side of my body to get pinched and renders me paralyzed with pain as a direct cause from binding. I'll miss at least 3 months of work a year from this…. I just really wish I would have been able to have the option to never know the pain from binding in the first place.

Stories also reflected the harmful consequences that denial of care can have on individual's mental health:

> I have health care that denies me trans-related health care. Due to this, I have cost my insurance company more money due to need for therapy/mental health services. Not having surgery and hormones covered by insurance causes me to require mental health/physical health treatment not otherwise needed if I did receive coverage…. When I receive coverage for surgery and hormones, I will be better equipped to overcome my mental/emotional health challenges and be a more productive member of society.

As shown in the following four stories, many transgender people also face denials of coverage because of the sex recorded on their insurance records or the sex they were assigned at birth, a practice that the 2016 Rule went on to prohibit:

> I have paid out of pocket for all of my hormone treatment because my insurance only covers testosterone injections for those who are legally recognized as male.

> [In my state] I cannot be legally male until I've had at least one gender reassignment surgery. I have been saving for surgery for a year and a half, and I'm still a few thousand dollars away from being able to afford the cheapest surgery offered. I feel like I might as well not have health insurance with the type of coverage I am getting, and I don't have many options for coverage due to my gender identity.
>
> When I was in college, I had my health insurance list me as male, and they denied coverage for my routine pap smear and a gynecological prescription due to my gender. I learned at that point that if I wanted to have my health insurance cover me, I needed to keep my ID at work as female, and so despite having lived for 8 years as male (and having been on testosterone for 6, having had chest surgery 5 years ago), all of my official documentation (driver's license, passport, birth certificate, teacher's license) still list me as female. I'm afraid to deal with bureaucracies for fear that I will have to out myself to every single person I speak with.
>
> I've been having difficulty regulating my testosterone levels, migraines, and chronic pelvic pain. Because of this, I've been trying to have a hysterectomy for over a year. I picked out a plan from Healthcare.gov that I thought covered it. Turns out that while the company covers it in some cases, my specific plan does not. I changed my gender on my health insurance [back] from 'M' to 'F' because that is the only way they said it would be covered. After submitting all the documentation for a pre-authorization for the surgery, my insurance said that not only would they not cover my surgery, but they also wouldn't be covering my testosterone anymore since females don't need testosterone. Now I'm forced to drive over 2 hours to get government-subsidized testosterone instead of going to my very friendly and accepting endocrinologist locally.
>
> I am a transgender man …, and I need regular Pap smears. I had a previous insurance company deny me coverage because I was registered with them as male and according to them, a pap smear is only for women. … [Discrimination] prevents me from obtaining legal documentation that aligns all of my gender markers AND keeping insurance that allows me to continue to receive gynecological care that I might need.

Some commenters reported facing discrimination from both providers and insurance companies, forcing them to expend time and resources finding new providers and to pay substantial out of pocket costs:

> When I came out to my primary care doctor I was told they do not treat "transgenders." I had to find another doctor… I have paid for all of my treatment and medication out of pocket because my insurance does not cover anything. I have done everything according to the "rules" but find treatment denied and coverage non-existent despite the science that supports the need for appropriate care.

Some commenters described experiencing delays in care and psychological stress due to coverage denials for prescribed treatments:

> While receiving medical treatment for transgender related issues, I was denied previously approved hormone therapy coverage… for the simple reason that I am transgender. This caused an enormous amount of stress, worry, and anxiety while my spouse and I, along with my doctor, went through the legal process of appeals to get the medication approved again. We even had to go so far as to send in a legal letter, from our state's insurance commissioner.

Some reported repeated difficulties in obtaining equal benefits through employee health plans, incurring major unanticipated out-of-pocket costs:

> Before I started transitioning, I never worried that a visit to the doctor would cost me more than my copay….After I started transitioning, I encountered a much bleaker picture. Any time any treatment I receive is coded to reflect that I am transgender, it is categorically denied by my insurance… I pay three times as much as [cisgender women]….I could be denied coverage if my insurance provider decides that [a treatment] is somehow related to me being transgender. Many of us go through all of that [discriminatory treatment] while also paying for health insurance, and the irony is not lost on us.
>
> I have gone back and forth with my employer's HR department about why they chose to exclude all coverage related to gender dysphoria. First, they told me that it was to save on costs. When I asked them to tell me how much they were saving, they told me that it wasn't really about costs, but about giving the majority of employees the best health care service they could. As I kept confronting them about their reasons, their reasons kept changing.

Some parents expressed fear about the potential impact of insurance discrimination on the health and safety of their children:

> My employer's health insurance has an exclusion on ALL services related to a diagnosis of gender dysphoria, including mental health services, hormone therapy, and surgeries. This means that when my [child] was suffering from suicidal ideation, [they] would not have received coverage for seeing [a] therapist or going to the hospital for a psychological evaluation if the doctors had coded those services as related to gender dysphoria.

b. Stories shared by numerous individual commenters on the current Proposed Rule reflect the continued harmful effects of discrimination.

Similarly, many individual commenters on the current Proposed Rule have shared personal stories that demonstrate the scope, nature, and costs of discrimination against transgender patients. While

NCTE has selected examples from among those comments collected by NCTE, many other examples from the current comment period provide similar evidence.[31]

Some commenters report being repeatedly turned away by primary care providers:

> Finding doctors that will even treat you is difficult. I can call several providers … and I tell the nursing staff or front desk I'm transgender and just want to make sure they see people such as myself, and they come back after speaking with the provider and tell me they don't specialize in people like me, or they don't treat people like me, or some other version, and all I'm trying to do is seek a primary care doctor. These among many other things are the numerous mental stabbings I endure. These are the many things that make people question whether they belong and if they should continue to live. I am not mad, but rather sad that we are all living creatures on a somewhat small planet in the grand scheme of life and that we treat people so undoubtedly disgusting. It's just not ok.

Another commenter reported similar experiences:

> I have been turned away by a health-care provider on at least two occasions, including when I was seeking routine care, for the sole reason that I am transgender. As a result of that, I often avoid or delay seeking medical care. This has resulted in some serious issues with my health that could have been avoided.
>
> Recently, after moving to a new city I sought out a health care provider to refill my hormone prescriptions. I looked online, through my insurance provider to find someone close to me who advertised that they worked in that field. During the intake interview, the doctor was very polite and solicitous obviously glad to have a new patient. Then, she asked when my last menstrual cycle had been. When I then told her that I was transgender, her demeanor abruptly changed and she said "I don't treat transgenders; I think you better look for another doctor." I hurried out of the office, embarrassed and mortified. Even as an attorney, I was unable in that moment of rejection and discrimination to advocate on my own behalf.

Some commenters report being turned away when seeking urgent and emergency care, such as this commenter who is himself a nurse:

> As a transgender person, this rule is terrifying. I have been a patient in urgent need of medical care and turned away because medical staff were "uncomfortable" helping me. How does my status as a transgender person have any bearing on receiving care for a rapidly swelling throat?

Another commenter described watching a family member have a similar experience:

[31] These excerpts have been edited lightly for grammar and punctuation only.

> My daughter is 33 years old and transgender. I am worried about her medical safety almost every day.
>
> While she was visiting me, she had a painful ear infection. I accompanied her to an urgent care operated by our local hospital. The hospital is over half an hour away. The receptionist kindly wrote her name on the outside of her folder with a request not to use her former masculine name, which was in their system from her childhood. Not only did the nurse practitioner refuse to address her by her new name but began a line of extended of provocative verbal harassment about her transition, completely unrelated to her ear infection. He did eventually confirm that she had an ear infection.
>
> When I went to fill the prescription, the pharmacist cautioned me that the Rx would cost over $300 for the generic version. She was confused as to why nurse practitioner would prescribe the most expensive, and potentially inappropriate antibiotic for an ear infection.

Another commenter shared an experienced faced by his husband:

> My husband is in law enforcement and a very hard worker. He serves the state and should be treated like a valued member of society just like a cisgendered man. My husband has had health issues that have went dismissed because as soon as hospital staff realize he is transgendered he is sent home quickly with antibiotics instead of proper testing to find out why certain things are happening.

Some commenters report being denied prescription medications:

> I am a 20 year old trans man. Starting testosterone last year and getting top surgery actually saved my life. I wouldn't be here if it wasn't because of those things. I need my testosterone refilled about once a month. I have been declined service from pharmacies before trying to get a refill for my prescription, because the pharmacist knew I was trans, and didn't agree with it. If this law is at all altered, my life would be at stake literally in the hands of OTHER people.

Some commenters described facing discrimination in access mental health and substance abuse services:

> I have a friend, Elizabeth, who when we were about 19 or 20 years old, was sent to a clinic for depression. She was denied to be able to take her hormone pills, despite the fact that they were recommended by her primary care physician and patients were allowed to take their regular medicine in the clinic. It was very likely that the staff, since they could not describe any other reason for removing the hormones from her possession, were acting out of discrimination for her gender identity. That made the purpose of my friend's trip, feeling better, and working on mental health and coping mechanisms for depression, even harder. It is hard to feel like your health is valued if your doctors can discriminate against you.

Some commenters described how fear of discrimination sometimes deterred them from seeking needed care:

> I am 29 years old. My mother died when I was 11 of cervical cancer and my dad died when I was 25 of lung cancer. My grandma died of lung cancer. My grandpa died of kidney cancer. Two aunts have survived other forms of cancer. It's in both sides of my family and will very likely come for me in one way or another… I am scared to go to the doctor when I'm in pain, or for problems that come with my assigned gender at birth because my outside is not what they expect. I am a human being - and I want to live.

Many health care providers confirm these concerns based on their clinical experience:

> In my nine years as a nurse, I have treated trans patients, and have seen first-hand the trauma and discrimination they have faced on a daily basis. Many are mistrustful of health care to begin with, and have had traumatic experiences with health care providers. To neglect to protect trans people from discrimination puts them at even greater risk of not seeking and receiving the health care they deserve. This new rule is shameful and incredible harmful.

Many commenters report facing discrimination in accessing their health insurance coverage on the basis of sex, often delaying access to prescribed drugs and treatments:

> I am insured and am on medication that is covered by my insurance. Yet when I transitioned and changed my information with my insurance company, my medications were denied for nearly a month despite me having all the proper legal paperwork. This was WITH the protections. I'm terrified to know what the future will hold.

Some commenters express living with constant fear for their transgender loved ones—fear exacerbated by the Proposed Rule:

> As someone married to a transgender person, it terrifies me to think what would happen to him in a medical emergency outside of California. Why should anyone have to live with that kind of fear? Why should anyone not receive the medical care they need in order to survive and lead a healthy productive life? He is a father, a son, a husband, a nurse, an upstanding citizen who cares for those around him. He is a person, deserving of every bit of respect and care given to any other person.

Other family members expressed similar fears:

> My child is five and a half years old and has been telling us since she could talk that she is a girl, not a boy. She is transgender, and every day I live with the fear of what that will mean for her life...We have a supportive doctor and care team at our hospital, but I worry every time we take a vacation. I live in fear of what might

> happen if this rule changes, allowing doctors and hospitals to discriminate against transgender people who need basic life-saving care. What if she falls and breaks her arm - or g-d forbid worse - and we need to visit a strange ER? Will they refuse to treat her? My child could die...She's just a five-year-old child who sees the world in black and white, wrong and write, truth and lie. She knows herself and who she is, and she knows she is a girl. And every day I carry fear in my heart for her, and this proposed rule adds to our family's anxiety and fear about access to basic life-saving care.

Some parents expressed specific fears based on disabilities that might require urgent attention:

> I oppose this proposed rule because it will endanger the lives of real human beings like my son. My son, who is 15 years old, has allergies and a mild immune deficiency that he manages with injections and medication. He is passionate about spending time in nature and will hike in Virginia for three weeks this summer as part of his Quaker camp community. If, as has happened once before, he experiences an allergic reaction, he needs to know that a doctor will treat him. Period, full stop. Health care providers take an oath to care for everyone. The government should not be encouraging and enabling them to put human lives and health at risk.

Another commenter expresses similar fears:

> I have many trans friends, and two years ago I supported a close friend following a head injury that required hospitalization. Driving them to the hospital, I was terrified that they might be seriously injured, or even at risk of dying. I had no fear, though, that they would be turned away at the door on the basis of their gender. I was confident that, even if I didn't know how to help them (or save them!), I was delivering them into the care of professionals who knew what to do, and would take action to keep my friend safe.
>
> If this rule were to go into effect, we would have no such certainty. The idea that someone could show up in need of urgent healthcare services and be turned away because of a fundamental part of who they are is appalling and repellant, and flies in the face of two centuries of (often slow) progress towards equal rights for all Americans.

III. Health care discrimination can cause medical, psychological, economic, and other harms.

Health care discrimination against transgender patients, as well as intersex patients and others viewed as not conforming to sex stereotypes, has numerous economic and non-economic costs. The scope, nature, and impacts of such discrimination are well documented, and any analysis of the costs and benefits of the Proposed Rule should employ this literature to develop data-based projections about the potential health impacts of increased discrimination.

a. Health disparities resulting from anti-transgender discrimination are widely recognized.

Health disparities facing transgender people were recognized in a major 2011 report of the National Academy of Medicine (then the Institute of Medicine),[32] by the Department's Healthy People 2020 initiative,[33] and by numerous studies since.[34] These disparities do not reflect inherent pathology. As the American Psychiatric Association has stated, "[b]eing transgender or gender variant implies no impairment in judgment, stability, reliability, or general social or vocational capabilities; however, these individuals often experience discrimination due to a lack of civil rights protections for their gender identity or expression."[35] The then-Institute of Medicine made the following findings in 2011:

- "LGBT individuals face barriers to care related to sexual and transgender stigma."[36]
- "Stigma has exerted an enormous and continuing influence on the life and consequently the health status of LGBT individuals."[37]
- "LGBT people are frequently the targets of stigma and discrimination because of their sexual- and gender-minority status."[38]
- "Lack of health insurance (including the exclusion of some services, such as sex reassignment surgery, by third-party payers), fear of discrimination from providers, and dissatisfaction with services may act as barriers to accessing all health services for LGBT adults."[39]
- "Some research suggests that older LGBT individuals do not believe they will receive respectful care in old age and may delay seeking care for fear of discrimination."[40]

[32] Inst. of Medicine, *The Health of Lesbian, Gay, Bisexual, and Transgender People: Building a Foundation for Better Understanding* (2011), http://www.iom.edu/Reports/2011/The-Health-of-Lesbian-Gay-Bisexual-and-Transgender-People.aspx.
[33] Dep't of Health & Human Servs., *Healthy People 2020: LGBT Health Topic Area* (2015), http://www.healthypeople.gov/2020/topics-objectives/topic/lesbian-gay-bisexual-and-transgender-health ("LGBT individuals face health disparities linked to societal stigma, discrimination, and denial of their civil and human rights.")
[34] *See, e.g.,* James et al., *supra* note 20.
[35] Am. Psychiatric Ass'n, *supra* note 6.
[36] Inst. of Medicine, *The Health of Lesbian, Gay, Bisexual, and Transgender People: Building a Foundation for Better Understanding*, 74 (2011).
[37] *Id.* at 75.
[38] *Id.* at 233.
[39] *Id.* at 234.
[40] *Id*. at 283.

Discrimination and barriers to care exacerbate the marked health disparities affecting transgender individuals,[41] including by increasing transgender people's risk factors for poor physical and mental health[42] and driving high rates of HIV.[43]

Experiences of discrimination in health care themselves are stressful events that can negatively affect mental and physical health. A robust body of literature demonstrates the effects of this "minority stress" on morbidity, mortality, and health care costs.[44] Among other effects, "[e]]xperimental studies among diverse populations show that stressors have immediate effects on the body including diastolic blood pressure reactivity, increased cortisol output, and elevated cardiometabolic risk."[45] This "minority stress" can be caused both by a single extreme event and by many, repeated events of discrimination.

Among transgender people, gender-based discrimination is associated with increased rates of negative health outcomes such as depression[46] and attempted suicide,[47] One study found that discrimination in health care settings was associated with increased risk of adverse emotional and physical symptoms and a 2- to 3-fold risk of postponement of needed care when sick or injured.[48] Another found that both actual and anticipated experiences of discrimination in health care were

[41] *See, e.g.,* Ilan H. Meyer et al., *Demographic Characteristics and Health Status of Transgender Adults in Select US Regions: Behavioral Risk Factor Surveillance System, 2014*, 107 AM. J. PUB. HEALTH 582 (2017); Joint Comm'n, *Advancing Effective Communication, Cultural Competence, and Patient- and Family-Centered Care for the LGBT Community: A Field Guide* (2011), http://www.jointcommission.org/assets/1/18/LGBTFieldGuide.pdf.

[42] Ctrs. for Disease Control & Prevention, *Lesbian, Gay, Bisexual, and Transgender Health* (2014), http://www.cdc.gov/lgbthealth/about.htm.

[43] Ctrs. for Disease Control & Prevention, *HIV and Transgender Communities* (2016), https://www.cdc.gov/hiv/pdf/policies/cdc-hiv-transgender-brief.pdf.

[44] See, e.g., Mark L. Hatzenbuehler, et al., *Structural Stigma and All-Cause Mortality in Sexual Minority Populations*, 103 SOC. SCI. & MED. 33, 37 (2014) (finding life expectancy reduced by an average of 12 years for sexual minorities living in communities with high levels of anti-gay prejudice); Mark L. Hatzenbuehler, et al., *Stigma as a Fundamental Cause of Population Health Inequalities*, 103 AM. J. PUB. HEALTH 813, 816 (2013) (noting the corrosive impact of stigma on physical and mental health, social relationships, and self-esteem); Ilan H. Meyer, *Prejudice, Social Stress, and Mental Health in Lesbian, Gay, and Bisexual Populations: Conceptual Issues and Research Evidence*, 129 PSYCHOL. BULLETIN 674, 679-85 (2003) (summarizing empirical evidence of "minority stress" in lesbian, gay, and bisexual populations and attendant health consequences); Vickie M. Mays & Susan D. Cochran, *Mental Health Correlates of Perceived Discrimination Among Lesbian, Gay, and Bisexual Adults in the United States*, 91 AM. J. PUB. HEALTH 1869, 1874 (2001) (finding "robust association between experiences of discrimination and indicators of psychiatric morbidity" and noting that "social factors, such as discrimination against gay individuals, function as important risk factors for psychiatric morbidity").

[45] Jaclyn M. White Hughto, Sari L. Reisner, & John E. Pachankis, *Transgender Stigma and Health: A Critical Review of Stigma Determinants, Mechanisms, and Interventions*, 147 SOCIAL SCIENCE & MEDICINE 147, 222–231 (2015), doi:10.1016/j.socscimed.2015.11.010.

[46] Tohru Nemoto, Birte Bödeker, Mariko Iwamoto, *Social Support, Exposure to Violence and Transphobia, and Correlates of Depression Among Male-To-Female Transgender Women with a History of Sex Work*, 101 AM. J. PUBLIC HEALTH. 1980 (2011).

[47] Kristen Clements-Nolle, Rani Marx, Mitchell Katz, *Attempted Suicide Among Transgender Persons: The Influence of Gender-Based Discrimination and Victimization.* 51 J. HOMOSEXUALITY 53 (2009).

[48] Sari L. Reisner et al. *Legal Protections in Public Accommodations Settings: A Critical Public Health Issue for Gender Minority People*. Milbank Quarterly. 2015b;93(3):1–32.

highly associated with substance use.[49] Yet another recent study found that experiences of discrimination in health care among transgender people were associated with attempted suicide.[50]

b. Discrimination can delay, prevent, or deter patients from accessing needed care.

In addition to its more direct negative health impacts, experiencing discrimination in health care deters patients from seeking needed care in the future, which can lead to medical conditions going undetected or untreated. In just the year prior to taking the survey, 23% of respondents in the U.S. Transgender Survey avoided seeking medical care when they needed it because of fear of being mistreated, and 33% avoided seeking necessary health care because they could not afford it.[51] These barriers often result in underutilization of necessary services. For example, one study found that transgender men eligible for cervical cancer screenings are less likely to receive them than cisgender women.[52]

For many transgender people, especially those living outside of metropolitan areas, simply finding a different provider after facing discrimination is not a viable option. Many transgender respondents to the 2017 study reported that it would be very difficult or impossible for them to find alternative providers to get the care they need if they were turned away by a health care provider. For example, nearly one-third (31%) of transgender respondents said it would be "very difficult" or "not possible" to find the same type of service at a different hospital and 30% said it would be "very difficult" or "not possible" to find the same type of service at a different community health center or clinic.[53]

Having to delay or forego care because of discrimination is not simply an inconvenience; doing so can have serious consequences. For example, the *New England Journal of Medicine* recently published an article on the inappropriate triage of a transgender man that resulted in a life-threatening delay in care.[54] The patient presented to the emergency room reporting severe abdominal pain, a positive home pregnancy test, and other indications he may be in labor. Nevertheless, a nurse noted his obesity and high blood pressure and marked his case as non-urgent. It wasn't until several hours later that a physician examined him and confirmed he was undergoing advanced pregnancy complications that led to an emergency cesarean delivery and a stillbirth. Had

[49] Sari L. Reisner et al., *Substance Use to Cope with Stigma in Healthcare Among U.S. Female-to-Male Trans Masculine Adults*, 2 LGBT HEALTH, 324–332, doi:10.1089/lgbt.2015.0001.
[50] Meghan Romanelli, Wenhua Lu, & Michael A. Lindsey, *Examining Mechanisms and Moderators of the Relationship Between Discriminatory Health Care Encounters and Attempted Suicide Among U.S. Transgender Help-Seekers*. 45 ADMINISTRATION AND POLICY IN MENTAL HEALTH AND MENTAL HEALTH SERVICES RESEARCH, 831 (Mar. 2018).
[51] James et al., *supra* note 20 at 98.
[52] Sarah M. Peitzmeier, et al. *Pap Test Use Is Lower Among Female-to-Male Patients Than Non-Transgender Women*, 47 AM. J. PREV. MED. 808 (2014).
[53] Mirza & Rooney, *supra* note 27.
[54] Daphna Stroumsa et al., *The Power and Limits of Classification — A 32-Year-Old Man with Abdominal Pain*, 380 NEW ENGLAND JOURNAL OF MEDICINE 1885 (2019), https://www.nejm.org/doi/full/10.1056/NEJMp1811491; *see also* Marylinn Marchione, *Blurred Lines: A Pregnant Man's Tragedy Tests Gender Notions,* A.P. NEWS (May 15, 2019), https://www.apnews.com/b5e7bb73c6134d58a0df9e1cee2fb8ad.

he been a woman, the authors noted, he "would almost surely have been triaged and evaluated more urgently for pregnancy-related problems."[55]

For Jay Kallio, the denial of treatment led to delayed treatment of his aggressive breast cancer. Years after reportedly volunteering as a paramedic at Ground Zero following the 9/11 attacks, Jay Kallio sought a biopsy years later on a suspicious lump. The surgeon was reportedly so uncomfortable with Mr. Kallio's female assigned sex at birth and outward male sex characteristics that he did not contact the patient with the test results.[56] When Mr. Kallio discovered by a phone call from a radiologist weeks later that the biopsy revealed he had breast cancer, the surgeon told him he had "a problem" with Kallio's sex, stating, "I don't even know what to call you."[57] Another provider, a medical oncologist, refused to advise him on treatment options. Finding new doctors delayed his treatment past the recommended "therapeutic window," putting his life at risk.[58]

While these cases fortunately did not result in the death of the patient, such cases exist. In extreme cases, a patient's life can be threatened or cut short when care is denied solely because the patient has sex characteristics or a recorded sex not typically associated with the clinically needed service. Robert Eads was a transgender man who died due to a denial of care after being diagnosed with ovarian cancer.[59] When he sought out treatment, multiple providers refused to treat or evaluate him because he was a transgender man. It wasn't until a year after first seeking care that Robert found a provider that would treat him. Unfortunately, it was too late for Robert, as the cancer had already metastasized to other parts of his body. Despite aggressive treatment, he died less than two years later.[60]

IV. Nondiscrimination protections are critical for the health of transgender people.

a. Nondiscrimination protections are shown to improve health disparities.

Numerous studies have found that when transgender people are supported in their environment, including by accessing the health care they need without discrimination, the health disparities they experience decrease substantially.[61]

[55] Stroumsa et al., *supra* note **Error! Bookmark not defined.** at 1887.
[56] Susan Donaldson James, *Trans Man Denied Cancer Treatment; Now Feds Say It's Illegal*, ABC NEWS (Aug. 8, 2012), https://abcnews.go.com/Health/transgender-bias-now-banned-federal-law/story?id=16949817; Daniel Trotta, *Transgender Patients Face Fear and Stigma in the Doctor's Office*, REUTERS (Sept. 15, 2016), http://news.trust.org/item/20160915050232-findi.
[57] Trotta, *supra* note 56.
[58] James, *supra* note 56.
[59] Mathura Ravishankar, *The Story About Robert Eads*, The Global Health Journal (2012), https://archive.is/GoW7L#selection-351.0-351.27 (last visited 7/24/2019).
[60] Rosa Goldensohn, Terminal Cancer Patient Finds Help in Facebook Group, *DNAInfo* (June 20, 2015).
[61] *See, e.g.,* Lily Durwood, Katie A. McLaughlin, & Kristina R. Olson, *Mental Health and Self-Worth in Socially Transitioned Transgender Youth*, 56 J. AM. ACAD. CHILD ADOLESC. PSYCHIATRY 116 (2017); Kristina R. Olson et al., *Mental Health of Transgender Children Who Are Supported in Their Identities*, 137 PEDIATRICS (2016); Annelou L. C. de Vries et al., *Young Adult Psychological Outcome After Puberty Suppression and Gender Reassignment*, 134 PEDIATRICS (2014); Stephen T. Russel et al., *Chosen Name Use Is Linked to Reduced Depressive Symptoms, Suicidal Ideation, and Suicidal Behaviors Among Transgender Youth*, 64 J. ADOLESCENT HEALTH 503 (2018), https://www.jahonline.org/article/S1054-139X(18)30085-5/fulltext.

As leading medical organizations such as American Medical Association[62] and the American Psychological Association[63] have emphasized, robust laws protecting patients from discrimination are essential in addressing these disparities and reducing the barriers to care facing millions of Americans, including transgender Americans, while expanding religious exemptions can dangerously exacerbate those barriers to care. In addition, as the Department has noted, "adequate governmental enforcement mechanisms are critical to the enforcement of these laws."[64] In response to recent proposals by the Department, numerous medical organizations expressed concerns with regulatory actions that could increase barriers to health care for transgender people, including the American Psychiatric Association,[65] the American Psychological Association,[66] the American Medical Association,[67] the American Academy of Pediatrics,[68] and the American Academy of Nursing.[69]

Studies have indicated that state nondiscrimination protections can have significant impacts on transgender people's health. In addition to its more direct effect on barriers to health care services, the presence or absence of nondiscrimination protections can impact health outcomes in a number of indirect ways, including through the public message that high-profile civil rights policy changes can send to minority populations.[70] For example, a 2016 study based on Veterans Health Administration clinical data found that transgender patients living in states with explicit nondiscrimination protections were 26% less likely to be diagnosed with mood disorders and 43% less likely to suffer self-harm.[71] Similarly, another recent study found that, controlling for demographic and other factors, state marriage equality laws "were associated with a reduction in

[62] Am. Medical Ass'n, *Letter to Director Roger Severino* (Sept. 1, 2017), https://searchlf.ama-assn.org/undefined/documentDownload?uri=%2Funstructured%2Fbinary%2Fletter%2FLETTERS%2F2017-09-01_Letter-to-Severino-re-Section-1557-Identity-Protection.pdf.

[63] Am. Psychological Ass'n, Comment Letter on Request for Information on Patient Protection and Affordable Care Act: Reducing Regulatory Burdens and Improving Health Care Choices to Empower Patients (July 12, 2017), https://www.regulations.gov/document?D=CMS-2017-0078-2528.

[64] Protecting Statutory Conscience Rights in Health Care; Delegations of Authority; Final Rule, 84 Fed. Reg. 23170 23230, 23178 [hereinafter Conscience Rule].

[65] Am. Psychiatric Ass'n, Comment Letter on Request for Information on Removing Barriers for Religious and Faith-Based Organizations to Participate in HHS Programs and Receive Public Funding (Nov. 22, 2017), https://www.regulations.gov/document?D=HHS-OS-2017-0002-10700.

[66] Am. Psychological Ass'n, Comment Letter on Request for Information on Removing Barriers for Religious and Faith-Based Organizations to Participate in HHS Programs and Receive Public Funding (Nov. 21, 2017), https://www.regulations.gov/document?D=HHS-OS-2017-0002-8429.

[67] Am. Medical Ass'n, Comment Letter on Request for Information on Removing Barriers for Religious and Faith-Based Organizations to Participate in HHS Programs and Receive Public Funding (Nov. 17, 2017), https://www.regulations.gov/document?D=HHS-OS-2017-0002-7327https://www.regulations.gov/document?D=HHS-OS-2017-0002-7327.

[68] Am. Acad. of Pediatrics, Comment Letter on Request for Information on Removing Barriers for Religious and Faith-Based Organizations to Participate in HHS Programs and Receive Public Funding (Nov. 21, 2017), https://www.regulations.gov/document?D=HHS-OS-2017-0002-12098.

[69] Am. Academy of Nursing, Comment Letter on Request for Information on Removing Barriers for Religious and Faith-Based Organizations to Participate in HHS Programs and Receive Public Funding (Nov. 24, 2017), https://www.regulations.gov/document?D=HHS-OS-2017-0002-11760.

[70] *See, e.g.,* Mark L. Hatzenbuehler, et al., *Structural Stigma and All-Cause Mortality in Sexual Minority Populations*, 103 SOC. SCI. & MED. 33, 37 (2014).

[71] John R. Blosnich et al., *Mental Health of Transgender Veterans in US States With and Without Discrimination and Hate Crime Legal Protection*, 106 AM. J. PUB. HEALTH. 534 (2016), https://doi.org/10.2105/AJPH.2015.302981.

the proportion of high school students reporting suicide attempts."[72] The adoption of marriage equality in Massachusetts was also associated with a significant decrease in medical and mental health visits in the following year among sexual minority men.[73] Conversely, the repeal of nondiscrimination protections can negatively impact health by stigmatizing minority groups. For example, one study found that the passage of state constitutional bans on same-sex marriage was associated with increases in mood, anxiety, alcohol use, and other psychiatric diagnoses in those states among sexual minority adults, while states that did not pass such bans saw no such increases.[74] Even though these laws had no immediate practical effect because these states did not previously permit same-sex couples to marry, the public message of disapproval towards LGBTQ people caused measurable negative effects on health outcomes.

b. Enforcement of Section 1557 is key for protecting transgender people's health.

As discussed below, Section 1557 and its implementing rule has had a marked impact in reducing unlawful discrimination.[75] The Department's own complaint data show that Section 1557 and the 2016 implementing rule have enabled the Office for Civil Rights (OCR) to resolve many complaints of sex-based discrimination efficiently and effectively, without the need for costly and protracted litigation. One study of a small sampling of 34 OCR sex discrimination complaints found that the agency was able to provide effective resolution of complaints, benefiting the patient and the health care system:

> In two instances, HHS completed its investigation and found the complaints were substantiated; in other words, HHS issued actual findings of discrimination. Most of the closed complaints resulted in the subject of the complaint taking voluntary corrective action. In 22 cases, the covered entity worked with HHS to institute trainings or change policies or HHS provided technical assistance to address the complaint.[76]

These complaints involved a wide range of sex-based barriers experienced by transgender patients and other patients viewed as not conforming to sex stereotypes, including:

- A transgender woman who went to the hospital with cold symptoms, only to be peppered with repeated and inappropriate questions about her gender and anatomy at intake.
- A transgender woman with a disability who was repeatedly harassed by the driver of a medical transport service that took her to and from her doctor's appointments.

[72] Julia Raifman et al., *Difference-in-Differences Analysis of the Association Between State Same-Sex Marriage Policies and Adolescent Suicide Attempts*. 171 JAMA PEDIATR. 350 (2017). doi:10.1001/jamapediatrics.2016.4529.
[73] Mark L. Hatzenbuehler et al., *Effect of Same-Sex Marriage Laws on Health Care Use and Expenditures in Sexual Minority Men: A Quasi-Natural Experiment*, 102 AM. J. PUB. HEALTH 285 (2012), doi: 10.2105/AJPH.2011.300382.
[74] Mark L. Hatzenbuehler et al., *The Impact of Institutional Discrimination on Psychiatric Disorders in Lesbian, Gay, and Bisexual Populations: A Prospective Study*, 100 AM J. PUBLIC HEALTH, 452 (2010), doi:10.2105/AJPH.2009.168815.
[75] *See infra, e.g.,* notes 359–360 (tracking decreased rates of transgender exclusions in health insurance plans).
[76] Sharita Gruberg & Frank J. Bewkes, *The ACA's LGBTQ Nondiscrimination Regulations Prove Crucial* (2018), https://www.americanprogress.org/issues/lgbt/reports/2018/03/07/447414/acas- lgbtq-nondiscrimination-regulations-prove-crucial.

- A woman who was separated from her wife during an emergency room visit and her wife was not permitted to enter her room for more than two hours.
- A transgender woman who was denied a mammogram because of her sex assigned at birth.
- A transgender man who was refused screening for a urinary tract infection because the clinic stated it only treated women.
- A transgender man who was refused coverage for a breast cancer screening recommended by his doctor because of his gender identity and recorded sex.
- Patients who were denied sexual assault forensic examinations because they were transgender.
- Patients who were denied insurance coverage for prescription drugs or other prescribed treatments solely because they were deemed related to gender transition.[77]

Similarly, in 2015 OCR achieved a voluntary resolution agreement on behalf of a woman who was involuntarily labeled as a man and assigned to a double room with a male patient because of her transgender status.[78]

Countless other covered entities took voluntary steps to comply with Section 1557 based on the 2016 Rule and the guidance and case law that preceded it. Absent the 2016 Rule and the guidance that preceded it, OCR might not have been able to assist these patients and covered entities in ensuring compliance with Section 1557 and promoting access to quality care.

The importance of robust enforcement of Section 1557 is especially important for transgender people who live in places where state and local laws do not provide clear protections against discrimination in health care. For example, an estimated 53% of the LGBT adult population live in states that do not explicitly prohibit discrimination based on gender identity and sexual orientation in public accommodations, which often includes the delivery of health care services. [79]Similarly, 48% of the adult LGBT population lives in states that have not explicitly prohibited anti-transgender discrimination in health insurance.[80] In over 20 states without explicit statewide protections, fewer than 25% of residents enjoy such explicit protections at the local level.[81]

When assessing its Section 1557 rule, the Department has a legal and moral responsibility to take into account the pervasive discrimination that transgender people face in health care settings, the impact such discrimination can have on negative health outcomes and health disparities, and the critical role that nondiscrimination protections play in preventing and mitigating these harms. As discussed in the next section, however, the Department, however, has failed to do so.

[77] *Id.*
[78] Dep't of Health & Human Servs., Office for Civil Rights, *Bulletin: The Brooklyn Hospital Center Implements Non-Discriminatory Practices to Ensure Equal Care for Transgender Patients* (Jul. 14, 2015).
[79] Movement Advancement Project. *Equality Maps: State Non-Discrimination Laws*, http://www.lgbtmap.org/equality-maps/non_discrimination_laws (last visited Aug. 12, 2019).
[80] Movement Advancement Project. "Equality Maps: Healthcare Laws and Policies." http://www.lgbtmap.org/equality-maps/healthcare_laws_and_policies (last visited Aug. 12, 2019).
[81] Movement Advancement Project. "Equality Maps: Local Non-Discrimination Ordinances." http://www.lgbtmap.org/equality-maps/non_discrimination_ordinances (last visited Aug. 12, 2019).

PART 2: THE PROPOSED CHANGES ARE NOT SUPPORTED BY A REASONED ANALYSIS

I. The Department has failed to meet the requirement of providing a "reasoned justification" for repealing or amending provisions of the 2016 Rule.

a. Regulatory rescissions require a reasoned analysis for changing the agency's settled course.

Under the Administrative Procedure Act and binding Supreme Court precedent, when an agency seeks to change regulations in a manner that departs from prior policy, the agency must provide a "reasoned analysis for the change."[82] The preamble of the proposed rule attempts to dodge this Supreme Court precedent by asserting that "an agency action to substantially repeal a prior rule, or parts thereof, is not necessarily subject to a higher standard of justification."[83] However, this is not a question of a higher standard, but of providing the well-reasoned justification that the APA requires.[84]

Since the Department previously chose to implement Section 1557 of the ACA through rulemaking, a reasoned analysis is required when amending or repealing such regulation. An agency change in regulation should not be based on solely a policy disagreement, particularly when the rule serves to interpret and apply a statute that protects millions of patients. Agencies have ample latitude to change existing policies; however, when agencies change course, the presumption is "*against* changes in current policy that are not justified by the rulemaking record."[85] Furthermore, agencies cannot "depart from a prior policy *sub silentio* or simply disregard rules that are still on the books."[86] Rather, the agency must provide a "reasoned analysis" for each such change.

This requirement reflects the practical reality that "the revocation of an extant regulation is substantially different than a failure to act" in its impact on covered entities and the law's intended beneficiaries, because it upsets a "settled course of behavior."[87] In this case, by removing regulatory provisions without explanation, the Department may send the message that the apparently deregulated conduct is now lawful, despite remaining prohibited by the underlying statute and applicable case law. This has a different and potentially more harmful effect on both patients and covered entities than would have arisen from a failure to regulate in the first place. As discussed below, there has been widespread compliance with and reliance on the 2016 Rule (including, but not limited to, the provisions for which administrative enforcement by the Department has been preliminarily enjoined), underscoring the need for a reasoned explanation.

[82] *Motor Vehicles Mfrs. Ass'n v. State Farm Ins.*, 463 U.S. 29, 30 (1983).
[83] Nondiscrimination in Health and Health Education Programs or Activities, 84 Fed. Reg. 27846, 27850 (proposed June 14, 2019) [hereinafter "Proposed Rule"].
[84] *State Farm Ins.*, 463 U.S. at 32.
[85] *Id.* at 42 (emphasis in original).
[86] *FCC v. Fox Television Stations, Inc.,* 556 U.S. 502, 515 (2009).
[87] *State Farm Ins.*, 463 U.S. at 41 (*quoting Atchison, T. & S. F. R. Co. v. Wichita Bd. of Trade,* 412 U.S. 800, 807–08 (1973)).

As Justice Kennedy wrote in *FCC v. Fox Television Stations, Inc.*:

> Where there is a policy change the record may be much more developed because the agency based its prior policy on factual findings. In that instance, an agency's decision to change course may be arbitrary and capricious if the agency ignores or countermands its earlier factual findings without reasoned explanation for doing so. An agency cannot simply disregard contrary or inconvenient factual determinations that it made in the past, any more than it can ignore inconvenient facts when it writes on a blank slate.[88]

This is particularly true with respect to Section 1557, where the existing rule was the product of not one but two public comment periods drawing tens of thousands of comments from a variety of stakeholders, and where the existing rule was based on extensive factual findings and informed in part by guidance issued years prior. Thus, the Department's proposal to rescind numerous substantive and procedural provisions of the 2016 Rule requires a reasoned explanation for each of these changes that sufficiently explains each change in the Department's position, acknowledging the Department's settled course of action, its previous findings of fact and legal reasoning, and any reliance interests.

b. The Department fails to provide a reasoned analysis for numerous regulatory rescissions.

The Department does not meet the standard for changing prior regulations as set forth in *State Farm* and succeeding cases. In a recent Supreme Court case addressing an agency change in policy, the Court emphasized that an agency explanation for such change "must examine the relevant data and articulate a satisfactory explanation for its action."[89] This includes providing a reasoned explanation that engages with the facts and circumstances that underlay an earlier action when an agency is changing prior regulation.[90] In the present case, the Proposed Rule is purely based on a policy difference between administrations. The Department fails to address the facts, circumstances, and body of case law upon which the 2016 Rule and sets forth no new facts that support its change in regulation.

As discussed further below, the Department's explanation for rescinding the gender identity provisions in the 2016 Rule relies heavily upon a single outlier district court decision.[91] It fails to provide a "reasoned analysis" for ignoring a mountain of contrary precedent, discussed below, that supports this aspect of the 2016 Rule. Rather than engaging the contrary precedent, the Department instead relegates numerous well-reasoned court of appeals decisions to a footnote and ignores others altogether.[92]

[88] 556 U.S. at 537 (Kennedy, J., concurring in part and in judgment).
[89] *Encino Motorcars, LLC v. Navarro*, 136 S. Ct. 2117, 2125 (2017) (quoting *State Farm,* 463 U.S. at 43.
[90] *See Encino*, 136 S. Ct. at 2125-26. *See also Fox Television Stations,* 556 U.S. at 515.
[91] *See* Proposed Rule, 84 Fed. Reg. at 27848 (citing *Franciscan Alliance, Inc. v. Burwell*, 227 F. Supp. 3d 660 (N.D. Texas 2017)).
[92] Proposed Rule, 84 Fed. Reg. at 27855, n. 61.

In addition to relying on one outlying district court decision with respect to the gender identity provision of the 2016 Rule, the Department provides no "reasoned analysis," and indeed no real analysis of any kind, for numerous other regulatory changes. These include:

- Repealing any recognition of the Supreme Court's precedent in *Price Waterhouse v. Hopkins*;[93]
- Repealing any recognition of longstanding precedent on associational discrimination;
- Repealing all provisions related to discrimination in insurance coverage (well beyond those solely related to discrimination based on gender identity);
- Repealing all provisions related to sex discrimination in health care services;
- Repealing provisions of ten unrelated, and in many cases longstanding, CMS rules; and
- Repealing a provision of an unrelated and longstanding Title IX rule.

The reasoning the Department sets forth does not meet the standard of justification that the APA and Supreme Court precedent require. While there may not be a *higher* standard for an agency choosing to repeal a prior rule, the APA requires a reasoned analysis for the change, beyond what would be required to decline to adopt rules in the first place. Since the Department chose to implement Section 1557 through regulation, and it now seeks to repeal most of the 2016 Rule, including numerous distinct substantive and procedural provisions, the Department is required to provide a "reasoned analysis" for each of these changes. The Proposed Rule does not do so, "depart[ing] from a prior policy *sub silentio*" with respect to some provisions,[94] while providing cursory or incoherent explanations for others.

For these reasons, and as explained further below, the Proposed Rule is arbitrary and capricious and should be withdrawn. With respect to several provisions, the Proposed Rule also violates the notice and comment requirement, because "[n]otice of a proposed rule must include sufficient detail on its content and *basis in law and evidence* to allow for meaningful and informed comment."[95]

II. The Department's position that Section 1557 does not protect against anti-transgender discrimination is contrary to the statutory text and well-established law.

The Department's proposal to rescind all references to discrimination on the basis of gender identity, gender transition, or transgender status in sections 92.4, 92.206, and 92.207 is not only harmful to patients and contrary to the purpose of the ACA and the mission of the Department, but also legally unsound. The position that sex discrimination under Section 1557 does not include discrimination because an individual is transgender runs contrary to the plain text of statute and the overwhelming consensus of two decades of case law. As the Supreme Court recently emphasized, "scant legal reasoning" such as that found in this proposed rule is "insufficient to satisfy the Department's obligation to explain its departure from its prior stated view."[96]

[93] 490 U.S. 228 (1989).
[94] *Fox Television Stations,* 556 U.S. at 515.
[95] *Am. Med. Ass'n v. Reno*, 57 F.3d 1129, 1132 (D.C. Cir. 1995) (citation omitted) (emphasis added).
[96] *NAACP v. Trump*, 298 F.Supp.3d 209, 238 (D.D.C. 2018).

a. *One outlier district court decision does not mandate that the Department revise the rule.*

In December 2016, a single district court issued a preliminary injunction in *Franciscan Alliance v. Burwell,* temporarily preventing "Defendants [U.S. Department of Health and Human Services]…from enforcing the Rule's prohibition against discrimination on the basis of gender identity or termination of pregnancy."[97] This decision represents the first and only merits ruling that Section 1557 does not prohibit anti-transgender discrimination. While the Government has chosen not to appeal the preliminary injunction or defend the 2016 Rule, neither the preliminary injunction against administrative enforcement nor the Government's voluntary acquiescence in it require the rule's rescission. The injunction is preliminary in nature, enjoins only enforcement actions by the Department itself, does not require or even refer to new rulemaking, and has been contested by proposed interveners. At this time, the district court is considering Plaintiffs' motion for summary judgment. The Government itself has asked the district court both to delay a ruling on summary judgment pending its voluntary rulemaking activity, and to limit any ruling to enforcement against named plaintiffs, which would free the Department to enforce Section 1557 consistent with the 2016 Rule nationwide except with respect to those parties.[98]

Moreover, the substantive analysis in the *Franciscan Alliance* ruling is conclusory and unpersuasive, and completely fails to acknowledge or engage with numerous contrary precedents. With respect to the definition of "sex," the very historical sources relied on by the court demonstrate the long-acknowledged variability and complexity of the concept of sex, which encompasses "[t]he *sum* of the morphological, physiological, *and behavioral* peculiarities of living beings."[99] As other courts have recognized, these and other contemporary sources demonstrate "that a hard-and-fast binary division on the basis of reproductive organs—although useful in most cases—was not universally descriptive."[100] The *Franciscan Alliance* court also did not have occasion to consider evidence regarding the wide variability in physical sex characteristics, including the 1.7% of the population born intersex.[101] Nor did the *Franciscan Alliance* court have occasion to consider evidence that, even if "sex" were construed solely as pertaining to anatomical and physiological factors, gender identity is such a factor because it may have a biological basis.[102]

[97] 227 F. Supp.3d 660, 696 (N.D. Tex. 2016). The *Franciscan Alliance* ruling does not address at all most of the provisions the Proposed Rule would repeal, including most of sections 92.206 and 92.207, the entirety of section 92.209, provisions related to language access and disability, and numerous definitions, including the definition of "on the basis of sex" to include sex stereotyping.
[98] *Franciscan Alliance v. Azar*, Defendants' Memorandum in Response to Plaintiffs' Motion for Summary Judgment, Case No. 7:16-cv-00108 (N.D. Tex., *filed* Apr. 5, 2019).
[99] *Franciscan Alliance*, 227 F. Supp.3d at 668 n. 24 (*quoting* WEBSTER'S THIRD NEW INTERNATIONAL DICTIONARY 2081 (1971)) (emphasis added).
[100] *G.G. ex rel. Grimm v. Gloucester Cty. Sch. Bd.*, 822 F.3d 709, 721 (4th Cir. 2016), *vacated and remanded on other grounds*, 137 S.Ct. 1239 (2017). As discussed below, the Fourth Circuit's textual analysis on this issue remains circuit law.
[101] *See, e.g.*, Peter A. Lee et al., *Global Disorders of Sex Development Update Since 2006: Perceptions, Approach and Care*, 85 HORM. RES. PAEDIATR. 180 (2016), doi: 10.1159/000442975; I.A. Hughes et al., *Consensus Statement on Management of Intersex Disorders*, 118 PEDIATRICS 488, 491 (2006); *SRY gene*, National Institutes of Health, https://ghr.nlm.nih.gov/gene/SRY (last visited May 7, 2019).
[102] *See*, *e.g.*, Int'l Gender Diversity Genomics Consortium, *The Biological Contributions to Gender Identity and Gender Diversity: Bringing Data to the Table*, 48 BEHAVIOR GENETICS 95 (2018), https://doi.org/10.1007/s10519-018-9889-z; Am. Acad. of Pediatrics, *supra* note 2; https://doi.org/10.1542/peds.2018-2162; Francine Russo, *Is There*

Moreover, as further discussed below, the *Franciscan Alliance* opinion fails to consider, as many other courts have, that anti-transgender discrimination may be discrimination "on the basis of sex" even under the narrow definition of "sex" it adopts.

As recognized by courts that have considered on the issue since the *Franciscan Alliance* ruling, the preliminary injunction does not change the underlying statute,[103] and it is the statute rather than the court ruling that is ultimately the source of the Department's obligation to enforce Section 1557. The Department cannot absolve itself of responsibility for choosing to rescind the 2016 Rule simply by acquiescing in a single district court's preliminary injunction. Just as "[a]n agency must explain *why* it chose to rely on certain comments rather than others,"[104] the Department must justify its choice to rely on a single, outlying district court decision and disregard the views of the vast majority of courts.

b. The Department completely disregards the decisions of the federal courts of appeal and most federal courts that have considered the issue.

The Department's position is contrary to that taken by the vast majority of federal courts to have considered the issue, including several courts of appeal. The Department deals with this mountain of well-reasoned precedent summarily, stating that "[w]hile four appellate courts have addressed the issue, a large volume of district court opinions have been inconsistent on the issue."[105] In fact, in addition to the rulings from the Third, Fourth, Sixth, and Seventh Circuits that the Department relegates to a footnote, the First, Ninth, and Eleventh Circuits have also issued rulings, discussed below, on the applicability of sex discrimination laws to anti-transgender bias.[106] Dozens of district court rulings from every circuit have held similarly, while only the *Franciscan Alliance* court has

Something Unique About the Transgender Brain? SCIENTIFIC AMERICAN (Jan. 1, 2016), https://www.scientificamerican.com/article/is-there-something-unique-aboutthe-transgender-brain; Peggy T. Cohen-Kettenis, Henriette A. Delemarre-van de Waal, & Louis J. G. Gooren, *The Treatment of Adolescent Transsexuals: Changing Insights*, 5 J. SEXUAL MEDICINE 1892, 1895 (2008); Arianne B. Dessens, Froukje M.E. Slijper, Stevert L.S. Drop, *Gender Dysphoria and Gender Change in Chromosomal Females with Congenital Adrenal Hyperplasia*, 34 ARCHIVES SEXUAL BEHAVIOR 389, 395 (2005).

[103] *See, e.g., Prescott v. Rady Children's Hosp.-San Diego*, 265 F. Supp. 3d 1090, 1105 (S.D. Cal. 2017) ("[T]he ACA claim and the Court's decision under the ACA do not depend on the enforcement or constitutionality of HHS' regulation," but on the statutory text.). *See also Boyden v. Conlin,* 2018 WL 2191733 (W.D. Wis. May 11, 2018) (denying defendants' motion to stay by affirming that plaintiffs relied on Section 1557 itself rather than the Department's regulation to bring discrimination claims based on transgender status, and that *Franciscan Alliance* is not controlling authority).

[104] *AARP v. U.S. Equal Emp't Opportunity Comm'n*, 267 F. Supp. 3d 14, 32 (D.D.C. 2017) (emphasis in original).

[105] Proposed Rule, 84 Fed. Reg. at 27855.

[106] As the Department notes, the Third Circuit has held that Title IX does not *prohibit* covered institutions from taking steps to prevent discrimination against transgender individuals, and that there is no right under Title IX to be free from the presence of a transgender person. *Doe ex rel. Doe v. Boyertown Area Sch. Dist.*, 897 F.3d 518 (3d Cir. 2018), *rehearing en banc denied*, 897 F.3d 515 (3d Cir. 2018). Notably, no member of the en banc court dissented from the panel's core holding that Title IX permits schools to take steps to prohibit discrimination against transgender students. The panel revised its opinion to omit certain dicta on the question of whether Title IX itself prohibits anti-transgender bias, solely on the ground that this question was not before the panel. *See id.* at 536 ("We need not decide that very different issue here"). The revision of panel opinions to omit dicta on issues not squarely before the court is a fairly common occurrence, and in no way supports the Department's interpretation of section 1557.

held otherwise, along with one other district court that has since questioned its prior ruling.[107] The Department fails to engage with, let alone refute, the analysis in any of these rulings supporting the 2016 Rule, or to explain why it is unpersuaded and chooses to disregard them.

Over the past two decades, an overwhelming number of federal courts have applied Supreme Court precedents to determine that anti-transgender discrimination is unlawful under federal sex nondiscrimination laws, including Section 1557 and Title IX of the Educational Amendments of 1972. These courts have concluded that the Supreme Court's decision in *Price Waterhouse v. Hopkins*, holding that Title VII of the Civil Rights Act of 1964 prohibits discrimination based on a wide range of sex-related characteristics, naturally and necessarily means that discrimination because an individual is transgender is prohibited. The plaintiff in that case, Ann Hopkins, was denied a partnership in an accounting firm in part because her demeanor, appearance, and personality were deemed insufficiently "feminine."[108] To improve her chances for partnership, Hopkins was told that she should "walk more femininely, talk more femininely, dress more femininely, wear make-up, have her hair styled, and wear jewelry."[109] The Supreme Court held that the words "because of…sex" encompassed discrimination where "the employer relied upon sex-based considerations in coming to its decision," including behavioral and social sex-based considerations, rather than narrowly applying to discrimination based on physical differences or a blanket refusal to promote women as a group.[110] The Court held:

> As for the legal relevance of sex stereotyping, we are beyond the day when an employer could evaluate employees by assuming or insisting that they matched the stereotype associated with their group, for "[i]n forbidding employers to discriminate against individuals because of their sex, Congress intended to strike at the entire spectrum of disparate treatment of men and women resulting from sex stereotypes."[111]

The Court interpreted the terms "because of such individual's….sex" in Title VII as prohibiting employment actions based on *any* characteristic related to gender, stating emphatically, "We take these words to mean that gender must be irrelevant to employment decisions."[112] Applying this bedrock principle to the fact of the case, the Court concluded that, "[i]n the specific context of sex

[107] In *Johnston v. University of Pittsburgh*, the court acknowledge that some cases of anti-transgender discrimination may be covered under Title IX, but concluded that in the case before it the university did not violate Title IX by excluding a male transgender student from men's restrooms. 97 F.Supp.3d 657 (W.D. Pa. 2015). Two years later, however, in another case involving transgender students' access to restrooms, the same district court stated that "the decision law has developed further [since *Johnston*], and has done so rather swiftly." *Evancho v. Pine-Richland Sch. Dist.*, 237 F.Supp.3d 267, 288 n.33 (W.D. Pa. 2017). Granting the plaintiffs in that case a preliminary injunction, the court noted, "Plaintiffs have demonstrated a reasonable likelihood of showing that Title IX's prohibition of sex discrimination includes discrimination as to transgender individuals based on their transgender status and gender identity." *Id.* at 297. While declining to base an injunction on the plaintiff's Title IX claim in light of the Supreme Court's then-pending review in a similar case, the court held that a school policy forcing transgender students to use separate restrooms likely violated the Equal Protection Clause. *Id.* at 295.
[108] *Price Waterhouse v. Hopkins*, 490 U.S. 228, 234–35 (1989).
[109] *Id.* at 235.
[110] *Id.* at 242.
[111] *Id.* at 251 (quoting *City of Los Angeles Dep't of Water & Power v. Manhart*, 435 U.S. 702, 707 n.13 (1978)).
[112] *Id.* at 240.

stereotyping, an employer who acts on the basis of a belief that a woman cannot be aggressive, or that she must not be, has acted on the basis of gender."[113]

The Supreme Court has also rejected the notion that Title VII applies only to types of sex-based considerations that Members of Congress anticipated at its passage. For example, in *Oncale v. Sundowner Offshore Oil Services*, Justice Scalia authored a unanimous opinion in favor of Joseph Oncale, who sued his former employer under Title VII alleging that his male coworkers subjected him to sexual harassment and attacks.[114] The Court stated that even if Congress was primarily concerned about other forms of sex-based discrimination when enacting Title VII, "statutory prohibitions often go beyond the principal evil [intended by Congress] to cover reasonably comparable evils, and it is ultimately the provisions of our laws rather than the principal concerns of our legislators by which we are governed."[115] In other words, Title VII—along with other federal sex discrimination laws—applies to actions that take a person's sex into account, regardless of whether legislators had those fact patterns in mind in 1964.

Since the *Oncale* decision in 1998, an overwhelming majority of federal courts addressing the issue have applied the Supreme Court precedents in *Price Waterhouse* and *Oncale* to hold that discrimination because a person is transgender or is undergoing gender transition constitutes unlawful sex discrimination under a variety of federal laws. For example, in *Schwenk v. Hartford*, the **Ninth Circuit** relied on *Price Waterhouse* and *Oncale* in concluding that transgender people must be protected under the Gender Motivated Violence Act.[116] The plaintiff in the case, Crystal Schwenk, a transgender prisoner, alleged that a guard targeted her for a physical assault because she was transgender. On appeal, the guard argued that sex nondiscrimination laws do not protect transgender people, relying on the Ninth Circuit's 1977 decision in *Holloway v. Arthur Anderson*, where the court rejected a claim by a transgender plaintiff.[117] The court, however, stated that:

> The initial judicial approach taken in cases such as *Holloway* has been overruled by the logic and language of *Price Waterhouse*. In *Price Waterhouse*…, the Supreme Court held that Title VII barred not just discrimination based on the fact that Hopkins was a woman, but also discrimination based on the fact that she failed "to act like a woman"—that is, to conform to socially-constructed gender expectations. Thus, under *Price Waterhouse*, "sex" under Title VII encompasses both sex—that is, the biological differences between men and women—and gender.… Indeed, for purposes of [Title VII and similar laws], the terms "sex" and "gender" have become interchangeable.[118]

Likewise, the **First Circuit** followed the logic of *Price Waterhouse* in reaching the conclusion that discriminating against a person because they are transgender or do not conform to gender stereotypes is unlawful under sex discrimination laws. In that case, a bank teller refused to serve a customer she perceived to be male because the customer wore traditionally feminine clothing,

[113] *Id.*
[114] 523 U.S. 75, 77 (1998).
[115] *Id.* at 79.
[116] 204 F.3d 1187 (9th Cir. 2000).
[117] *See* 566 F.2d 659 (9th Cir. 1977).
[118] *Id.* at 1201–02.

instructing the customer to go home and change.[119] Describing the customer in now-outdated language as "cross-dressing," the First Circuit held that the customer could state a sex discrimination claim under the Equal Credit Opportunity Act, because the teller perceived the customer to be male and "she thought that [the customer's] attire did not accord with his male gender," whereas she would have served a customer dressed the same and perceived the be female.[120]

Similarly, in a series of cases beginning in 2004, the **Sixth Circuit** held that a firefighter, police officer, and funeral home employee each stated a Title VII claim by alleging they were terminated because of being transgender.[121] As in *Schwenk*, the Sixth Circuit in *Smith v. City of Salem, Ohio* held that "[t]he Supreme Court made clear that in the context of Title VII, discrimination because of 'sex' includes gender discrimination."[122] The court explained:

> By holding that Title VII protected a woman who failed to conform to social expectations concerning how a woman should look and behave, the Supreme Court established that Title VII's reference to "sex" encompasses both the biological differences between men and women, and gender discrimination, that is, discrimination based on a failure to conform to stereotypical gender norms.…
>
> As such, discrimination against a plaintiff who is a transsexual—and therefore fails to act and/or identify with his or her gender [as assigned at birth]—is no different from the discrimination directed against Ann Hopkins in Price Waterhouse, who, in sex-stereotypical terms, did not act like a woman. Sex stereotyping based on a person's gender non-conforming behavior is impermissible discrimination, irrespective of the cause of that behavior; a label, such as "transsexual," is not fatal to a sex discrimination claim where the victim has suffered discrimination because of his or her gender non-conformity.[123]

The Sixth Circuit affirmed this holding a year later in *Barnes v. City of Cincinnati*,[124] and again a decade later in *Dodds v. Department of Education*, applying these holdings to Title IX.[125]

In its most recent ruling on the subject, the Sixth Circuit explained further:

[119] *Rosa v. Park West Bank & Trust Co.,* 214 F.3d 213 (1st Cir. 2000).
[120] *Id.* at 215–16.
[121] *Smith v. City of Salem,* 378 F.3d 566 (6th Cir. 2004); *Barnes v. City of Cincinnati,* 401 F.3d 729 (6th Cir. 2005); *EEOC v. Harris Funeral Homes,* 884 F.3d 560, 566 (6th Cir. 2018), *cert. granted in part sub nom. R.G. & G.R. Harris Funeral Homes v. EEOC*, No. 18107 (Apr. 22, 2019). *See also Dodds v. U.S. Dep't of Educ.*, 845 F.3d 217, 221 (6th Cir. 2016) (denying stay pending appeal and pointing to "settled law" that anti-transgender discrimination is prohibited under sex discrimination law). As further discussed below, to the extent that the Supreme Court's partial grant of *certiorari* in *Harris Funeral Homes* with respect to the Title VII statute is relevant to this rulemaking, it counsels against rulemaking prior to the Supreme Court's decision in that case.
[122] *Smith,* 378 F.3d at 572.
[123] *Id.* at 573, 575.
[124] 401 F.3d at 737.
[125] 845 F.3d at 221.

> First, it is analytically impossible to fire an employee based on that employee's status as a transgender person without being motivated, at least in part, by the employee's sex…. Second, discrimination against transgender persons necessarily implicates Title VII's proscriptions against sex stereotyping…. An employer cannot discriminate on the basis of transgender status without imposing its stereotypical notions of how sexual organs and gender identity ought to align. There is no way to disaggregate discrimination on the basis of transgender status from discrimination on the basis of gender non-conformity, and we see no reason to try…. Title VII protects transgender persons because of their transgender or transitioning status, because transgender or transitioning status constitutes an inherently gender non-conforming trait.[126]

The **Eleventh Circuit** has likewise recognized *Price Waterhouse* as holding that "Title VII barred not just discrimination because of biological sex, but also gender stereotyping — failing to act and appear according to expectations defined by gender."[127] Further, it held in that discrimination based on failure to conform to sex stereotypes is sex-based discrimination, and that this necessarily meant that anti-transgender discrimination is inherently sex discrimination, since "a person is defined as transgender precisely because of the perception that his or her behavior transgresses gender stereotypes."[128]

Following the well-established principle of looking to Title VII case to interpret Title IX, the **Seventh Circuit** held that "by definition, a transgender individual does not conform to the sex-based stereotypes of the sex that he or she was assigned at birth," and that discrimination based on such conformity violates Title IX.[129] Accordingly, the court held that a school policy that requires a student to be treated in a manner "that does not conform with his or her gender identity punishes that individual for his or her gender non-conformance, which in turn violates Title IX."[130]

In another Title IX case, the **Fourth Circuit** held that the text of Title IX and its implementing regulations were "silent as to how a school should determine whether a transgender individual is a male or female," and were "susceptible to more than one plausible reading" with respect to claims of anti-transgender discrimination.[131] The Fourth Circuit at that time deferred to the Department of Education's interpretation that Title IX prohibits such discrimination because it was a reasonable construction of the statutory and regulatory text.[132] As the Department notes, the Fourth Circuit's judgment was vacated and remanded by the Supreme Court in light of the Department of

[126] *Harris Funeral Homes,* 884 F.3d at 575–77. *See also Parker v. Strawser Construction, Inc.*, 307 F. Supp. 3d 744 (S.D. Ohio 2018) (holding that termination of employee based on transgender status violates Title VII); *Mickens v. Gen. Elec. Co.*, No. 16-603 (W.D. Ky. Nov. 28, 2016) (same).
[127] *Glenn v. Brumby,* 663 F.3d 1312, 1316 (11th Cir. 2011). While the Eleventh Circuit's ruling arose in the context of the application of intermediate scrutiny to sex discrimination under the Equal Protection Clause of the Constitution, it applied Title VII principles.
[128] *Id.*
[129] *Whitaker v. Kenosha Unified Sch. Dist.*, 858 F.3d 1034, 1048 (7th Cir. 2017), *cert. dismissed sub nom. Kenosha Unified Sch. Dist. No. 1 Bd. of Educ. v. Whitaker ex rel. Whitaker*, 138 S. Ct. 1260 (2018)
[130] *Id.* at 1049.
[131] *G.G.,* 822 F.3d at 721.
[132] *Id.* at 721-23.

Education's subsequent reversal of its interpretation.[133] The district court on remand, together with another district court in the Fourth Circuit, have held that the Fourth Circuit's decision "remains binding law" to the extent that it holds the text of the Title IX statute and regulation are at least susceptible to the interpretation that they prohibit anti-transgender bias.[134]

Contrary to the Department's characterization, dozens of district courts in *every circuit* have followed these circuit precedents in affirming that anti-transgender discrimination constitutes sex-based discrimination under various federal laws—including Title VII of the Civil Rights Act, Title IX of the Educational Amendments of 1972, Section 1557 of the Affordable Care Act, and the Equal Protection Clause of the Constitution.[135] The Department does not engage with any of these well-reasoned decisions.

Other than *Franciscan Alliance*, every court to rule on the merits of the issue has held that section 1557 specifically prohibits discrimination because an individual is transgender have concluded that it does. For example, a district court held in *Rumble v. Fairview Health Services* that Jakob Rumble, a hospital patient, who was mistreated because of he was transgender stated a sex discrimination claim under Section 1557, basing its decision on longstanding circuit court case law on Title VII and Title IX.[136] In *Prescott v. Rady Children's Hospital-San Diego*, the district court considered a lawsuit filed by the mother of a deceased transgender child alleging that a children's hospital had violated Section 1557 by discriminating against her son, Kyler Prescott, because of his transgender status.[137] The district court held that "the plain language of the ACA" prohibits such discrimination, based on numerous Title VII and Title IX precedents.[138]

Courts have held similarly in cases of anti-transgender discrimination in health insurance. In a recent decision, a federal court held that excluding transgender-specific care from coverage under

[133] *Gloucester Cty. Sch. Bd. v. G. G. ex rel. Grimm*, 137 S.Ct. 1239 (2017).
[134] *Grimm v. Gloucester Cty. Sch. Bd.*, 302 F.Supp.3d 730, 743 n. 6 (E.D. Va. 2018); *M.A.B. v. Bd. of Educ. of Talbot Cty.*, 286 F.Supp.3d 704, 712 n. 5 (D. Md. 2018).
[135] *See, e.g., J.A.W. v. Evansville Vanderburgh School Corp.*, --- F.Supp.3d ----, No. 3:18-cv-37 (S.D. Ind. 2019), *EEOC v. A&E Tire*, 325 F.Supp.3d 1129 (D. Colo. 2018); *Adams v. Sch. Bd. Of St. Johns Cty.,* 318 F. Supp. 3d 1293 (M.D. Fla. 2018); *Doe v. Mass. Dep't of Corr.*, No. CV-17-12255-RGS, 2018 WL 2994403 (D. Mass. June 14, 2018); *Grimm*, 302 F.Supp.3d 730; *Parker v. Strawser Construction*, 307 F.Supp.3d 744 (S.D. Ohio 2018); *M.A.B. v. Bd. of Educ. of Talbot Cty.*, 286 F. Supp.3d 704 (D. Md. 2018); *F.V. v. Barron*, 286 F. Supp. 3d 1131 (D. Idaho 2018); *Karnoski v. Trump*, No. C17-1297-MJP, 2017 WL 6311305 (W.D. Wash. Dec 11, 2017); *A.H. ex rel. Handling v. Minersville Area Sch. Dist.*, 290 F. Supp. 3d 321 (M.D. Pa. 2017); *Prescott v. Rady Children's Hosp.-San Diego*, 265 F. Supp. 3d 1090 (S.D. Cal. 2017); *E.E.O.C. v. Rent-a-Center East, Inc.*, 264 F. Supp. 3d 952 (C.D. Ill. 2017); Smith v. Avanti, 249 F. Supp. 3d 1149 (D. Colo. 2017); *Brown v. Dep't of Health & Human Servs.*, No. 8:16DCV569, 2017 WL 2414567 (D. Neb. June 2, 2017); *Mickens v. Gen. Elec. Co.*, No. 16-603, 2016 WL 7015665 (W.D. Ky. Nov. 29, 2016); *Roberts v. Clark Cty. Sch. Dist.*, 215 F.Supp.3d 1001 (D. Nev. 2016); *Doe v. Arizona*, No. CV-15-02399-PHX-DGC, 2016 WL 1089743 (D. Ariz. Mar. 21, 2016); *Fabian v. Hosp. of Cent. Conn.*, 172 F. Supp. 3d 509 (D. Conn. 2016); *Norsworthy v. Beard*, 87 F. Supp. 3d 1164 (N.D. Ca. 2015); *Dawson v. H&H Elec., Inc.*, No. 4:14CV00583 SWW, 2015 WL 5437101 (E.D. Ark. Sept. 15, 2015); *U.S. v. S.E. Okla. State Univ.*, No. CIV–15–324–C, 2015, WL 4606079 (W.D. Okla. July 10, 2015); *Finkle v. Howard Cty.*, 12 F. Supp. 3d 780 (D. Md. 2014); *Schroer v. Billington*, 577 F. Supp. 2d 293 (D.D.C. 2008); *Lopez v. River Oaks Imaging & Diagnostic Grp., Inc.*, 542 F. Supp. 2d 653 (S.D. Tex. 2008); *Tronetti v. Healthnet Lakeshore Hosp.*, No. 03–CV–0375E, 2003 WL 22757935 (W.D.N.Y. Sept. 26, 2003).
[136] No. 14-CV-2037, 2015 WL 1197415 (D. Minn. Mar. 16, 2015).
[137] 265 F.Supp.3d 1090 (S.D. Cal. Sept. 27, 2017).
[138] *Id.* at 1098.

Wisconsin's Medicaid program was "text-book discrimination based on sex" in violation of Section 1557.[139] The court emphasized that even if it were to accept the defendants' "tortured" interpretation that "sex" referred only to physical attributes, the exclusion "certainly denies coverage for medically necessary surgical procedures based on a patient's *natal* sex, the same 'immutable' sex the defendants claim the ACA intends to cover."[140] The court further explained that the exclusion "expressly *singles out and bars* a medically necessary treatment solely for transgender people suffering from gender dysphoria."[141] Other federal courts have similarly found that exclusions of transgender-specific care in Medicaid and employee health plans violated Section 1557.[142]

In addition to *Franciscan Alliance*, the Department also cites to a Title IX decision from the Western District of Pennsylvania to support the proposed rescission.[143] In *Johnston v. University of Pittsburgh*, the court acknowledged that some cases of anti-transgender discrimination may be covered under Title IX, but concluded that in the case before it the university did not violate Title IX by excluding a male transgender student from men's restrooms.[144] Two years later, however, in another case involving transgender students' access to restrooms, the same district court questioned the continued viability of its prior holding: "The Court believes as Johnston predicted might occur that the decisional law has developed further, and has done so rather swiftly."[145] It recognized that "[c]ourts have long interpreted 'sex' for Title VII purposes to go beyond assigned sex as defined by the respective presence of male or female genitalia," and to include gender identity and gender transition.[146] Accordingly, this decision provides little if any support for the Proposed Rule.

The Department also relies on a decision by the Tenth Circuit, the only circuit court precedent today stating—seemingly in dicta—that anti-transgender discrimination is not *per se* sex discrimination.[147] The Tenth Circuit's reasoning is flawed in several respects, relies heavily on

[139] *Flack v. Wis. Dep't of Health Servs.*, 328 F. Supp. 3d 931, 950 (W.D. Wis. 2018).
[140] *Id.* at 948.
[141] *Id. at* 950.
[142] *See, e.g., Tovar v. Essentia Health*, 342 F.Supp.3d 947, 957 (D. Minn. 2018) ("Section 1557 prohibits discrimination based on gender identity [based] on the plain, unambiguous language of the statute"); *Boyden,* 341 F.Supp.3d at 997 ("Whether because of differential treatment based on natal sex, or because of a form of sex stereotyping where an individual is required effectively to maintain his or her natal sex characteristics, the Exclusion [in Wisconsin's state employee plan] on its face treats transgender individuals differently on the basis of sex, thus triggering the protections of Title VII and the ACA's anti-discrimination provision"); *Cruz v. Zucker*, 195 F.Supp.3d 554 (S.D.N.Y. 2016) (holding Medicaid transgender exclusion invalid under Section 1557).
[143] *Johnston v. Univ. of Pittsburgh*, 97 F. Supp. 3d 657 (W.D. Pa. 2015).
[144] 97 F.Supp.3d 657 (W.D. Pa. 2015).
[145] *Evancho v. Pine-Richland Sch. Dist.*, 237 F.Supp.3d 267, 288 n. 33 ("The Court believes as *Johnston* predicted might occur that the decisional law has developed further, and has done so rather swiftly.") The *Evancho* court added that "many of the cases relied on in *Johnston*, as to a degree *Johnston* did itself, came to that conclusion based on the absence of precedent" from the Third Circuit and the Supreme Court "squarely ruling on the question," and indicated that relying on this basis may have been in error because "[t]he Court is obligated to apply the Supreme Court's existing analytical tests for determining what Equal Protection standard is to be applied…notwithstanding that the Supreme Court or the regional court of appeals has not yet weighed in" on the specific circumstances where it is being applied. *Id.*
[146] *Id.* at 296.
[147] *Etsitty v. Utah Transit Authority*, 502 F.3d 1215 (10th Cir. 2005).

since-overturned precedent from the Seventh Circuit, and represents a minority view.[148] In any case, the Tenth Circuit's precedent still does not go as far as the Department's proposal. The Tenth Circuit acknowledged that sex discrimination encompasses discrimination based on sex stereotypes, and that discrimination against a transgender person based on the perception that they do not conform to sex stereotypes may be actionable under Title VII.[149] Indeed, under this precedent, district courts in the Tenth Circuit have concluded that discrimination against transgender individuals violates Title VII and the Fair Housing Act.[150] Accordingly, the Tenth Circuit's questionable and limited dicta do not support the Proposed Rule.

c. *The Department is incorrect in claiming that the 2016 rule is inconsistent with other Department rules and policies.*

The Department claims that the 2016 Rule is inconsistent with policies and regulations related to sex adopted by other Department components, and that this "has resulted in substantial confusion and inconsistency."[151] The Department cherry-picks and mischaracterizes statements by other Department components, and misstates their relevance to Section 1557's "on the basis of sex" standard. The Department points to no evidence that the 2016 Rule has caused any confusion or obstacles in implementing any program of other Department components. In reaching such determinations, "conclusory statements will not do; an agency's statement must be one of *reasoning*."[152]

The Proposed Rule ignores other Department components' determinations that are consistent with a broad and nuanced view of the concept of sex. For example, Centers for Disease Control has determined that the term "women" in the Breast and Cervical Cancer Mortality Prevention Act of

[148] *See id.* at 1221, citing *Ulane v. E. Airlines, Inc.*, 742 F.2d 1081, 1084 (7th Cir.1984). Ultimately, *Etsitty*'s central holding is that even if the plaintiff established a *prima facie* case, a "good faith" fear of litigation was a defense without regard to the legal merits of that fear. It is at best unclear whether that holding survives *Ricci v. De Stefano*, which held that a fear of third-party litigation cannot constitute a legitimate nondiscriminatory motive under Title VII absent "a strong basis in evidence that, had it not taken the [challenged] action, it would have been liable" to third parties. 557 U.S. 557, 562 (2009). In any case, *Etsitty*'s fact-specific holding is not relevant to this rulemaking.

[149] 502 F.3d. 1223–24. The *Etsitty* court acknowledged that the plaintiff may have a valid claim that she faced unlawful discrimination because she did not conform to stereotypes, but stated that addressing this claim is unnecessary for its holding that the employer had a legitimate nondiscriminatory motive:

> This court need not decide whether discrimination based on an employee's failure to conform to sex stereotypes always constitutes discrimination "because of sex" and we need not decide whether such a claim may extend Title VII protection to transsexuals who act and appear as a member of the opposite sex. Instead, because we conclude Etsitty has not presented a genuine issue of material fact as to whether UTA's stated motivation for her termination is pretextual, we assume, without deciding, that such a claim is available and that Etsitty has satisfied her prima facie burden.

[150] *See, e.g., Tudor v. Se. Okla. State Univ.*, No. 15-324, 2017 WL 4849118 (W.D. Okla. Oct. 26, 2017) (holding that a professor who was denied tenure and promotion due to being transgender stated a Title VII claim); *Smith v. Avanti*, 249 F. Supp. 3d 1149 (D. Colo. 2017) (holding that tenants evicted in part due to being transgender constituted stated a sex discrimination claim under the Fair Housing Act).

[151] Proposed Rule, 84 Fed. Reg. at 27853.

[152] *Amerijet Int'l, Inc. v. Pistole*, 753 F.3d 1343, 1350 (D.C. Cir. 2014) (emphasis in original, internal quotation marks and citations omitted).

1990, applies to transgender women for whom screenings are clinically indicated.[153] The Substance Abuse and Mental Health Services Administration (SAMHSA) has recognized the medical consensus that gender identity has, at least in part, a biological basis.[154]

Additionally, the 2016 Rule is fully consistent with public policies and research that take account of the range of sex-linked biological characteristics. Indeed, section 92.206 of the 2016 Rule—which the Department now proposes to rescind completely without explanation—explicitly acknowledges and allows for covered entities' need to take account of a variety of sex-linked characteristics in clinical and research settings. Thus, the Proposed Rule does not interfere in any way with, for example, the Department's Health Information Technology standards.

Finally, as explained above, these varying definitions of the concept of "sex" are not determinative of the application of the statutory phrase, "on the basis of sex." It is in part because civil rights statutes focus on causality rather than sorting individuals into groups that the Supreme Court in *Price Waterhouse* and elsewhere uses the terms "sex" and "gender" interchangeably.[155] Because anti-transgender discrimination necessarily "takes gender into account," including sex assigned at birth, the 2016 Rule is consistent with the varying definitions and emphases regarding the concept of "sex" applied by the Department in other contexts. For example, where a transgender woman applies for and is offered a job as a woman and the employer withdraws the job offer after learning she was assigned male at birth, the employer was previously aware of her gender identity but bases the termination on her assigned sex at birth.[156]

d. Congressional action or inaction on other legislation does not justify ignoring the law's text.

The Department argues that "Congressional activity in this area suggests that 'sex' under Title IX does not include sexual orientation or gender identity."[157] But Congressional action and inaction on other legislation does not afford any basis for excluding transgender patients from the protection of Section 1557's statutory requirements.

The Department cites one judicial precedent for this argument,[158] but that case is inapposite. In *FDA v. Brown & Williamson Tobacco Corporation*, the Court held that the text and structure of the Food, Drug, and Cosmetic Act, including various amendments to that statute, "created a distinct regulatory scheme to address the problem of tobacco and health, and that scheme, as presently constructed, precludes any role for the FDA."[159] In that case, Congress repeatedly

[153] *See* Nat'l Ctr. for Chronic Disease Prevention and Health Promotion, Div. of Cancer Prevention and Control, *Virtual Meeting of the Breast and Cervical Cancer Early Detection and Control Advisory Committee* (February 3, 2014).
[154] Substance Abuse and Mental Health Services Administration, *Ending Conversion Therapy: Supporting and Affirming LGBTQ Youth* 16 (Oct. 2016) ("The development of gender identity appears to be the result of a complex interplay between biological, environmental, and psychological factors").
[155] *See, e.g., Price Waterhouse*, 490 U.S. at 237–43.
[156] This is the exact fact pattern in *Lopez v. River Oaks Imaging & Diagnostic Group, Inc.*, 542 F.Supp.2d 653 (S.D. Tex. 2008).
[157] Proposed Rule, 84 Fed. Reg. at 27853.
[158] *Id.*
[159] 529 U.S. 120, 144 (2000).

amended a single statute scheme dealing with a single subject. Moreover, that case involved the scope of delegated authority to the agency to create new substantive requirements, rather than the interpretation of the specific requirements Congress adopted.

By contrast, here the Department seeks to rely on unenacted bills and amendments to other statutes to displace the natural reading of statutory requirements. In this context, the Supreme Court has stated repeatedly that "[p]ost-enactment legislative history is not a legitimate tool of statutory interpretation."[160] The Court has further stated that "failed legislative proposals are a particularly dangerous ground on which to rest an interpretation of a prior statute," because there are so many possible reasons why a bill does not become a law.[161]

The axiom against relying on Congressional *inaction* has its greatest force in a context such as this one, where legislators have introduced bills seeking to expressly *exclude* anti-transgender discrimination within sex discrimination laws such as Section 1557 and Title IX, as well as bills seeking to expressly enumerate it.[162] That subsequent Congresses have adopted neither set of proposals tells us nothing about the meaning of "on the basis of sex."

Nor does the fact that Congress has separately enumerated terms such as *sex*, *gender identity*, and *sexual orientation* in other statutes (such as the Violence Against Women Act) demonstrate an intent to completely divorce them in another. Congress frequently uses overlapping terms in legislation, including civil rights legislation. For example, "the terms [race and national origin] overlap as a legal matter,"[163] such that "[t]he line dividing [them] is fuzzy at best, and in some contexts, national origin discrimination is so closely related to racial discrimination as to be indistinguishable."[164] Similarly, the fact that Congress chose to expressly state that a "former employee" is covered under one statute does not mean that the term "employee" in another statute should be read to exclude them.[165]

Instead of relying on the action or inaction of other Congresses with respect to other legislation, the phrase "on the basis of sex" as incorporated in Section 1557 should be interpreted based on its text and binding Supreme Court precedent.

[160] *Bruesewitz v. Wyeth LLC*, 562 U.S. 223, 242 (2011).
[161] *United States v. Craft*, 535 U.S. 274, 287 (2002) (internal quotation marks and citation omitted).
[162] *See* Civil Rights Uniformity Act of 2017, H.R. 2796, 115th Cong. § 3(b) (proposing that "No Federal civil rights law shall be interpreted to treat gender identity or transgender status as a protected class, unless such law expressly designates 'gender identity' or 'transgender status' as a protected class."); Title IX Clarification Act of 2016, H.R. 5307, 114th Cong. § 2 (proposing an amendment to Title IX stating that "the term 'sex' means with respect to an individual the biological sex of such individual").
[163] *Francis Coll. v. Al-Khazraji*, 481 U.S. 604, 614 (1987) (Brennan, J., concurring).
[164] *Reyes v. Pharma Chemie, Inc.*, 890 F. Supp. 2d 1147, 1158 (D. Neb. 2012).
[165] *See, e.g., Robinson v. Shell Oil Co.*, 519 U.S. 337, 341–42 (1997) (emphasis in original) (explaining that the fact that other statutes expressly state that they cover "former employees" does not mean that the term "employees" as used in the anti-retaliation provision of Title VII does not also include former employees).

e. Any final rule should be delayed pending the Title VII cases currently before the Supreme Court.

Whatever the merits of the Department's legal positions, the legal landscape in this area could soon shift. It would be inappropriate to move forward with any rulemaking at this time in light of the Supreme Court's decision to grant certiorari for three cases potentially impacting the legal underpinnings of this rule. The first two consolidated cases, *Bostock v. Clayton County Georgia* and *Altitude Express, Inc. v. Zarda* present the question of whether the prohibition of sex-based discrimination in Title VII of the Civil Rights Act of 1964 applies to discrimination based on an individual's sexual orientation.[166] In a third case to be heard separately, *R.G. & G.R. Harris Funeral Homes v. Equal Employment Opportunity Commission*, the Supreme Court will decide whether Title VII prohibits discrimination against transgender people based on (1) their transgender status or (2) sex stereotyping under *Price Waterhouse*.[167]

In its status report of December 14, 2018, filed in *Franciscan Alliance v. Azar*, the Department stated that these three cases "may well have an impact on the resolution of the rulemaking in this case," and informed the court that "Defendants are evaluating their draft proposed rule in light of these developments."[168] In the preamble to the Proposed Rule, the Department reiterates that these cases "will likely have ramifications" for Section 1557.[169] In light of the Department's own statements of the potential impact of the Supreme Court's now-pending decisions in these cases on the present rulemaking, it would be improper for the Department to move forward with any rulemaking prior to assessing the impact of the Supreme Court's decision in these cases. While the Department now claims that these pending decisions support its decision to forge ahead with repeal of the 2016 Rule, "predicted future actions cannot be used to support a decision already made."[170]

Although Section 1557 of the Affordable Care Act is a separate and distinct statute from Title VII of the Civil Rights Act, the resolution of these cases could potentially have the effect of altering the contours of or even invalidating the legal underpinnings of the Proposed Rule. This could render any resulting regulation either invalid or unnecessary, or require further rulemaking to clarify or correct its provisions. As such, proceeding with rulemaking at this time could lead to overwhelming confusion and legal uncertainty for health care industry stakeholders, health care professionals, and patients. Additionally, given the implications of these pending decisions for the substance of this Proposed Rule, a final rule adopted without benefit of public comment in light of the Supreme Court's rulings would deprive the public of a meaningful opportunity to comment under the APA. While we have strongly criticized the Government's failure to defend the 2016 rule and to contest the preliminary injunction in *Franciscan Alliance*, this state of affairs means that delaying any final rule would maintain the status quo while the Supreme Court considers these three cases. This supplies an additional and compelling reason for the Department not to finalize the Proposed Rule at this time.

[166] 139 S.Ct. 1599 (2019).
[167] *Id.*
[168] No. 7:16-CV-00108-O.
[169] Proposed Rule, 84 Fed. Reg. at 27855.
[170] *Becerra v. U.S. Dept. of the Interior*, 381 F.Supp.3d 1151, 1171 (N.D. Cal. 2019).

III. The Department has not provided any justification for rescinding all language recognizing that Section 1557 prohibits discrimination based on sex stereotypes.

Without any justification or explanation, the Department is proposing to remove all references in section 92.4 affirming the principle established in *Price Waterhouse* that sex discrimination law prohibits discrimination based on stereotypes about how people of different genders act or should act.[171] Sex stereotyping discrimination goes well beyond discrimination against transgender people, so the Department's reasoning (flawed as it is) for rescinding the gender identity provisions is inapposite to the rescission of the sex stereotyping provision. While the Department briefly suggests that covered entities will save money by ignoring discrimination based on sex stereotypes, the Proposed Rule completely fails to engage with binding law, or with the costs and benefits of this rescission given that covered entities remain liable for sex stereotyping discrimination.

As previously discussed, the Supreme Court in *Price Waterhouse* concluded that the words "because of…sex" in Title VII encompassed discrimination where "the employer relied upon sex-based considerations in coming to its decision."[172] The Court emphasized that sex-based considerations included behavioral and social sex-based considerations: "In the specific context of sex stereotyping, an employer who acts on the basis of a belief that a woman cannot be aggressive, or that she must not be, has acted on the basis of gender."[173] "As for the legal relevance of sex stereotyping," the Court added, "we are beyond the day when an employer could evaluate employees by assuming or insisting that they matched the stereotype associated with their group, for '[i]n forbidding employers to discriminate against individuals because of their sex, Congress intended to strike at the entire spectrum of disparate treatment of men and women resulting from sex stereotypes.'"[174]

Courts have regularly applied *Price Waterhouse*'s holding to Title IX,[175] and the Department of Education has consistently interpreted Title IX to prohibit harassment and other forms of discrimination based on sex stereotypes.[176] For example, in its 2010 Dear Colleague Letter on bullying and harassment, the Department of Education stated:

> Title IX prohibits harassment of both male and female students regardless of the sex of the harasser—i.e., even if the harasser and target are members of the same sex. It also prohibits gender-based harassment, which may include acts of verbal, nonverbal, or physical aggression, intimidation, or hostility based on sex or sex-stereotyping. Thus, it can be sex discrimination if students are harassed either for

[171] *See Price Waterhouse*, 490 U.S. at 240.
[172] *Id.* at 242.
[173] *Id.* at 250.
[174] *Id.* at 251 (quoting *City of Los Angeles Dep't of Water & Power v. Manhart*, 435 U.S. 702, 707 n.13 (1978)).
[175] *See, e.g., Doe v. Brimfield Grade Sch.*, 552 F. Supp. 2d 816, 823 (C.D. Ill. 2008); *Riccio v. New Haven Bd. of Educ.*, 467 F. Supp. 2d 219, 226 (D. Conn. 2006); *Theno v. Tonganoxie Unified Sch. Dist. No. 464*, 377 F.Supp.2d 952 D. Kan. 2005); *Montgomery v. Indep. Sch. Dist. No. 709*, 109 F.Supp.2d 1081 (D. Minn. 2000).
[176] *See*, *e.g.*, Dep't of Educ., *Dear Colleague Letter: Harassment and Bullying* (Oct. 26, 2010), https://www2.ed.gov/about/offices/list/ocr/letters/colleague-201010.pdf [hereinafter "Harassment Guidance"*]*; Dep't of Educ., *Revised Sexual Harassment Guidance: Harassment of Students by School Employees, Other Students, or Third Parties* (Jan. 19, 2001), https://www2.ed.gov/about/offices/list/ocr/docs/shguide.pdf.

> exhibiting what is perceived as a stereotypical characteristic for their sex, or for failing to conform to stereotypical notions of masculinity and femininity.[177]

The Department of Education under the current administration has continued to affirm that discrimination based on sex stereotyping is prohibited under Title IX, whether against transgender or non-transgender students.[178]

The principle that the Supreme Court codified in *Price Waterhouse* applies equally to health care settings covered under Section 1557. For example, if Ann Hopkins were a doctor who was denied a promotion or fired because her behavior and appearance was deemed to be insufficiently feminine, a court would undoubtedly conclude that such an action constituted discrimination based on sex in violation of Section 1557. Similarly, a patient who is turned away because she is deemed to not conform to stereotypes about women would similarly suffer a violation of her rights under Section 1557. This would be true regardless of whether the stereotype involved the patient failing to conform to stereotypes about feminine appearance,[179] because the provider arbitrarily favored working mothers over working fathers,[180] or on the basis of any other sex-related stereotype. Similarly, a health care facility that turned a blind eye to harassment of a male patient because his mannerisms were perceived as too effeminate would violate Section 1557.[181] Section 1557 also prohibits harassment or other discrimination on the basis of sex stereotyping against intersex patients in health care settings, on the basis that their physical sex characteristics do not conform to common assumptions about male and female bodies.[182]

While the removal of the section on sex stereotyping does not and cannot change the meaning of Section 1557, it will likely cause confusion for covered entities and patients. Removing this section could cause covered entities to be unsure about their legal obligations, causing hardships both for entities who must now undertake their own analysis of the law and for patients who may be subjected to discrimination and not realize they have legal recourse. The Department's references to sex stereotyping claims in its Regulatory Impact Analysis illustrate this problem:

[177] Harassment Guidance, *supra* note 176 at 7–8.
[178] *See, e.g.,* Dep't of Educ., *Q & A on Campus Sexual Misconduct* at 5 (Sept. 2017), https://www2.ed.gov/about/offices/list/ocr/docs/qa-title-ix-201709.pdf ("Decision-making techniques or approaches that apply sex stereotypes or generalizations may violate Title IX"); Acting Assistant Secretary for Civil Rights Candice Jackson, *OCR Letter to the Field re: Complaints Involving Transgender Students* at 1 (Jun. 6, 2017), https://assets.documentcloud.org/documents/3866816/OCR-Instructions-to-the-Field-Re-Transgender.pdf (affirming that the Office of Civil Rights has the authority to engaged in Title IX enforcement when a complaint alleges "gender based-harassment…based on sex stereotyping").
[179] *Cf. Lewis v. Heartland Inns of Am., L.L.C.*, 591 F.3d 1033 (8th Cir. 2010).
[180] *Cf. Back v. Hastings on Hudson Union Free Sch. Dist.*, 365 F.3d 107, 121 (2d Cir. 2004).
[181] *Cf. Prowel v. Wise Bus. Forms, Inc.*, 579 F.3d 285, 287 (3d Cir. 2009).
[182] *See, e.g.*, Human Rights Watch & interACT, *"I Want To Be Like Nature Made Me": Medically Unnecessary Surgeries on Intersex Children in the U.S.*, 60 (2017), https://bit.ly/2Y1N6DZ (quoting a patient who reported: "I've had doctors write 'ambiguous genitalia' on the front of all of my charts.… So when I get checked in or even go get my blood drawn, that's the first thing everyone sees, and it determines how I get treated. They giggle at me, and I've had one person refuse to draw my blood before"); Anne Tamar-Mattis, *Report to the Inter-American Commission on Human Rights: Medical Treatment of People with Intersex Conditions as a Human Rights Violation*, Advocates for Informed Choice (March 2013) at 2, https://goo.gl/Nf7Xt7; Katrina Karkazis, Anne Tamar-Mattis & Alexander A. Kon, *Genital Surgery for Disorders of Sex Development: Implementing a Shared Decision-Making Approach*, 23 J. PEDIATR. ENDOCRINOL. METAB. 789 (2010).

> The Department estimates that, under the proposed rule, covered entities would no longer have to incur certain labor costs associated with processing grievances related to sex discrimination complaints as they relate to…sex-stereotyping as defined under the Final Rule because such definitions would be repealed and no longer binding under the proposed rule. This proposed repeal would not, however, affect the independent obligations of Section 1557 covered entities to comply with Federal regulations under…Title IX to have written processes in place to handle grievances alleging certain…sex discrimination claims, respectively.[183]

The Department's proposed distinction between "costs associated with processing grievances related to sex discrimination complaints as they relate to…sex-stereotyping" and "the independent obligations of Section 1557 covered entities…to have written processes in place to handle grievances alleging certain…sex discrimination claims" is meaningless, given *Price Waterhouse*'s determination that discrimination based on sex stereotypes is unlawful discrimination under federal sex discrimination statutes. The only likely change is that some covered entities will fail to prevent or respond to claims of discrimination that are incontrovertibly covered by the statute per *Price Waterhouse*, and that some patients who face such discrimination will not file complaints in the first place. This, plainly, is a cost, not a benefit.

In the absence of any reasoned analysis for the removal of this section and in light of the clear harms of doing so, the complete rescission of any reference to sex stereotyping is arbitrary and capricious.

IV. The Department does not provide a justification for repealing the entirety of section 92.206 regarding discrimination in health care services.

The Department did not explain or justify removing the entire section 92.206 of the 2016 Rule ensuring equal access to health care services without respect to sex, including the discriminatory denials of services typically associated with one gender. Bizarrely, the Department appears to completely ignore the text of section 92.206 in asserting that the 2016 Rule would "require[e] health care entities to code as male all persons who self-identify as male, regardless of biology, [which] may lead to adverse health consequences."[184] This is precisely the opposite of what the 2016 Rule, through section 92.206, does.

Section 92.206 correctly prohibits, among other things, the arbitrary denial of care based not on clinical considerations but solely on the patient's sex as assigned at birth or as recorded in medical or insurance records. As the Department noted when proposing this section in 2015, "[f]or example, a covered entity may not deny an individual treatment for ovarian cancer where the individual could benefit medically from the treatment, based on the individual's identification as a transgender male" or because he is recorded as a male in medical or insurance records.[185] For the

[183] Proposed Rule, 84 Fed. Reg. at 27883.
[184] *Id.* at 27855 n. 59.
[185] Nondiscrimination in Health Programs and Activities, 80 Fed. Reg. 54172, 54188 (proposed Sept. 8, 2015) (to be codified at 45 C.F.R. pt. 92).

same reason, a transgender woman may not be denied access to screening or treatment for prostate or testicular cancer because of her female gender. Nor may a woman be denied clinically appropriate screening or treatment for breast cancer because medical or insurance records list or formerly listed her as male. While section 92.206 specifically mentions transgender patients based on well-documented cases involving this population, Section 1557 prohibits such discrimination against non-transgender and transgender patients alike, including intersex patients, as well as others who need "gender-atypical" care, such as men with or at risk for breast cancer.[186]

As discussed above, once an agency has chosen to implement a regulation, removal of such regulation requires a "reasoned analysis for the change."[187] With respect to section 92.206, the Department did not provide any legal, policy, or cost-benefit justification for removing this entire provision. Indeed, the Proposed Rule's preamble does not even mention section 92.206, let alone discuss it. A regulatory rescission is invalid when the agency offers "no explanation for the change."[188] To the extent the Department relies on its stated reasons for removing other provisions related to discrimination based on gender identity (which, as we discuss elsewhere, are fatally flawed), those reasons do not explain or justify deleting the whole of section 92.206. Quite apart from the Department's interpretation regarding discrimination based on *transgender status* or *gender identity*, Section 1557 clearly prohibits denying clinically appropriate services solely because of a patient's *recorded sex*, or because of *external or internal sex characteristics* that are not clinically relevant to those services.

This section is critical for addressing an all-too-common problem faced by transgender patients. It prohibits precisely the type of denial of treatment experienced by the pregnant patient discussed in Part 1, whose urgent pregnancy-related complications were not addressed in part because he was a transgender man.[189] Inexplicably, the Department points to this case to argue that the 2016 Rule increases the likelihood of such tragedies, when it fact its plain text seeks to prevent them. Section 92.206 expressly provides that "a covered entity may not deny or limit health services"—including assessing for and treating pregnancy-related complications—solely because of a patient's male gender identity, or male designation on a driver's license or insurance record. By prohibiting such discriminatory actions and encouraging covered entities to adopt procedures and train staff to prevent such denials and delays based on flawed assumptions about typically sex-linked services, the 2016 Rule helps ensure that all patients receive appropriate care based on an assessment of their clinical needs, which may require taking multiple sex-linked characteristics into account. In this way, section 92.206 complements the Department's Health Information Technology standards, which encourage separately coding patient's gender identity and sex assigned at birth.[190]

[186] *See* Susan G. Komen Foundation, *Facts for Life Breast Cancer in Men* (2016), https://ww5.komen.org/uploadedfiles/_komen/content/about_breast_cancer/tools_and_resources/fact_sheets_and_breast_self_awareness_cards/breastcancerinmen.pdf.
[187] *Motor Vehicles Mfrs. Ass'n v. State Farm Ins.*, 463 U.S. 29, 30 (1983).
[188] *United Steel v. Mine Safety and Health Admin.*, 925 F.3d 1279, 1284 (D.C. Cir. 2019).
[189] *See supra* note 54.
[190] 45 C.F.R. § 170.315(a)(5).

Section 92.206 simply prohibits discrimination in health care services based on sex-based traits, including a patient's recorded sex or sex assigned at birth. The Department has not provide any explanation, let alone a "reasoned analysis," for completely deleting this section.

V. The Department does not provide a "reasoned analysis" for repealing the entire section 92.207 regarding insurance coverage.

The Department also has not provided any "reasoned analysis" for the complete rescission of section 92.207, prohibiting discrimination based on race, color, national origin, age, disability, or sex in insurance coverage. The Department did not provide any reasoned legal, policy, or cost-benefit analysis for removing all of these provisions, including:

- Section 92.207(b)(1), which prohibits denying, canceling, limiting, or imposing additional cost sharing or limitations on coverage on the basis of race, color, national origin, sex, age, or disability;
- Section 92.207(b)(2), which prohibits marketing practices or benefit designs that discriminate on the basis of race, color, national origin, sex, age, or disability; and
- Section 92.207(b)(3), which prohibits denial of coverage based on sex coding.

There is no information presented regarding the removal of these provisions. The Department simply disregards this section of regulation, along with multiple other 1557 regulations, claiming that they are "[r]edundant [p]rovisions [d]uplicative of [p]re-existing [r]egulations," namely those adopted under Title VI, Rehabilitation Act, and Title IX.[191] However, the Department provides not even the most cursory analysis of how these provisions correspond to those of section 92.207. In fact, these existing regulations do not specifically address key components of section 92.207, including discrimination in cost sharing, coverage limitations, marketing practices, benefit designs, or on the basis of discrepancies in recorded sex.

The Department has previously explained how Section 1557 protects consumers from discriminatory benefit designs with respect to disability such as adverse tiering of drugs for a specific condition, or benefit exclusions that single out patients with particular developmental disabilities.[192] Without this protection, plans are encouraged to find indirect ways to evade the ACA's guaranteed issue provision by discouraging people with pre-existing conditions from enrolling. These protections are critical, for example, for patients living with HIV and AIDS. This includes a disproportionate number of transgender people: a recent meta-analysis estimated 14% of transgender women and 3% of transgender men in the United States were living with HIV, compared to less than 1% of the general population.[193] The Department fails to provide a reasoned legal, policy, or cost-benefit analysis for rescinding the benefit design provision of this section.

[191] Proposed Rule, 84 Fed. Reg. 27869.
[192] 2016 Rule, 81 Fed. Reg. at 31429; *HHS Notice of Benefit and Payment Parameters for 2016*, 80 Fed. Reg. 10,750, 10,822 (Feb. 17, 2015); CMS CCIIO, QHP Master Review Tools for 2015, Non-Discrimination in Benefit Design (2015), http://insurance.ohio.gov/Company/Documents/2015_Non-Discriminatory_Benefit_Design_QHP_Standards.pdf.
[193] Jeffrey S. Becasen et al., *Estimating the Prevalence of HIV and Sexual Behaviors Among the US Transgender Population: A Systematic Review and Meta-Analysis, 2006–2017*, 109 AM. J. PUBLIC HEALTH e1–e8 (Dec. 19, 2018), https://doi.org/10.2105/AJPH.2018.304727.

As discussed above, to the extent that the Department relies on its stated reasons for rescinding the 2016 Rule's gender identity provisions, such reasoning is inapplicable to section 92.207(b)(3). Separate and apart from the Department's interpretation regarding discrimination based on *transgender status* or *gender identity*, Section 1557 clearly prohibits denying coverage of clinically appropriate and otherwise-covered services solely because of a patient's *recorded sex*, or because of external or internal *sex characteristics* that are not clinically relevant to those services.

Many health insurers specifically target the transgender population by denying them coverage of services when those same services are covered for non-transgender people under the same plan. In many cases, transgender-related exclusions are broad and sweeping, arbitrarily targeting transgender people for discrimination by forcing them to pay out-of-pocket for the same medically necessary services provided to non-transgender people or for diagnoses other than gender dysphoria. Moreover, such exclusions have often been applied broadly to deny transgender people coverage for services that are unrelated to gender transition. While some of these exclusions were adopted many years ago, today there is a consensus among authoritative medical organizations that such exclusions have no scientific or evidentiary basis. [194] As discussed above, the discrimination that transgender people face in healthcare services is sex-based discrimination.

Data from the 2015 U.S. Transgender Survey shows that insurance discrimination, including automatic denials based on gender coding without regard to clinical need, is common. In this national sample of nearly 28,000 adults, just in the previous year, more than one in eight (13%) of those who sought coverage for services often considered to be gender-specific, including routine sexual or reproductive health screenings (such as Pap smears, prostate exams, and mammograms), were denied because of being transgender.[195] Overall, in the previous year, 25% of the sample overall experienced some form of discrimination in health insurance because of being transgender.[196] The Department's own complaint data showed that the Office for Civil Rights has successfully helped address this type of discrimination in the past without need for costly or protracted litigation.[197] As further explained below, any claim that prohibitions on discrimination in health insurance coverage are costly and unduly burdensome are unfounded.

Section 1557 clearly prohibits discrimination in health insurance based on race, color, national origin, age, disability, and sex—including on the basis of recorded sex or sex assigned at birth. The Department has failed to provide a reasoned legal, policy, or cost-benefit analysis for completing rescinding section 92.207, and the proposal to do so is arbitrary and capricious.

[194] *See*, *e.g.*, Am. Academy of Fam. Physicians, *Resolution No. 1004* (2012); Am. Medical Assn., *Resolution 122 (A-08), Removing Financial Barriers to Care for Transgender Patients* (2008); Am. Psychiatric Assn., *Position Statement: Access to Care for Transgender and Gender Variant Individuals* (2012); Am. Psychological Assn., *Policy on Transgender, Gender Identity & Gender Expression Non-Discrimination* (2008); Am. College of Physicians, *Lesbian, Gay, Bisexual, and Transgender Health Disparities: A Policy Position Paper*, 163 ANN INTERN MED. 135–137 (2015); Am. Coll. of Obstetricians & Gynecologists, *Committee Op. 512*, 118 OBSTETRICS & GYNECOLOGY 1454 (2011); Nat'l Ass'n of Social Workers, *Trans and Gender Identity Issues Policy Statement* (2008).
[195] Sandy E. James et al., *The Report of the 2015 U.S. Transgender Survey* 96 (2016), www.ustranssurvey.org/report.
[196] *Id*.
[197] Sharita Gruberg & Frank J. Bewkes, *The ACA's LGBTQ Nondiscrimination Regulations Prove Crucial* (2018), https://www.americanprogress.org/issues/lgbt/reports/2018/03/07/447414/acas- lgbtq-nondiscrimination-regulations-prove-crucial.

VI. The Department did not justify the wholesale removal of the employer liability provision (section 92.208).

The Department fails to provide a reasoned legal, policy, or cost-benefit analysis to support the wholesale removal of this section. The Department cursorily states that these provisions "are duplicative of, inconsistent with, or may be confusing in relation to" the Department's Title IX regulations.[198] This explanation is flawed and inadequate, in part because (1) many covered entities under Section 1557 are not covered under the Department's Title IX regulation, and because (2) the Title IX regulation applies only to discrimination based on sex, while Section 1557 comprehensively covers discrimination on the basis of race, color, national origin, disability, age, or sex. OCR has jurisdiction over complaints regarding covered employee health plans, and employers and employees benefit from the clarity this provision provides.

VII. The Department did not justify the wholesale removal of the associational discrimination provision (section 92.209)

"Associational discrimination" refers to discrimination against an individual because of who they are dating, married to, or otherwise associated with. In the context of healthcare, this could include refusing care to a patient because the patient's parent, spouse, or partner is transgender or does not conform to sex stereotypes. With the wholesale removal of the associational discrimination provision within section 92.209, the Department is suggesting that this type of discrimination is permissible. Further, the Department does not provide any sort of analysis or reasoning for why they are rescinding these regulations. This is a clear violation of both substantive and procedural standards under the APA.

a. Under well-settled law, Section 1557 prohibits associational discrimination.

Courts have uniformly held for decades that discrimination on the basis of a protected characteristic of a person with whom one has a relationship or association falls under nondiscrimination laws.[199] Most cases of associational discrimination come in the context of employment with someone being fired because of the protected class of their loved one. Although many of those cases involve associations between persons of different races, many courts have recognized that the principles of associational discrimination apply equally to all of Title VII's protected classifications, including sex.[200] Indeed, as the Supreme Court said in *Price Waterhouse v. Hopkins* regarding Title VII, "the statute on its face treats each of the enumerated categories exactly the same."[201] This same principle applies here and supports the text of section 92.209.

[198] Proposed Rule, 84 Fed Reg. at 27869.
[199] *See, e.g.*, *Holcomb v. Iona Coll.*, 521 F.3d 130, 139 (2d Cir. 2008); *Tetro v. Elliott Popham Pontiac, Oldsmobile, Buick, & GMC Trucks, Inc.*, 173 F.3d 988, 994–95 (6th Cir. 1999); *Deffenbaugh-Williams v. Wal-Mart Stores, Inc.*, 156 F.3d 581, 589 (5th Cir. 1998), *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); *Barret v. Whirlpool,* 556 F.3d 502 (6th Cir. 2009).
[200] *See, e.g., Hively v. Ivy Tech Cmty. Coll. of Ind.*, 853 F.3d 339, 345 (7th Cir. 2017) (en banc); *Barrett v. Whirlpool Corp.*, 556 F.3d 502, 512 (6th Cir. 2009).
[201] 490 U.S. at 243 n. 9.

The U.S. Court of Appeals for the Seventh Circuit clearly articulated this reasoning in a recent case. In *Hively v. Ivy Tech*, a woman made the argument that she was not selected for permanent positions of employment because she was a woman and was in an intimate relationship with another woman. She applied for a permanent position several times over the timespan of five years, but she was denied every time and was eventually let go from her part-time position. Focusing on the statutory text, the en banc Seventh Circuit held:

> The fact that [previous cases] deal with racial associations, as opposed to those based on color, national origin, religion, or sex, is of no moment. The text of the statute draws no distinction, for this purpose, among the different varieties of discrimination it addresses—a fact recognized by the *Hopkins* plurality. This means that to the extent that the statute prohibits discrimination on the basis of the race of someone with whom the plaintiff associates, it also prohibits discrimination on the basis of the national origin, or the color, or the religion, or (as relevant here) the sex of the associate. No matter which category is involved, the essence of the claim is that the plaintiff would not be suffering the adverse action had his or her sex, race, color, national origin, or religion been different.[202]

Accordingly, the en banc court held that Hively could assert an associational sex discrimination claim.

Similarly, a New York court held that discrimination on the basis of the religion of an employee's spouse constituted discrimination "because of an individual's…religion" under a state law paralleling Title VII.[203] In that case, an employee suffered severe harassment in the work place because of his wife's Jewish identity and faith. The employer claimed that a spouse's religion was not a covered ground under the law, but the appellate court, drawing on federal Title VII law, concluded that "the plaintiff sufficiently demonstrated his membership in a protected class by virtue of the defendants' alleged discriminatory conduct stemming from his marriage to a Jewish person."[204]

This reasoning applies to discrimination based on race, color, national origin, age, disability, or sex under Section 1557 and similar laws, and no court has held otherwise.[205] Consider for example the scenario where an individual is turned away by a hospital or a long-term care facility because of, for example, their partner's race or religion, or faces harassment based on that association. In such cases, the partner's race or religion would be the but-for cause of discrimination against the

[202] *Hively*, 853 F.3d at 349 (internal citations omitted).
[203] *Chiara v. Town of New Castle*, 126 A.D.3d 111 (N.Y. App. Div. 2015).
[204] *Id.* at 121.
[205] Two courts have rejected associational sex discrimination claims on fact-specific grounds. In *Partners Healthcare System v. Sullivan*, the court held that associational sex discrimination claims were barred to the extent they would"serve to protect sexual orientation in any context where sex discrimination is protected," on the ground that this would be inconsistent with First Circuit precedent on sexual orientation.. 497 F.Supp.2d 29, 39 (D. Mass. 2007). The court's holding was not based on analysis of the statutory text. In *Stezzi v. Aramark Sports, LLC*, the court recognized that "an associational sex discrimination claim may be cognizable under the right facts," but held that the instant case did not present those facts. No. CIV.A. 07-5121, at *10 (E.D. Pa. July 30, 2009).

patient.[206] The same would be true for discrimination based on the race, color, national origin, sex, age, or disability of a patient's parent or other family member. Such cases exist, such as that faced by Jami and Krista Contreras, whose six-day-old daughter was turned away by a pediatrician in 2015 because of the sex of her parents.[207] There is no basis in the text of Title VII, or the text of Section 1557, for distinguishing between the listed characteristics with respect to this well-established doctrine.

b. The Department fails to even mention, let alone explain, its rescission of section 92.209

The Department does not provide any sort of legal, policy, or cost-benefit analysis for this change and its potential impact on patients. In fact, the preamble to the Proposed Rule contains no reference at all to section 92.209. Such denials of care could delay needed diagnosis or treatment and lead to negative health outcomes, with economic and non-economic costs for patients and the health care system. As the late Justice Scalia wrote, "the requirement that an agency provide reasoned explanation for its action would ordinarily demand that it display awareness that it *is* changing position."[208] Here, the Department appears to "depart from a prior policy *sub silentio*,"[209] with no explanation or acknowledgement that it is changing a settled position—let alone one uniformly supported by decades of case law. The Department not only offers "no explanation for the change,"[210] it fails to even acknowledge it is deleting this entire provision. This is arbitrary and capricious, and deprives the public of an adequate opportunity to comment on the proposal.[211]

VIII. The Department cannot justify shoehorning ten unrelated CMS rule changes into a Section 1557 rule.

Separate from the revisions to 45 C.F.R. part 92 implementing Section 1557 of the ACA, the Department proposes to rescind portions of no fewer than ten separate, unrelated regulations adopted by the Centers for Medicare and Medicaid Services (CMS) between 2006 and 2016. The Department describes these as "conforming amendments," but they are not conforming in any sense of that word. While the bulk of the Proposed Rule relates to the interpretation and enforcement of Section 1557 of the ACA, these CMS rules do not interpret Section 1557 or any sex discrimination statute, and were adopted under other, unrelated statutory authorities. The Department offers no legal, policy, or cost-benefit analysis regarding these rules, the impacts they have had during the years they have been in place, or the costs and benefits of rescinding them. In fact, each of these provisions is legally sound and a reasonable measure to protect patients and effectively implement statutory programs.

[206] *Cf. Parr*, 791 F.2d at 892.
[207] Abby Phillip, *Pediatrician Refuses to Treat Baby with Lesbian Parents and There's Nothing Illegal About It*, WASH. POST (Feb. 19, 2015), https://www.washingtonpost.com/news/morning-mix/wp/2015/02/19/pediatrician-refuses-to-treat-baby-with-lesbian-parents-and-theres-nothing-illegal-about-it; *see also* Amicus Brief of Lambda Legal Defense and Education Fund et al., *Masterpiece Cakeshop v. Colo. Civil Rights Comm'n,* No. 16-111, 17–19 (Sup. Ct. *filed* Oct. 30, 2017).
[208] *Fox Television Stations,* 556 U.S. at 515.
[209] *Id.*
[210] *United Steel v. Mine Safety and Health Admin.*, 925 F.3d 1279 (D.C. Cir. 2019).
[211] *See Am. Med. Ass'n v. Reno*, 57 F.3d 1129, 1132 (D.C. Cir. 1995) ("[n]otice of a proposed rule must include sufficient detail on its content and basis in law and evidence to allow for meaningful and informed comment").

a. *These CMS rules were adopted under widely varying authorities unrelated to Section 1557.*

The Department's legal arguments regarding anti-transgender discrimination, insufficient as they are, are all targeted at the interpretation of sex discrimination under Section 1557. The CMS regulations it proposes to change, however, were adopted based on statutory authorities and factual findings that bear no connection to the Department's interpretation of Section 1557. The Department offers no legal basis for reversing its position in these regulations and no evidence of changes in circumstances that would permit it to override its previous well-reasoned justifications. Its sole explanation for these rescissions is that "the regulations are not based on independent statutory authority which expressly provides such prohibition."[212] However, each of these rules was clearly and explicitly adopted based on authorities that grant the Secretary discretion to promulgate appropriate regulations, including prohibiting practices harmful to patients.

1. Section 1321 of the ACA

Several of the regulations that the Department now proposes to revise were adopted under the authority of section 1321 of the ACA. Section 1321 directs the Secretary to "issue regulations setting standards" for "the establishment and operation of Exchanges," "the offering of qualified health plans," and "such other requirements as the Secretary determines appropriate."[213] Based upon this authority, the Department adopted several regulations that it reasonably determined were necessary to execute to Congress's intent of providing quality, affordable health coverage to all eligible individuals. The Department has not provided any legal or factual analysis to explain its rejection of these well-supported regulations. As these regulations rely on the Secretary's authority under section 1321 and bears no relevance to the Department's new position on Section 1557, Title IX, or sex discrimination statutes, the Department's attempt to shoehorn a repeal of this provision into an unrelated regulation in the absence of any justification is arbitrary and capricious.

ACA Exchange Standards (45 CFR 155.120). Pursuant to its authority under section 1321, the Department adopted various appropriate requirements for Exchanges, including standards related to minimum Exchange functions, eligibility and enrollment, product discontinuation and renewal, quality reporting, and nondiscrimination. Recognizing the evidence of discrimination based on gender identity and sexual orientation in health insurance and related industries discussed elsewhere in this comment, the Department used the discretion that Congress granted to it under section 1321 to include gender identity and sexual orientation in the list of characteristics upon which Exchanges may not discriminate. This regulation's text and structure make clear the Department's intent to supplement existing nondiscrimination statutes with additional consumer protections based on the Secretary's grant of authority to set reasonable standards for Exchanges. Section 155.120 first provides that each State and Exchange must "(i) comply with applicable non-discrimination statutes," and, *in addition*, must "(ii) [n]ot discriminate based on race, color, national origin, disability, age, sex, gender identity or sexual orientation."

[212] Proposed Rule, 84 Fed. Reg. at 27871.
[213] 42 U.S.C. § 18051(a).

ACA Marketing and Benefit Design Standards (45 CFR 147.104). This regulation was adopted in 2013 under section 1321 as well as section 2792 of the Public Health Service Act. Pursuant to its authority under section 1321, the Department adopted appropriate requirements to ensure the guaranteed availability of coverage to eligible consumers, including requirements related to enrollment periods, financial capacity limits, and unfair marketing practices and benefit designs. The regulation prohibits marketing or benefit designs "that will have the effect of discouraging the enrollment of individuals with significant health needs in health insurance coverage." Relatedly, it prohibits practices that discriminate on the basis of race, color, national origin, present or predicted disability, age, sex, gender identity, sexual orientation, expected length of life, degree of medical dependency, quality of life, or other health conditions. The Department determined that "discriminatory marketing practices or benefit designs represent a failure by issuers to comply with the guaranteed availability requirements."[214] In adopting this rule, the Department made clear its intent to supplement consumer protections expressly provided in sections 1302 and 1557 of the ACA.[215] The Department has made substantive updates to section 147.104 on seven occasions, most recently in April 2017 and April 2018, and has not previously identified reason for reconsidering its nondiscrimination protections, nor has it done so now.[216]

ACA Qualified Health Plan (QHP) Standards (45 CFR 156.200). Adopted in 2012 under section 1321, this regulation sets forth various requirements to ensure access to qualified, affordable coverage for all eligible consumers. As with the other regulations discussed above, some of these requirements directly implement statutory requirements, while others are based on the Secretary's determination that they were necessary to implement the purposes of QHPs as established by Congress. In order to protect consumers from harm and to advance Congress's purposes of ensuring access to quality, affordable coverage for all eligible individuals, this regulation prohibits discrimination in QHPs on the basis of race, color, national origin, disability, age, sex, gender identity, and sexual orientation. The Department stated explicitly that this subsection (e) was adopted "pursuant to the authority to set QHP standards in section 1321(a)(1)(B)" rather than Section 1557. The Department has updated section 156.200 five times, most recently in 2018, and has not previously identified reason for reconsidering its nondiscrimination protections, nor has it done so now.[217]

ACA Direct Enrollment Standards (45 CFR 156.1230). This regulation sets out requirements, including nondiscrimination requirements, that parallel those adopted for brokers and agents under section 155.220, discussed below, and are aimed at addressing the same consumer protection concerns. The Department reasonably determined that these requirements were appropriate to meet Congress's purpose of providing quality, affordable health coverage to all eligible individuals. Since adding these nondiscrimination provisions, the Department has updated section 156.1230 in

[214] Patient Protection and Affordable Care Act; Health Insurance Market Rules; Rate Review, 78 Fed. Reg. 13406, 13416 (Feb. 27, 2013).

[215] *Id.* (noting that this provision incorporates grounds enumerated in those statutory provisions as well as grounds enumerated the Department's ACA Exchange regulation, discussed above).

[216] 78 Fed. Reg. 65092 (Oct. 30, 2013); 78 Fed. Reg. 76217 (Dec. 17, 2013); 79 Fed. Reg. 30339 (May 27, 2014); 80 Fed. Reg. 10862 (Feb. 27, 2015); 81 Fed. Reg. 94173 (Dec. 22, 2016); 82 Fed. Reg. 18381 (Apr. 18, 2017); 83 Fed. Reg. 17058 (Apr. 17, 2018).

[217] 78 Fed. Reg. 15535 (Mar. 11, 2013); 79 Fed. Reg. 30351 (May 27, 2014); 80 Fed. Reg. 10873 (Feb. 27, 2015); 81 Fed. Reg. 94181 (Dec. 22, 2016); 83 Fed. Reg. 17069 (Apr. 17, 2018).

April 2018 and again in April 2019, and has not previously identified reason for reconsidering its nondiscrimination protections, nor has it done so in the Proposed Rule.[218] This regulation is based on statutory authorities unrelated to any interpretation of sex discrimination statutes, and it remains a reasonable and valid measure to protect consumers. With regard to those determinations, "the Department [has] failed to acknowledge, much less to address, the inconsistency between its current view…and its prior conclusion.… [A]n unacknowledged and unexplained inconsistency is the hallmark of arbitrary and capricious decision-making."[219]

2. Section 1312 of the ACA

The Department's **ACA Broker and Agent Standards (45 CFR 155.220)** were adopted under the authority of section 1312 of the ACA, not Section 1557. Section 1312(e) authorizes the Secretary to establish rules for agents and brokers to enroll individuals in ACA plans and assist them in applying for premium tax credits.[220] Pursuant to this authority, the Department has adopted various appropriate requirements for agents and brokers, including requirements for registration and protections for consumers against coercion, deception, privacy violations, and discrimination. The Department adopted these standards "to protect against agent and broker conduct that is harmful towards consumers, or prevents the efficient operation of the FFEs."[221]

To protect consumers from harm and to advance Congress's purposes of ensuring access to quality, affordable coverage, this regulation prohibits agents or brokers from "marketing or conduct that is misleading (including by having a direct enrollment Web site 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, sex, gender identity, or sexual orientation."[222] This regulation's text and structure make clear the Department's intent to supplement existing nondiscrimination statutes with additional consumer protections based on the Secretary's grant of authority to set reasonable standards for agents and brokers operating within Exchanges. Section 155.220(j)(2)(v) requires agents and brokers to "[c]omply with all applicable Federal laws and regulations," while subsection (j)(2)(i) additionally requires them to refrain from conduct that is coercive, deceptive, misleading, or discriminates on bases including gender identity and sexual orientation.

The Department reasonably determined that these requirements were appropriate to meet Congress's purpose of providing quality, affordable health coverage to all eligible individuals. The Department updated section 155.220, including subsection (j), in April 2019. At that time, it did not identify any reason for reconsidering its nondiscrimination protections,[223] nor has it done so now. As with the regulations discussed above, this regulation was not promulgated based on the Department's interpretation of sex discrimination or Section 1557, but rather as on an independent

[218] 83 Fed. Reg. 17070 (Apr. 17, 2018); 84 Fed. Reg. 17568 (Apr. 25, 2019).
[219] *Bauer v. DeVos*, 325 F.Supp.3d 74, 109 (D.D.C. 2018).
[220] 42 U.S.C. § 18032(e).
[221] Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2017, 80 Fed. Reg. 75488, 75526 (proposed Dec. 2, 2015).
[222] 45 C.F.R. § 155.220(c)(3).
[223] Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2020, 84 Fed. Reg. 17563 (Apr. 25, 2019).

provision of the ACA, and so Department's arguments regarding the interpretation of Section 1557 provide no justification for the change to this regulation.

3. Program for All-Inclusive Care for the Elderly (PACE) Standards (42 CFR 460.98 and 460.112)

The PACE nondiscrimination provisions were adopted in 1999 and updated in 2006—prior to the 2010 passage of the Affordable Care Act—under the authority of Section 1894 of the Social Security Act and Section 902 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA). Section 460.98 provides that "[t]he PACE organization may not discriminate against any participant in the delivery of required PACE services based on race, ethnicity, national origin, religion, sex, age, sexual orientation, mental or physical disability, or source of payment."[224] Section 460.112 provides that "[e]ach participant has the right to considerate, respectful care from all PACE employees and contractors at all times and under all circumstances," including "the right not to be discriminated against in the delivery of required PACE services."[225]

Like the PACE regulations generally, these nondiscrimination provisions reflect the principles of the Consumer Bill of Rights and Responsibilities developed by the President's Advisory Commission on Consumer Protection and Quality in the Health Care Industry and published in 1998.[226] They are also based on the original PACE Protocol first published in 1995, which guarantees participants "the right to have dignity, privacy, and humane care."[227] Explaining the addition of "sexual orientation" to the rule's nondiscrimination provisions in 2006, the Department stated, "we do not believe anyone should be denied enrollment in PACE because of discrimination of any kind."[228]

The Department reasonably determined that these requirements were appropriate to meet Congress's purpose of providing an effective program of all-inclusive care to eligible elderly individuals, consistent with the principles of dignity and humane care that made PACE a demonstrated success. These requirements were adopted prior to the passage of the ACA under statutory authorities unrelated to the interpretation of sex discrimination laws, and they remain reasonable and valid measures to protect Medicare beneficiaries participating in PACE. The Department has not provided any reasoned analysis to the contrary, and repealing them would be arbitrary and capricious.

4. Medicaid Managed Care Standards (42 CFR 438.3, 438.206, and 440.262)

These regulations were adopted under the authority of section 1902 of the Social Security Act, not Section 1557 of the ACA. Section 1902 directs the Secretary to develop "such methods of administration…as are found by the Secretary to be necessary for the proper and efficient

[224] 42 C.F.R. § 460.98(b)(3).
[225] 42 C.F.R. § 460.112(a).
[226] Advisory Commission on Health Consumer Protection and Quality in the Health Care Industry, *Quality First: Better Health Care for All Americans*. Washington, DC: US Government Printing Office, 1998.
[227] Medicare and Medicaid Programs; Programs of All-Inclusive Care for the Elderly (PACE); Program Revisions; Final Rule, 71 Fed. Reg. 71244, 71294 (Dec. 8, 2006).
[228] *Id.* at 71295.

operation" of Medicaid plans. Pursuant to this authority, the Department has adopted various reasonable requirements to ensure the integrity and efficacy of managed care plans, including standards for contract review and approval, covered services, payment, network adequacy and choice of provider, timeliness of services, physician incentives, subcontracts, financial integrity, conflicts of interests, and nondiscrimination.

With respect to adding sex, sexual orientation, and gender identity to section 438.3's enrollment nondiscrimination provision in, the Department previously stated:

> We believe that the obligation for the state plan to promote access and delivery of services without discrimination is necessary to assure that care and services are provided in a manner consistent with the best interest of beneficiaries under section 1902(a)(19) of the Act. Prohibiting a managed care plan from discriminating in enrollment on these bases is necessary to ensure access and provision of services in a culturally competent manner. We believe that the best interest of beneficiaries is appropriately met when access to managed care enrollment (as well as access to services themselves) is provided in a non-discriminatory manner; adopting these additional methods of administration is also necessary for the proper operation of the state plan under section 1902(a)(4) of the Act.[229]

While noting that the addition of "on the basis of…sex" to this provision was in part motivated by a desire for consistency with Section 1557, the Department also grounded its explicit enumeration of sexual orientation and gender identity in section 1902:

> We also proposed to add sex as a protected category for purposes of MCO, PIHP, PAHP, PCCM, or PCCM entity enrollment practices in the enrollment provisions proposed to be moved to § 438.3(d)(4), because adding this category is consistent with the scope of Section 1557 of the Affordable Care Act. We also proposed to add sexual orientation and gender identity because managed care plans are obligated to promote access and delivery of services without discrimination and must ensure that care and services are provided in a manner consistent with the best interest of beneficiaries under section 1902(a)(19) of the Act.[230]

The Department similarly explained its addition of requirements for cultural competence and nondiscrimination in section 438.206 and section 440.262:

> In paragraph (c)(2), we proposed to add to the standards to ensure that MCOs, PIHPs, and PAHPs participate in states' efforts to promote access in a culturally competent manner to all enrollees. This includes those with limited English proficiency, diverse cultural and ethnic background, disabilities, and regardless of an enrollee's gender, sexual orientation, or gender identity. We also proposed to add a corresponding standard in a new § 440.262 so that the state would similarly

[229] Medicaid and Children's Health Insurance Program (CHIP) Programs; Medicaid Managed Care, CHIP Delivered in Managed Care, and Revisions Related to Third Party Liability, 81 Fed. Reg. 27498, 27538 (May 6, 2016).
[230] *Id.* at 27539.

> ensure cultural competence and non-discrimination in access to services under FFS. We believe that the obligation for the state plan to promote access and delivery of services without discrimination is necessary to assure that care and services are provided in a manner consistent with the best interest of beneficiaries under section 1902(a)(19) of the Act. We noted that the best interest of beneficiaries is appropriately met when access is provided in a non-discriminatory manner; adopting these additional methods of administration is also necessary for the proper operation of the state plan under section 1902(a)(4) of the Act.[231]

The Department reasonably determined that these requirements were appropriate to achieve Congress's purpose of providing quality care to all eligible Medicaid beneficiaries. These requirements were adopted under a statutory authority unrelated to the interpretation of sex discrimination laws, and they remain reasonable and valid measures to protect Medicaid beneficiaries participating in managed care plans. The Department has not provided any reasoned analysis to the contrary, and repealing them would be arbitrary and capricious.

b. The Proposed Rule arbitrarily singles out sexual orientation and gender identity among several characteristics that are not enumerated in Section 1557.

While the Department seeks to remove protections based sexual orientation and gender identity, it preserves protections for other characteristics that are not expressly enumerated in the relevant nondiscrimination statute. The Department has adequate authority for all the provisions in these nondiscrimination regulations separate and apart from Section 1557, and has reasonably determined they are necessary. The Department's decision to rescind protections for characteristic not listed in Section 1557, but not for others, further underscores the arbitrary nature of these proposed rescissions.

For example, sections 460.98 and 460.112 of the PACE regulations also prohibit discrimination on the basis of religion, a provision originally adopted in 1999. Like sexual orientation and gender identity, these prohibitions on religious discrimination were validly adopted not under Title VI or the not-yet-enacted section 1557, but under the Department's authorities under the Social Security Act and the Medicare Modernization Act.

Similarly, section 438.206 requires managed care plans to "participate[ ] 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." Similarly, section 440.262 requires states to "promote access and delivery of services in a culturally competent manner to all beneficiaries, including those with limited English proficiency [and] diverse cultural and ethnic backgrounds." "Diverse cultural and ethnic backgrounds" is a broad category that overlaps with, but also goes beyond, the requirements of Title VI. Like the enumeration of sexual orientation and gender identity, these provisions are validly grounded in the Department's authority under the Medicaid statute, and the Department reasonably determined they are necessary to protect patients.

[231] *Id.* at 27666.

c. The Proposed Rule deletes provisions unrelated to protections against discrimination based on sexual orientation or gender identity without explanation.

Also unexplained is the proposed rescission of regulatory provisions unrelated to sexual orientation and gender identity in these rules. Specifically, in addition to deleting references to gender identity and sexual orientation, the Department proposes to delete a vitally important sentence from section 440.220 of the Medicaid managed care regulations. This section requires that states "have methods to promote access and delivery of services in a culturally competent manner," and states: "These methods must ensure that beneficiaries have access to covered services that are delivered in a manner that meet their unique needs." The Proposed Rule deletes this latter sentence in its entirety, *sub silentio*. The deleted sentence is a critical component for many patients, including those with disabilities or limited English proficiency, for whom a lack of access to services that meet their unique needs can be equivalent to lack of access altogether. The deletion of this sentence would further render this provision almost entirely ineffectual, since it would be reduced to a vague requirement that states "have methods" to promote culturally competent services, rather than requiring these methods to meet even minimal standards of effectiveness. In light of the potential harms of this change, the Department's failure to even acknowledge this change, let alone provide legal, policy, or cost-benefit analysis to justify its rescission, is deeply troubling, and once again indicates that the revision is likely arbitrary or capricious.

IX. The Department's longstanding Title IX "rules of appearance" regulation is well supported by Title IX law and the Department provides no reasoned analysis for rescinding it.

The Proposed Rule seeks to remove language from a regulation implementing Title IX of the Educational Amendments Act, which prohibits discrimination "against any person in the application of any rules of appearance" in Department-funded education programs and activities.[232] Like the proposed changes to unrelated CMS rules, the Department's proposed deletion of 45 CFR § 86.31(b)(5) is not in any sense a "conforming amendment." Instead, this is an unrelated rule change relating to an entirely separate area of Department regulations and has no relevance to the implementation of Section 1557 or any provision of the Affordable Care Act.

The Department notes that other agencies do not have similar provisions in their Title IX regulations related to rules of appearance, and that the parallel Department of Education (then the Department of Health, Education, and Welfare, or HEW) regulation was previously revoked. The parallel HEW regulation was first adopted in 1975. A proposal to rescind it was first published in 1978,[233] withdrawn in 1979,[234] proposed again in 1981,[235] and finalized in 1982.[236] None of these regulatory actions provided any legal analysis of the text of the Title IX statute or applicable case law or identified any evidence of real-world problems caused by the regulation, and none reflect subsequent developments that have shed new light on their costs and benefits. Nor are these

[232] 84 Fed. Reg. at 27871 (citing 45 C.F.R. § 86.31(b)(5)).
[233] 43 Fed. Reg. 58076 (1978).
[234] 44 Fed. Reg. 66626 (1979).
[235] 46 Fed. Reg. 23081 (1981).
[236] 47 Fed. Reg. 32526 (1982).

agencies' current regulations, as written, inconsistent with the Department's current rules of appearance rule.[237] Critically, neither HEW, nor the Department of Education, nor any other agency has ever interpreted Title IX or related statutes to completely insulate rules of appearance or their application from sex discrimination analysis.

Moreover, contrary to the Department's assertion that deleting this provision could eliminate confusion, its revision would in fact cause confusion and send an erroneous message that covered entities may freely use rules of appearance in ways that discriminate based on sex, or are pretext for discrimination based on sex. Subsequent to the HEW rule change in 1982, the Supreme Court held in *Price Waterhouse* that Title VII prohibits discrimination based on sex stereotypes. Under *Price Waterhouse*, courts have held uniformly that the application of rules of appearance may be challenged under Title VII, though the analysis of such claims may be fact-sensitive. For example, in *Lewis v. Heartland Inns of America, L.L.C.*, the Eighth Circuit held that a requirement that female employees appear "pretty" and present a "Midwestern girl look" not appear "tomboyish" violated Title VII.[238]

The Department cites to *Jespersen v. Harrah's Operating Co.,*[239] arising under Title VII of the Civil Rights Act of 1964, and suggests that the provision proposed for deletion is in conflict with that precedent. Assuming that *Jespersen* is correct in its analysis of the law, that case does not hold that Title VII or Title IX never apply to any rules of appearance or their application. Rather, relying on the requirement that "discrimination" under Title VII must involve an adverse action that materially alters the "terms" and "conditions" of employment for an individual.[240] *Jespersen* held that a specific set of rules of appearance that included requirements for men and requirements for women, absent evidence that it imposed an unequal burden on plaintiff on the basis of sex, did not constitute an adverse action. Neither *Jespersen* nor any other Title VII or Title IX precedent carves sex-specific appearance rules out from sex discrimination protections or insulates them from review as a general matter.

In fact, *Jespersen* explicitly rejected such a view, stating: "we hold that appearance standards, including makeup requirements, may well be the subject of a Title VII claim for sexual stereotyping, but that on this record Jespersen has failed to create any triable issue of fact that the challenged policy was part of a policy motivated by sex stereotyping."[241] The en banc court found this point important enough to stress it twice, concluding: "We emphasize that we do not preclude, as a matter of law, a claim of sex-stereotyping on the basis of dress or appearance codes."[242] Simply put, *Jespersen*, like *Lewis*, actually undercuts this proposed change.

[237] 34 C.F.R. § 106.31(b)(4); ("subject[ing] any person to separate or different rules of behavior, sanctions, or other treatment").
[238] 591 F.3d 1033, 1036 (8th Cir. 2010). *See also Hayden v. Greensburg Cmty. Sch. Corp.,* 743 F.3d 569 (7th Cir. 2014) (holding hair length policy that applied only to male student athletes violated Title IX and Equal Protection Clause); *Sturgis v. Copiah Cty. Sch. Dist.,* No. 3:10-CV-455, 2011 WL 4351355, at *1-4 (S.D. Miss. Sept. 15, 2011) (holding challenge to school policy that required female students to wear drapes and male students to wear tuxedos for their senior yearbook portraits stated Title IX and Equal Protection claims).
[239] 444 F.3d 1104, 1107 (9th Cir. 2006) (en banc).
[240] 42 U.S.C. § 2000e-2(a)(1).
[241] 444 F.3d at 1107 (en banc).
[242] *Id.* at 1113.

The Department's Regulatory Impact Analysis does not even mention the deletion of section 86.31(b)(5), let alone analyze any costs or benefits of this change. While the Department suggests that this provision contributes to litigation (a potential cost), recognition by the Department of the statute's potential application in this area makes it more likely that any potential violations could be addressed through the far more efficient OCR complaint mechanism rather than through litigation. Even if the Department had identified any potential benefits to deletion, it did not consider the cost to students of encouraging the application of rules that may, under *Price Waterhouse*, *Jespersen*, and *Lewis*, result in unlawful discrimination against them, costing them educational opportunities and causing other harms.

Finally, even if the Department had offered a compelling legal and cost-benefit analysis, this is a particularly inappropriate time to change this provision. As discussed previously, the U.S. Supreme Court is currently reviewing the case of *R.G. & G.R. Harris Funeral Homes v. E.E.O.C. and Stephens*,[243] which may well address the scope of permissible claims related to rules of dress and appearance under Title VII. This pending decision could render this rule change either superfluous or invalid or require further clarification by the Department. For this reason, in addition to all the others discussed above, the Department should not make this rule change at this time but should continue to evaluate guidance from the Supreme Court and the lower federal courts.

X. The Department failed to justify deleting other definitions in section 92.4.

The Department proposes to completely rescind the definitions of numerous critical terms, including:

- Covered entity;
- Electronic and information technology;
- Employee health benefit program;
- Federal financial assistance;
- Individual with a disability;
- Individual with LEP;
- National origin;
- Qualified bilingual/multilingual staff;
- Qualified individual with a disability; and
- Recipient.

These definitions have been helpful to patients and covered entities, and the fact that some of them are included in other regulations applying to different sets of covered entities does not justify removing them. These definitions provide clarity and consistency for entities covered by Section 1557, who may not be covered by or familiar with the regulations adopted under other statutes. These deletions will provide no net benefit, and the Department should retain these definitions.

[243] 139 S.Ct. 1599 (2019).

XI. The Department improperly proposes to rescind language affirming that sex discrimination includes discrimination on the basis of pregnancy and termination of pregnancy.

We strongly oppose the Department's proposal to rescind all language recognizing that Section 1557 prohibits discrimination on the basis of pregnancy or termination of pregnancy, as well as the Department's proposal to graft the Title IX Danforth Amendment exemption onto Section 1557.

Despite the Department's heavy reliance on its Title IX regulation elsewhere in the Proposed Rule and its preamble, the Department inexplicably proposes to rescind the prohibition on discrimination on the basis of termination of pregnancy, even though it exactly tracks the Title IX regulation and is consistent with relevant case law.[244] The Department relies on the *Franciscan Alliance* preliminary injunction for this rescission, but as explained above, that preliminary injunction does not require this regulatory change. Moreover, the district court's opinion provides only cursory analysis on this issue and fails to engage with contrary case law.

The Department does not provide a reasoned legal, policy, or cost-benefit analysis for this rescission. In a footnote, the Department declines to state a position on whether or not Section 1557 in fact prohibits discrimination on the fact of pregnancy and termination of pregnancy.[245] The Department speculates regarding the types of pregnancy-related discrimination claims it "could" "consider," without any analysis. Particularly given that the Department refuses to take any legal position, it is remarkable that the Department fails to consider the impact on patients and providers of withdrawing the clear guidance provided by the 2016 Rule. This could cause confusion for both patients and providers and require them to additionally assess whether such discrimination could result in violations of other laws. The Department fails to consider the potential costs to patients and the health care system of this rescission, including medical harms caused by delay or denial of follow-up or emergency care related to pregnancy or termination of pregnancy.

As discussed above, Section 1557 incorporates the grounds and the enforcement mechanisms of the referenced statutes, but not their exemptions. Specifically, the statute explicitly incorporates the specific exemptions enumerated in Title I of the ACA, but does not incorporate the Danforth Amendment from Title IX regarding abortion care, which is overlapping but different in scope.[246] The Department erroneously grafts this extra-textual exemption onto Section 1557, without adequate analysis of the statutory text or other justification.

[244] *Compare with* 45 CFR § 86.40(b); *Newport News Shipbuilding & Dry Dock Co. v. E.E.O.C.*, 462 U.S. 669, 684 (1983) (holding the Pregnancy Discrimination Act makes it clear that "for all Title VII purposes, discrimination based on a woman's pregnancy is, on its face, discrimination because of her sex"); *Doe v. C.A.R.S. Protection Plus, Inc.*, 527 F.3d 358, 364 (3d Cir. 2008) (holding that Title VII as amended by the PDA protects women against discrimination based on their decision to have an abortion); *Turic v. Holland Hospitality, Inc.*, 85 F.3d 1211, 1214 (6th Cir. 1996) (holding that discharge of pregnant employee because she contemplated having an abortion procedure violated Title VII as amended by the PDA); *Ducharme v. Crescent City Deja Vu, L.L.C.*, No. CV 18-4484, 2019 WL 2088625, at *5 (E.D. La. May 13, 2019) (holding that abortion is protected by the pregnancy language of Title VII).
[245] Proposed Rule, 84 Fed. Reg. at 27870.
[246] *Compare* 42 U.S.C. §§ 18023, 18113, *with* 20 U.S.C. § 1688.

XII. The Department improperly proposes to narrow disability protections.

The 2015 US Transgender Survey (USTS) found that transgender adults in the survey were substantially more likely to have a disability, as defined by the American Community Survey's measure, than the general population. Nearly four in ten (39%) respondents had a disability, nearly three times the rate in the adult population.[247] This rate is even higher among people of color; for example, the rate reached 55% among American Indian and Alaska Native respondents.[248] Transgender people with disabilities already face significant barriers to accessing appropriate care. For example, 42% of transgender respondents who saw a doctor in the past year experienced anti-transgender mistreatment during that year, a higher rate than the USTS sample overall (33%).[249] The rescission of key protections would exacerbate the barriers that transgender people with disabilities already face.

We oppose the deletion of the definitions in section 92.4, including with respect to effective communications with individuals with disabilities. This will cause confusion and could lead to delay or denial of necessary care.

We also note that the incorporation in proposed section 92.202 of definitions from Americans with Disabilities Act regulations omits critical terms in several places. We urge the Department to amend these provisions to track existing definitions, particularly the definition of auxiliary aids and services and the requirement that all forms of communication assistance (not only interpretation services) be provided free of charge and in a timely manner.[250]

We strongly oppose the suggestion of exempting entities with fewer than 15 employees from the effective communication requirements. Such an exemption has no basis in the text of Section 1557, and the costs to patients and the health care system from these types of barriers to care do not vary based on the number of employees a covered entity has.

We oppose the suggestion of importing new exemptions for physical accessibility into section 92.203. These exemptions, as they exist in other regulations, are outdated. Moreover, they are manifestly inappropriate in the context of health care, given the potential harms to patients and the health care system of delays or denials of appropriate care.

We oppose the suggestion of weakening the text of proposed section 92.105 with exemptions and standards from employment law, specifically the concepts of "reasonable accommodation," "known physical or mental limitation," and "undue hardship." Such standards are not grounded in the statutory text of section 1557 and are inappropriate in the health care context.

XIII. The Department improperly proposes to completely rescind tagline requirements

[247] Sandy E. James et al., *The Report of the 2015 U.S. Transgender Survey* 57 (2016), www.ustranssurvey.org/report.
[248] Sandy E. James et al., *2015 U.S. Transgender Survey: Report on the Experiences of American Indian & Alaska Native Respondents* at 6 (2017), https://transequality.org/sites/default/files/docs/usts/USTS-AIAN-Report-Dec17.pdf.
[249] James et al., *supra* note 247 at 97.
[250] *See* 28 C.F.R. §§ 35.104, 35.130.

We strongly oppose the complete rescission of the tagline requirements. The Department reasonably determined in its 2016 Rule that the mere availability of language services could not provide meaningful access without meaningful notice, and adopted this requirement as an alternative to more burdensome methods such as requiring full translation of notices and other documents.[251] Many covered entities are already covered by taglines requirements of other regulations, reducing the costs added by this requirement under Section 1557.[252] Comments by covered entities on the 2015 Proposed Rule and the current Proposed Rule, along with "Supporting Documents" provided by the Department in conjunction with the Proposed Rule, demonstrate that industry stakeholders have not sought the complete rescission of tagline requirements, but suggested various other regulatory alternatives. "When considering revoking a rule, an agency must consider alternatives in lieu of a complete repeal."[253] The Department does not provide a "reasoned analysis" for rejecting those proposed alternatives in favor of complete rescission.

Finally, the Department's Regulatory Impact Analysis relies on limited and inadequate data to reassess the cost of these requirements to industry and, more importantly, fails to adequately address the *net* costs of repeal. An adequate analysis of the *net* impact of the rule would include assessing the economic and non-economic costs to patients and the health care system as a whole of patients lacking knowledge of the availability of language assistance. The Department previously and reasonably determined that the benefits of taglines outweigh their costs, because they are "critical to providing an equal opportunity to access health care and health coverage."[254] The Department presents no "reasoned analysis" for departing from this conclusion.

XIV. The Department improperly proposes to rescind other language access protections

We strongly oppose the complete elimination of key language access protections in the Proposed Rule, including the complete rescission of tagline requirements.

We appreciate section 92.101(b)(2)'s recognition that language assistance services must be free, accurate, timely, and protect the patient's privacy and independence, consistent with clear judicial precedents.[255] However, we oppose the revision in proposed section 92.101(a) that changes the emphasis from "each individual" to "meaningful access…by limited English proficient individuals." Section 1557 refers to discrimination against "an individual," and requires covered

[251] 2016 Rule, 81 Fed. Reg. at 31398.

[252] *See* 45 C.F.R. § 155.205(c)(2)(iii)(A); 45 C.F.R. § 147.136€(2)(iii), (e)(3); 29 C.F.R. §2590.715-2719(e)(2)(iii), (3).

[253] *Becerra v. U.S. Dept. of the Interior*, 381 F.Supp.3d 1151, 1169 (N.D. Cal. 2019). *See also Public Citizen v. Steed*, 733 F.2d 93, 103–05 (D.C.Cir.1984) (NHTSA suspension of tire-grading regulation was arbitrary and capricious because agency failed to pursue available alternatives); *ILGWU v. Donovan*, 722 F.2d at 815–18 (failure to consider less far-reaching choices than complete rescission of homework restrictions was arbitrary and capricious); *Office of Commc'n of United Church of Christ v. FCC*, 707 F.2d 1413, 1440 (D.C. Cir. 1983) (FCC's failure to give sufficient consideration to modification, rather than elimination of programming log requirements was arbitrary and capricious); *Action on Smoking & Health v. CAB*, 699 F.2d 1209 (D.C. Cir. 1983), *opinion supplemented by* 713 F.2d 795 (D.C. Cir. 1983) (CAB's failure to consider alternatives to rescission of certain restrictions on smoking in airplanes mandated remand).

[254] 2016 Rule, 81 Fed. Reg. at 31401.

[255] *Lau v. Nichols*, 414 U.S. 563, 568 (1974); *Esparza v. Univ. Med. Ctr. Mgmt. Corp.*, No. CV 17-4803, 2017 WL 4791185, at *17 (E.D. La. Oct. 24, 2017).

entities to ensure access for each individual, not simply that "limited English proficient individuals" as a whole are not denied access.[256]

We also oppose the change in proposed section 92.101(b) that appears to provide the Department and covered entities with "flexibility" regarding language access beyond that permitted by the statutory text. Again, the statute prohibits discrimination against "an individual," and the 2016 Rule appropriately recognizes that covered entities maintain discretion as to *how*, not *whether*, language access is provided. The 2016 Rule describes in detail how the Department reasonably concluded that listing only four illustrative factors for assessing "meaningful access" would be unduly narrow and could cause confusion.[257]

Similarly, the elimination of language recognizing that individuals "eligible to be served" are protected by the statute is unnecessary, unjustified, and could cause harm to patients, as the Department has previously observed in its LEP guidance.[258]

We also oppose deletion of language providing for consideration of a language access plan from this section. The 2016 Rule does not mandate language assistance plans, but provides for considering them as a factor. Many entities are already required to adopt such plans and have benefitted from guidance previously provided by the Department in developing them.

We also strongly oppose the proposal to instruct covered entities that providing oral interpretation is simply an option. In many circumstances, oral interpretation is necessary to provide meaningful access, and may be provided in a variety of ways.[259]

We oppose the removal of technical and training standards for video remote interpreting services, because telephonic interpretation is inadequate in some circumstances, and low quality video interpreting can prevent meaningful access. The Department fails to provide a "reasoned analysis for the change."

We support the prohibition in proposed section 92.101(4) on requiring individuals to provide their own interpreter or relying on an individual accompanying a patient to provide interpretation absent emergency circumstances or the patient's request. We urge the Department to require that, in addition, entities be required to document the provision of language services and any request to use interpretation by an accompanying individual.

XV. The Department failed to justify wholesale removal of notice, grievance, and responsible employee requirements.

We strongly oppose the proposed wholesale rescission of the requirement notice, grievance procedures, and responsible employee requirements. These requirements are essential for ensuring that patients understand their rights and that covered entities have adequate procedures to comply

[256] 42 U.S.C. § 18116(a).
[257] 2016 Rule, 81 Fed. Reg. 31453-4, 31461-2.
[258] HHS LEP Guidance, 68 Fed. Reg. 47312, 47314 (2003).
[259] *Id.* at 47311.

with Section 1557 and avoid litigation. These rescissions are unrelated to the proposed changes to the substantive requirements of the 2016 Rule.

Completely removing these provisions stands in stark contrast to the Department's approach in its recent rule on "Protecting Statutory Conscience Rights in Health Care." There, the Department proposed comparable notice requirements for the purpose of protecting the ability of health care staff to refuse care, "[f]or consistency with other notice requirements in civil rights regulations.[260] In the final rule—in a departure from the Department's and other agencies' civil rights regulations—the Department ultimately changed this requirement to a provision that "OCR will consider an entity's voluntary posting of a notice of nondiscrimination as non-dispositive evidence of compliance."[261] While seeking to provide more flexibility, the Department emphasized the importance of addressing "lack of awareness" concerning "anti-discrimination rights" that "stems from inadequate information and understanding about such Federal law, leading to possible violations of law."[262] This is precisely the problem addressed here, and the Department should place at least as much weight on this goal with respect to the rights of patients. This is why the Department's and other agencies' civil rights regulations routinely include notice provisions. The Department has also consistently included notice requirements in voluntary resolution agreements, including for large entities where the administrative effort involved may be significant.[263]

Contrary to the Department's claims, these requirements in the 2016 Rule are not duplicative of existing requirements under Title VI, Title IX, the Rehabilitation Act, or the Age Discrimination Act. The 2016 Rule reflects that the requirements in Section 1557 are more comprehensive than those in the other laws cited in addressing discrimination based on race, color, national origin, age, disability, and sex, and that Section 1557 addresses the specific context of health care. These other varying regulations are not designed to address the full range of covered grounds under Section 1557, do not all apply to the same universe of covered entities as Section 1557, and are not all designed for the health care context. In particular, most entities covered under Section 1557 are not covered by Title IX of the Education Amendments of 1972, and therefore are not otherwise required to notify patients of their right to receive care and coverage without discrimination on the basis of sex.

Moreover, in its 2016 Rule, the Department reasonably determined that covered entities could avoid duplication by using comprehensive notices and procedures that satisfy all the applicable statutes.[264] The Department helped reduce the cost of implementation by providing an optional and fully sufficient sample notice translated into 64 languages.[265] Comments on the 2013 RFI on Section 1557, the 2015 Proposed Rule, the 2017 RFI on regulatory reform, and the present

[260] *See* 83 Fed. Reg. 18 at 3887–88 (Jan. 26, 2018).
[261] 45 C.F.R. § 88.5.
[262] Conscience Rule, 84 Fed. Reg. at 23228.
[263] *See, e.g.,* Voluntary Resolution Agreement Between the U.S. Dept. of Health and Human Services and the Board of Trustees of Michigan State University and MSU Healthteam and MSU Health Care, Inc. (Aug. 6, 2019).
[264] 45 C.F.R. § 92.8(h).
[265] Appendix A to Part 92 – Sample Notice Informing Individuals About Nondiscrimination and Accessibility Requirements and Sample Nondiscrimination Statement: Discrimination is Against the Law, *see also* OCR, Translated Resources for Covered Entities, https://www.hhs.gov/civil-rights/for-individuals/section-1557/translated-resources/index.html.

Proposed Rule suggest that covered entities do not find these requirements as a whole unduly burdensome and have not asked for their wholesale rescission. Covered entities and patient advocates have proposed a range of alternative methods by which the Department could further reduce the costs of these requirements, such as including in regulations or guidance a definition of "significant document," or otherwise clarifying how often notices must be provided to the same individual in one year.

XVI. The Department's proposed definition of Section 1557's scope is unduly narrow.

We strongly oppose the Department's proposed changes to sections 92.2 and 92.3 regarding the scope of covered entities under Section 1557.

Section 1557's plain text is broad applying to (1) any health program or activity, any part of which receives federal financial assistance, defined broadly to include all "credits, subsidies, and contracts of insurance"; (2) "any program or activity that is administered by an Executive Agency"; and, (3) "any program or activity that is administered by…any entity established under this title (or amendments)."[266] The 2016 Rule reasonably applied the plain statutory text to apply to all Exchanges, Qualified Health Plans, and all federal health programs, among other entities, and the Department's proposed change is unreasonable and inadequately justified.

The 2016 Rule appropriately defines federal financial assistance broadly, consistent with the Department's current rules regarding Title VI of the 1964 Civil Rights Act, as well as the Department's recent Final Rule on "Protecting Statutory Conscience Rights in Health Care."[267] The Department provides no "reasoned analysis" for adopting an inconsistent approach here.

The 2016 Rule appropriately reflects that Section 1557 applies to entity "under any program or activity that is administered by an Executive Agency *or* any entity established under this title."[268] The Proposed Rule would effectively change the statutory text from "or" to "and," limiting its application to entities established under Title I of the ACA. This proposal flies in the face of the statutory text and would inappropriately exempt programs and activities administered by many federal agencies, including various components of the Department, from coverage.

The 2016 Rule reasonably interpreted "health programs and activities" to include health insurance. Naturally, health insurance *by definition* is uniquely concerned with health services, and operates differently than other forms of insurance. The text, structure, and history of Title I of the ACA reflect the obvious fact that health insurance coverage is a prerequisite for many people in the United States to obtain health care services. Health insurance coverage has a direct impact on individuals' access to care and their health outcomes, which is the entire reason it exists in the first place and why Congress sought to expand coverage through the ACA.[269] The Department need

[266] 42 U.S.C. § 18116(a).
[267] 45 C.F.R. § 88.2; 45 C.F.R. § 80.13.
[268] 42 U.S.C. § 18116(a) (emphasis added).
[269] *See also* Institute of Medicine*, Controlling Costs and Changing Patient Care? The Role of Utilization Management* 13 (1989); Joseph B. Clamon, *Does My Health Insurance Cover It - Using Evidence-Based Medicine and Binding Arbitrator Techniques to Determine What Therapies Fall under Experimental Exclusion Clauses in Health Insurance Contracts*, 54 Drake L. Rev. 473, 508 (2006).

not consider the ACA's legislative history to recognize this obvious fact and to construe the plain text to include health insurance.

The Department failed to even attempt any assessment of the change in the number of covered entities based on the changes in these provisions, their market share, or the number of individuals affected. The Department relies on its prior estimates of the number of covered entities throughout the Proposed Rule, but these changes will substantially change that number, and the Department provides no new estimate to support its Regulatory Impact Assessment and for the public to comment on. By contrast, the Department at least attempted to estimate the number of persons and entities covered by another recent OCR rule, arriving at an estimate of 392,301 to 502,899.[270]

In addition, the Department's Regulatory Impact Analysis fails to assess the potential harms of this narrowed definition to consumers. Affected consumers include those who may purchase coverage (including but not limited to short-term limited duration insurance), unaware that they are foregoing Section 1557's consumer protections under the Department's approach. It also includes beneficiaries of other programs administered by federal agencies not established by Title I of the ACA who may not realize they are unprotected under the Department's approach. In adopting the 2016 Rule, the Department reasonably determined that many consumers and ultimately the health care service and insurance industries would also be harmed if Section 1557 was not properly enforced with respect to health insurance.[271] The Department provides no "reasoned analysis" for rejecting this assessment, or for departing from the plain text of the statute and other similar rules adopted by the Department.

XVII. The Department failed to adequately justify changes to the rule's enforcement provisions.

We strongly oppose the proposed changes to section 92.301, redesignated as section 92.5, and to section 92.302.

The Proposed Rule adopts the view that Section 1557 establishes separate procedures, standards of proof, and remedies for the various prohibited grounds of discrimination. This issue is unsettled, as lower courts have adopted conflicting positions on this question.[272] Since Section 1557 applies all the covered grounds to a range of entities not necessarily covered by the referenced statutes, it is more logical and more readily administrable for the statute to be read in a unitary fashion.

While this may lead to different results in some cases than would have obtained under the referenced statutes, this outcome is consistent with the text, structure, and purpose of Section 1557, which establish new civil rights protections in the area of health care. The text of Congress states that the "enforcement mechanisms for and available under [ ] title VI, title IX, section 504, *or* such Age Discrimination Act shall apply," without limitation.[273] Congress could have, but did not, adopt

[270] Conscience Rule, 84 Fed. Reg. at 23236.
[271] 2016 Rule, 81 Fed. Reg. at 31444.
[272] *Compare Doe v. BlueCross BlueShield of Tennessee, Inc*., 926 F.3d 235, 241 (6th Cir. 2019), with *Rumble*, 2015 WL 1197415 at *11 (holding that Section 1557 establishes "a new, health-specific, anti-discrimination cause of action that is subject to a singular standard, regardless of a plaintiff's protected class status").
[273] 42 U.S.C. § 18116(a) (emphasis added).

a text limiting such mechanisms by tying different mechanisms to different grounds. Unlike the referenced statutes that apply to a wide range of federally assisted programs and activities, Section 1557 was specifically designed to govern health care, and so it makes sense that Congress chose a unitary approach, which is easier for entities not previously covered by the other statutes to understand. In any case, the limitations proposed by the Department have no basis in the statutory text.

The 2016 Rule reasonably determined that Section 1557 provides for a private right of action in federal court. While the Department points to a handful of lower court decisions with respect to disparate impact claims in particular, no court has held that Section 1557 does not generally authorize private right of action with respect to any or all of its prohibited grounds. The Department provides no "reasoned analysis" for reversing its position that Section 1557 generally provides for a private right of action, including for claims of intentional discrimination.

The Department also fails to assess the costs and benefits of its attempts to narrow the statute's enforcement mechanisms. In another recent rulemaking, the Department emphasized the importance of addressing "[i]nadequate enforcement tools to address unlawful discrimination and coercion faced by protected persons, entities, or health care entities."[274] The Department should take that goal at least as seriously here, when enforcing a law designed to protect vulnerable patients and ensure access to potentially lifesaving care.

XVIII. The Department's suspension of subregulatory guidance is inadequately explained and justified.

The Department states without elaboration that it is suspending "all subregulatory guidance issued before this proposed rule that interprets or implements Section 1557 (including FAQs, letters, and the preamble to the current Section 1557 Regulation) that is inconsistent with any provision in this proposed rule (including the preamble) or with the requirements of the underlying civil rights statutes cross-referenced by Section 1557 or their implementing regulations."[275] The Department fails to explain whether it has determined that each of the referenced documents "is inconsistent with … this proposed rule" in its entirety, or to specify which portions of such documents it is and is not suspending. This is likely to cause confusion and place patients at greater risk of adverse health care experiences.

For example, the 2016 Rule preamble stated that "the prohibition on sex discrimination extends to discrimination on the basis of intersex traits or atypical sex characteristics."[276] On its face, this statement is consistent with the current Proposed Rule's interpretation of "sex" as referring to "biological and anatomical differences," since it focuses explicitly on biological traits.[277] However, some could argue that this portion of the 2016 Rule preamble is "inconsistent" with the Proposed Rule's emphasis on "sex" as a "binary" trait. Because intersex traits and atypical sex

[274] Conscience Rule, 84 Fed. Reg. at 23228.
[275] Proposed Rule, 84 Fed. Reg. at 27872.
[276] Nondiscrimination in Health Programs and Activities; Final Rule, 81 Fed. Reg. 31376, 31389 (May 18, 2016).
[277] *See, e.g.,* I.A. Hughes et al., *Consensus Statement on Management of Intersex Disorders*, 118 PEDIATRICS 488, 491 (2006).

characteristics relate to "biological" aspects of sex but are not "binary," it is unclear whether the Department would view this prior guidance as suspended or not.

To avoid this conclusion, and because the Department's prior guidance is consistent with the plain text of the statute and uncontradicted by any case law, the Department should expressly reaffirm that Section 1557 prohibits discrimination on the basis of intersex traits or atypical sex characteristics. If the Department determines, as it should, not to finalize any change to the 2016 Rule at this time, it should issue appropriate guidance to clarify this issue.

XIX. The Department has failed to reconcile the Proposed Rule with its public health initiatives.

The Department must also "address…the inconsistency between its current view" and the findings, goals, and activities of other public health initiatives under the Department.[278] By retreating from efforts to combat stigma and discrimination against transgender and other minority patients, and by sending a high-profile negative and stigmatizing message about vulnerable populations, the Proposed Rule undermines efforts to combat stigma and health disparities and to connect vulnerable populations with care and keep them in care.

The Proposed Rule creates inconsistency with President's *Ending the HIV Epidemic: A Plan for America* initiative, which seeks to reduce new HIV infections by 75% in five years and by 90% in ten years. Among the strategies identified to meet those goals are:

- to target communities "where HIV is spreading most rapidly" to expand prevention, care, and treatment;
- to "provide medicine to protect persons at highest risk from getting HIV";
- "to follow up with individuals no longer receiving care" and "re-engage them in effective HIV care and treatment"; and
- to combat "stigma – which can be a debilitating barrier preventing someone living with HIV or at risk for HIV from receiving the healthcare, services and respect they need and deserve."[279]

As previously discussed, transgender people are among the most vulnerable populations with respect to HIV and AIDS. The Proposed Rule will undermine each of these strategies by promoting stigma, increasing discrimination, and deterring patients from connecting or re-connecting with care among some of the most critical populations that must be reached to meet the goals of *Ending the HIV Epidemic*.

The Proposed rule also creates inconsistency with the Department's *Strategy to Combat Opioid Abuse, Misuse, and Overdose*, which seeks to "use[ ] the best science and evidence to directly

[278] *See Bauer*, 325 F.Supp.3d at 109.
[279] Sec. Alex Azar, *Ending the HIV Epidemic: A Plan for America*, U.S. Health and Human Services Blog (Feb. 5, 2019), https://www.hhs.gov/blog/2019/02/05/ending-the-hiv-epidemic-a-plan-for-america.html.

address this public health emergency."[280] The *Strategy* seeks to meet this goal by, among other things, "eliminat[ing] stigma associated with the disease" and with seeking treatment, and "[i]dentify[ing] individuals who are at risk of opioid use disorder and mak[ing] available prevention and early intervention services and other supportive services."[281] Studies indicate that transgender people are at especially high risk for opioid use disorder. For example, an analysis of the 2017 Youth Risk Behavior Survey found that transgender youth were more likely than their peers to have used drugs in their lifetime, including 36% who reported misusing prescription opioids (compared to 11.5% of non-transgender boys and 12% of non-transgender girls), and 26% who reported using heroin (compared to 2% of non-transgender boys and less than 1% of non-transgender girls).[282] In addition, actual and anticipated discrimination in health care are associated both with delays and seeking care and with increased substance use among transgender people.[283] The Proposed Rule would undermine the goals of the Department's *Strategy* increasing risk factors for substance use and delayed care-seeking among a population already at heightened risk. In addition, while not promoting stigma directly associated with opioid use disorders, by increasing anti-transgender stigma the Department would contribute to a society that more readily stigmatizes vulnerable minority populations, contrary to the framework set out by the *Strategy*.

The Proposed Rule would also create inconsistency with the Department's Healthy People 2030 (HP 2030) initiative. The mission of HP 2030 is "[t]o promote, strengthen and evaluate the Nation's efforts to improve the health and well-being of all people."[284] HP 2030 seeks to achieve this mission by providing goals and objectives that can guide policies and action by local, state, and federal governments and entities, including the Department.[285] Among the "Overarching Goals" of HP 2030 are to "[e]liminate health disparities, achieve health equity, and attain health literacy to improve the health and well-being of all," and to "[c]reate social, physical, and economic environments that promote attaining full potential for health and well-being for all."[286] While measurable HP 2030 objectives are still being developed, it is clear that the Proposed Rule would undermine the goals of HP 2030 by exacerbating health care discrimination and health equities and contributing to a social environment that perpetuates stigma against transgender people and other vulnerable populations.

[280] Dept. of Health & Hum. Servs., *Strategy to Combat Opioid Abuse, Misuse, and Overdose: A Framework Based on the Five-Point Strategy* (Sept. 17, 2018), https://www.hhs.gov/opioids/sites/default/files/2018-09/opioid-fivepoint-strategy-20180917-508compliant.pdf.
[281] *Id.* at 3.
[282] Michelle M. Johns et al., *Transgender Identity and Experiences of Violence Victimization, Substance Use, Suicide Risk, and Sexual Risk Behaviors Among High School Students—19 States and Large Urban School Districts, 2017*, 63 MORBIDITY AND MORTALITY WEEKLY REPORT 67, 69 (Jan. 25, 2019), https://www.cdc.gov/mmwr/volumes/68/wr/pdfs/mm6803a3-H.pdf. *See also* James et al., *supra* note 247 at 119 (finding higher rate of illicit drug use among transgender adults than the general adult population).
[283] Sari L. Reisner et al., *Substance Use to Cope with Stigma in Healthcare Among U.S. Female-to-Male Trans Masculine Adults*, 2 LGBT HEALTH, 324–332, doi:10.1089/lgbt.2015.0001; James et al., *supra* note 247 at 219 (finding that 22% of transgender adults who went to a drug or alcohol treatment facility were denied equal treatment, harassed, or assaulted because of being transgender).
[284] Office of Disease Prevention & Health Promotion, *Health People 2030 Framework* (last visited Aug. 13, 2019), https://www.healthypeople.gov/2020/About-Healthy-People/Development-Healthy-People-2030/Framework.
[285] *Id.*
[286] *Id.*

PART 3: IMPROPER ADDITION OF RELIGIOUS EXEMPTION INTO SECTION 1557

We strongly oppose the language in section 92.6(b) that seeks to graft extra-textual exemptions on Section 1557, including but not limited to the broad religious exemption in Title IX.

I. The Department's proposed grafting of Title IX's religious exemption into Section 1557 is not a valid interpretation of the statute.

The Department proposes to add a new section, designated as section 92.6(b), that would attempt to incorporate all exemptions listed in Section 1557's four referenced statutes, as well as several exemptions from other statutes not mentioned in Section 1557's text. The Department states that this language is intended, in part, to incorporate Title IX's broad religious exemption into Section 1557. Neither statutory nor legislative history, however, supports adding these exemptions to Section 1557, which includes no exemptions itself, beyond those already enumerated in the ACA, such as in sections 1553 and 1303.[287] The proposed new language is inconsistent with the statutory text and structure of Section 1557, conflicts with the primary purpose of the ACA, and will impose undue costs on patients and the health care system.

Section 1557(a) establishes only the "ground [on which discrimination is] prohibited" by reference to the enumerated civil rights statutes.[288] In specifying the *protected characteristics*, it does not also import the disparate exemptions from each of the cited statutes. Indeed, Section 1557 goes on to explicitly set out the entities covered under its requirements—*any* federally funded or federally run health program or activity—making it clear that Section 1557 itself, rather than the previously enumerated laws, determine which entities need to comply with it and which may be exempted. If Congress had meant to incorporate every element and limitation of the referenced statutes, it could simply have expanded each of those statutes directly to cover health programs and activities. It would require a tortured and unnatural reading of the statute to conclude that Section 1557 imports, *sub silentio*, all the exemptions from the referenced statutes.

Similarly, there is no basis in the text of Section 1557 for importing exemptions from other civil rights statutes such as the Architectural Barriers Act, the Americans with Disabilities Act, Section 508 of the Rehabilitation Act. Section 1557 does not reference these other statute in any way whatsoever. Congress chose only to incorporate those exemptions provided in Title I of the ACA, and the Department lacks authority to add additional exemptions.

Additionally, a reading of Section 1557 that creates different exemptions for each protected characteristic would result in "patently absurd consequences."[289] It "would lead to an illogical result, as different…standards would apply to a Section 1557 plaintiff depending on whether the plaintiff's claim is based on her race, sex, age, or disability."[290] As written, the proposed rule also provides no guidance on what scope of religious exemptions should apply when an individual faces discrimination on multiple bases.[291]

[287] *See* 42 U.S.C. § 18116(a).
[288] *Id.*
[289] *United States v. Brown*, 333 U.S. 18, 27 (1948).
[290] See *Rumble*, 2015 WL 1197415, at *11.
[291] *Id.* a *12.

Nor does the proposed rule provide any guidance regarding how the varied exemptions referenced, including the Title IX exemption, are to be interpreted and applied in the health care context, which is different from the context of education in many respects. The proposed rule fails to account for fundamental differences between the types of entities and activities covered under Section 1557 and Title IX and between the manner in which discrimination and religious objections manifest in health care and education settings, leaving patients and covered entity with almost no direction about the way in which the religious exemptions that the Department is attempting to import would be applied.

Even if the language of Section 1557 were ambiguous with respect to the application of religious exemptions or other additional exemptions, that ambiguity must be resolved in a manner that is consistent with the underlying purpose of the statute the rule is implementing. An expanded exemption to Section 1557's prohibition on sex discrimination runs counter to the clear congressional intended evidenced in this section to reduce harmful discrimination in health care settings. It also runs counter to the purpose of the ACA overall: to protect the rights of patients and reduce barriers to accessing care.[292]

II. The Department has not justified the reversal of its prior position on religious exemptions.

The Department already considered and rejected the argument that Title IX's religious exemptions apply to Section 1557 in 2016, and the proposed rule provides no "reasoned analysis" for reversing that position. In its 2016 rule, the Department determined that the claim that Section 1557 imported religious exemptions from Title IX was contrary to the plain meaning of the statute. It also presented a reasoned argument explaining why, as a policy matter, Congress likely chose not to incorporate Title IX exemptions into Section 1557:

> First, students or parents selecting religious educational institutions typically do so as a matter of choice; a student can attend public school (if K–12) or choose a different college. In the healthcare context, by contrast, individuals may have limited or no choice of providers, particularly in rural areas or where hospitals have merged with or are run by religious institutions. Moreover, the choice of providers may be even further circumscribed in emergency circumstances.
>
> Second, a blanket religious exemption could result in a denial or delay in the provision of health care to individuals and in discouraging individuals from seeking necessary care, with serious and, in some cases, life threatening results. Thus, it is appropriate to adopt a more nuanced approach in the health care context, rather than the blanket religious exemption applied for educational institutions under Title IX.[293]

[292] *See, e.g.,* 42 U.S.C. § 18114 (prohibiting the Department from promulgating any regulation that "creates any unreasonable barriers to…appropriate medical care" or "impedes timely access to health care services").
[293] 81 Fed. Reg. 31380.

The Department must provide "a reasoned explanation…for disregarding facts and circumstances that underlay or were engendered by the prior policy."[294] In its new proposed rule, the Department has not attempted to refute its previous analysis, nor has it cited a change in circumstances that would justify the reversal of its position, raising serious questions about whether the rule is arbitrary or capricious.[295] Nor does the Department attempt to ascertain the number of entities that could be covered by these new exemptions, their market share, or the number of patients potentially impacted.[296]

III. A new religious exemption under Section 1557 is unnecessary and has no net benefit.

In light of the harm the Department's proposal can cause for patients and the confusion and uncertainty it would cause of covered entities, it is particularly troubling that the Department has failed to identify any need for expanded exemptions apart from a preliminary injunction issued by an outlier court. In adopting its recent Final Rule on "Protecting Statutory Conscience Rights in Health Care," the Department failed to demonstrate the need for expanded religious exemptions in health care, relying exclusively on anecdotal evidence, decade-old statistics, and hypotheticals to justify a sweeping regulatory overhaul that jeopardizes patients' access to care.[297] The Department has provided no better evidence here, indeed no evidence at all, that additional exemptions are needed through the current Proposed Rule.

In truth, an expansion of religion-based exemptions under Section 1557 is unnecessary. Federal statutes and existing regulations already provide a broad range of special exemptions for religiously affiliated health care providers or entities. In its 2016 rule, the Department noted explicitly that the application of Section 1557 was subject to these existing protections, such as those expressly incorporated through Title I of the ACA, and the individualized application of the Religious Freedom Restoration Act to specific facts.[298] This robust constellation of laws more than adequately protects religiously affiliated entities' access to federal funding while protecting patients' rights to nondiscriminatory access to care.

Moreover, the Department must assess the net economic and non-economic effects of the proposed changes, including costs of discrimination for patients and the health care system. As discussed throughout this comment, such discrimination—regardless of its motivation—harms patients' health and financial security by delaying or denying care, which in turn worsens health outcomes and imposes costs on the health care system. While predicting the exact amount of increased discrimination and related costs that would attributable specifically to these purported exemptions, were they adopted, is difficult, the well-documented impacts that denial of care—and in particular denial of care based on religious objections—have on the populations that Section 1557 was crafted to protect indicate that the costs would be substantial. The Department's failure to undertake any assessment of these costs—or even to give them weight despite the difficulty of quantifying them—represents a critical flaw in its analysis.

[294] *Fox Television Stations*, 556 U.S. at 515–16.
[295] *See* 5 U.S.C. § 706.
[296] *Compare* Conscience Rule, 84 Fed. Reg. at 23236 (estimating 267,134 to 415,666 entities covered by certain exemptions).
[297] *See* 83 Fed. Reg. 18 at 3887–88 (Jan. 26, 2018).
[298] 81 Fed. Reg. 31379.

PART 4: FLAWED ANALYSIS OF THE REGULATION'S IMPACT

The Department's analyses of the regulation's impact, including its federalism and cost-benefit analyses, are incomplete, skewed, and inaccurate and are therefore insufficient to support the Proposed Rule's changes.

I. The Department's federalism analysis is flawed.

The Department errs in providing a vague, contradictory, and flawed federalism analysis. The Department states that it "does not believe that this rulemaking would (1) impose substantial direct requirements or costs on State or local governments; (2) preempt State law; or (3) otherwise have federalism implications."[299] The Department claims that the 2016 Rule imposed burdens on states that the Proposed Rule will relieve without imposing and new burdens. The evidence does not support this analysis.

a. The 2016 Rule does not create undue burden on state and local governments.

As the Department has stated elsewhere:

> Under the Supremacy and Spending Clauses of the Constitution, States and their political subdivisions are subject to Acts of Congress, and Federal…anti-discrimination laws are no exception. This rule holds States and local governments accountable for compliance with these laws by setting forth mechanisms for OCR investigation and HHS enforcement related to those requirements. The rule does not change the substantive…anti-discrimination requirements of these statutes.[300]

This analysis is fully applicable to the 2016 Rule. To the extent that the Department relies on Spending Clause cases to suggest the 2016 Rule unduly burdens states, those cases are inapposite. Section 1557 does not impose burdens on states that even remotely resemble the scope of those imposed by the ACA's Medicaid expansion. Nor were states without adequate notice, since case law before and since the adoption of the 2016 Rule, together with the Department's own 2012 guidance, provided more than adequate notice that the statute prohibits a wide range of sex-based discrimination. In addition, Section 1557's prohibition on health care discrimination is also supported by Congress's authority under the Commerce Clause and section 5 of the Fourteenth Amendment.[301]

To the extent the Department's comments are targeted towards the provision or coverage of medically necessary care related to gender transition, the Department points to no evidence of substantial burdens of States and localities, because there is none. The Department must rely on more than "conclusory statements."[302] As previous explained, the provision and coverage of

[299] Proposed Rule, 84 Fed. Reg. at 27886.
[300] Conscience Rule, 84 Fed. Reg. at 23256.
[301] *See, e.g., Katzenbach v. McClung*, 379 U.S. 294 (1964); *Heart of Atlanta Motel, Inc. v. United States*, 379 U.S. 241 (1964).
[302] *Getty v. Fed. Savs. & Loan Ins. Corp.*, 805 F.2d 1050, 1057 (D.C. Cir. 1986).

medical and surgical treatment for gender transition are fully supported by the consensus of the medical field today at the national and international levels, embraced by every major medical association, and in accordance with accepted clinical standards of care.[303] Nondiscriminatory coverage involves *de minimis* plan costs, and has already been widely implemented by States.

b. The Department is incorrect in asserting that its proposed rule does not create substantial requirements or costs for states.

As discussed further below, discrimination in health care can create substantial burdens of public health systems, as delaying or denying care can lead to higher prevalence of comorbid conditions and exac.erbate existing health disparities. The Proposed Rule can also impose costs on state governments who adopted policies related to private insurance and Medicaid based on the 2016 Rule, particular given the limitations potentially imposed by the new religious exemptions that the Department is attempting to add. The Department's abandonment of its role in enforcing transgender people's rights under Section 1557 also means that state governments may see an increase in health care discrimination complaints in their state-level human rights commissions as transgender patients are forced to seek avenues for recourse other than the Office for Civil Rights. Additionally, states that reinstate or maintain exclusions based on the Proposed Rule may face costly litigation. Thus far, states such as Wisconsin that have reversed course and reinstated exclusions based on the Government's support of the *Franciscan Alliance* injunction have faced expensive and unsuccessful lawsuits.[304]

c. The Proposed Rule does not create more flexibility, and even suggests that it may preempt existing state and local laws.

The Department argues that the 2016 rule "may stifle the ability of States, local governments, and covered entities to set their own policies and balance multiple competing interests on questions related to gender dysphoria."[305] It argues the Proposed Rule "would significantly restore the ability of States to establish policies in this area, based on their weighing the competing interests at stake."[306]

The Proposed Rule refers several times to "competing interests" regarding gender identity discrimination to argue that its rescission would provide states, local governments, and other covered entities with more flexibility.[307] The Department fails, however, to explain clearly what those competing interests are, to provide any evidence that they exist and are substantial, or to demonstrate that states, local governments, and covered entities have in fact been "stifle[d]" by the 2016 rule in their ability to consider these "competing interests." Naturally, a nondiscrimination rule prohibits some conduct—here, conduct prohibited by statute because it is "on the basis of sex." However, an entity's interest in violating federal law is not within the Department's purview to consider. Nor is an entity's interest in denying clinically appropriate

[303] *See supra* note 6.
[304] *See Flack*, 328 F. Supp. 3d at 950.
[305] *Id.* at 27857.
[306] *Id.*
[307] *Id.*

health care to patients in need, based on the patient's personal characteristics, a significant "competing" interest that the Department needs to protect from being "stifle[d]."

Additionally, the Proposed Rule suggests that existing policies in compliance with the 2016 Rule may be contrary to its own interpretation of Section 1557, potentially creating significant burdens for the numerous states, local governments, and private health care entities that have adopted nondiscrimination policies. Without citing any evidence, the Department alludes to "the sometimes competing privacy interests…especially when young children or intimate settings are involved" that may arise when addressing "issues related to gender dysphoria or sexual orientation."[308] The Department states that its position "will not bar covered entities from choosing to grant protections for sexual orientation and gender identity," so long as those protections "do not conflict with…any Federal law."[309] But the Department then goes on to imply that nondiscrimination policies could in fact violate federal law. The Proposed Rule states cryptically that "[p]olicies of covered entities that result in unwelcome exposure to, or by, persons of the opposite biological sex where either party may be in a state of undress—such as in changing rooms, shared living quarters, showers, or other shared intimate facilities—may trigger hostile environment concerns under Title IX," and presumably therefore under Section 1557 and the Proposed Rule.[310]

Exposure to members of the opposite sex, however, was never required by the 2016 Rule, or by any other federal, state, or local law or regulation prohibiting anti-transgender discrimination. In fact, numerous courts across the country over the last two decades have held that nondiscrimination laws and policies that permit transgender and non-transgender individuals alike to access public facilities consistent with their deeply and sincerely held gender identity do not violate any right to privacy or discriminate on the basis of sex.[311] But the Department's remark could inaccurately suggest to covered entities that nondiscrimination protections could increase their liability and invite challenges to state and local nondiscrimination laws and accepted best practices in the health care field. This vague statement would impose significant costs and burdens on state and local governments to the extent the Department is asserting preemption of a wide range of state and local laws and policies. Accordingly, the Department must clarify that under no circumstances would the application of such nondiscrimination requirements violate Title IX or Section 1557.

In sum, the Department's conclusion that "the proposed rule would not have sufficient federalism implications to warrant the preparation of a federalism summary impact statement under Executive Order 13132" is flawed and inadequate.[312] In fact, the Proposed Rule would increase uncertainty

[308] Proposed Rule, 84 Fed. Reg. at 27874.
[309] *Id.*
[310] *Id.* at 27874 n. 179.
[311] *Doe v. Boyertown Area School Dist.*, 897 F.3d 518 (3d Cir. 2018), *reh'g en banc denied*, 897 F.3d 515 (3d Cir. 2018); *Cruzan v. Special Sch. Dist. No. 1.*, 294 F.3d 981, 983 (8th Cir. 2002); *Parents for Privacy v. Dallas Sch. Dist. No. 2*, 326 F.Supp.3d 1075 (D. Or. 2018); *Crosby v. Reynolds*, 763 F. Supp. 666 (D. Me. 1991). In one recent case, a court held that a Title IX claim by a girl who objected to transgender-inclusive policies could withstand a motion to dismiss, noting that "[w]hether [plaintiff] can ultimately prevail on this claim is a question for another day." *Students and Parents for Privacy v. Township High Sch. Dist. 211*, 377 F.Supp.3d 891, 900 (N.D. Ill. 2019). The judge did not find there was any substantive violation, but observed that simply pleading "I was subjected to sexual harassment" is sufficient to survive a motion to dismiss under circuit precedent, *id.*, and that plaintiffs also alleged verbal harassment by peers and school officials. *Id.* at 895–96. The court dismissed the privacy claims. *Id.* at 901–02.
[312] Proposed Rule, 84 Fed. Reg. at 28786.

for states while not providing significant new flexibility. To the extent the Department suggests that hundreds of state and local nondiscrimination laws could violate the Proposed Rule, it would impose serious new burdens.

II. The rationale for the Proposed Rule's cost-savings analysis is flawed.

The Proposed Rule fails to comply with Executive Orders 12,866 and 13,563, which permit agencies to propose a rule only after conducting an accurate assessment of costs and benefits, and after reaching a reasoned determination that the benefits outweigh the costs and that the regulations are tailored "to impose the least burden on society."[313] The Department's Regulatory Impact Analysis is flawed in a number of respects. First, as discussed here, the Department falsely claims it had no choice but to remove the 2016 rule's language on gender identity. Second, as discussed in the following subsection, the Department has failed to conduct an accurate cost-benefit analysis.

The Department's cost-benefit analysis falsely states that it was legally mandated to remove all explicit protections based on gender identity from the rule. The Department justifies this assumption by saying that: (1) not taking regulatory action would be inconsistent with the nationwide injunction in *Franciscan Alliance*, (2) removing the parts of the rule on gender identity would be "more consistent with law"; and (3) the proposed rule will eliminate any confusion about patients' rights and covered entities' obligations.[314] Each of these statements is inaccurate.

First, as previously discussed, the preliminary injunction in *Franciscan Alliance* merely prohibits the Department from *enforcing* parts of the 2016 Rule related to gender identity. The District Court did not order the Department to undertake rulemaking, nor has it reached a final ruling on the constitutionality or legality of the 2016 Rule. A preliminary injunction, particularly in the face of a mountain of contrary case law, does not free the Department of the responsibility to provide a complete Regulatory Impact Analysis.

Second, the Department falsely states that removing the parts of the rule on gender identity and sex stereotyping would "revert to statutory interpretations more consistent with the law."[315] As previously discussed, this conclusory statement fails to provide a meaningful analysis of the statutory text, to take into account Supreme Court precedent, or to engage with the dozens of circuit and district rulings that have explicitly concluded that the plain language of Section 1557's sex discrimination protections includes discrimination based on gender identity. If the Department had appropriately conducted a comprehensive review of all relevant case law, including on Title IX and Section 1557 and related sex discrimination statutes, it would conclude that the *Franciscan Alliance* preliminary injunction runs contrary to the overwhelming majority of federal case law on this issue over the last two decades.

Third, the Department states that the new proposed rule would reduce "confusion among the public and covered entities" and would promote "consistent, predictable, and cost-effective

[313] Exec. Order No. 13,563, 76 Fed. Reg. 3821 (Jan. 21, 2011); Exec. Order No. 12,866, 58 Fed. Reg. 51735 (Oct. 4, 1993).
[314] Proposed Rule, 84 Fed. Reg. 27873.
[315] *Id.* at 27873.

enforcement."[316] In fact, if the proposed rule is finalized it is likely that the opposite would happen. The 2016 Rule was necessary to provide clarification on key applications of Section 1557, clarification that was welcomed by many covered entities. Replacing the clear and specific guidance that it provided with no guidance at all other than vague and unsubstantiated remarks in the Proposed Rule's preamble will return covered entities and patients to the state of confusion that the 2016 Rule needed to alleviate. If adopted, the rule would merely parrot the statutory text with respect to race, color, national origin, age, and sex discrimination—save for the addition of new exceptions not provided by statute—and not provide any clarity on covered entities' statutory obligations not to discriminate on these grounds. The result is "a conspicuously minimalistic regulatory scheme (compared to regulations implementing other civil rights laws OCR enforces)," that "provides considerably less notice and clarity about the conduct prohibited under Federal law and the enforcement mechanisms available to HHS."[317] The competing messages from the Department on the one hand and federal courts on the other will inevitably result in greater confusion for patients and covered entities about their rights and obligations, predictably leading to increased litigation.

III. The Department's cost-savings analysis is fundamentally flawed.

The Department's cost-savings analysis ignores numerous vitally important considerations relevant to the net costs of the Proposed Rule. As the Supreme Court has repeatedly said, "an agency must examine the relevant data" in adopting a regulation, and an agency action may be arbitrary and capricious if it "failed to consider an important aspect of the problem, [or] offered an explanation for its decision that runs counter to the evidence before the agency."[318] "[R]easonable regulation ordinarily requires paying attention to the advantages *and* the disadvantages of agency decisions."[319] Executive Order 12,866 requires agencies to "assess *all* costs and benefits" and "should select those approaches that maximize *net* benefits."[320] In the area of health care, a regulation may be arbitrary and capricious if it fails to consider the action's impact on the statute's underlying goals with respect to ensuring access to care.[321]

Here, the Department has failed to consider central "aspect[s] of the problem" completely, has failed to "examine the relevant data," and has failed to "assess all costs and benefits." In particular, the Department: (1) fails to address the Proposed Rule's impact on and costs to patients and the health care system, including the costs of health care discrimination to transgender patients, (2) ignores costs created from the withdrawal of federal guidance and technical support, (3) underestimates extent of reliance on and compliance with Section 1557, (4) fails to conduct a cost-benefit assessment of a variety of other rescissions, and (5) fails to adequately assess administrative and legal costs.

[316] *Id.* at 27875.
[317] Conscience Rule, 84 Fed. Reg. at 23230, 23254.
[318] *State Farm*, 463 U.S. at 43.
[319] Michigan v. EPA, 135 S.Ct. 2699, 2707 (2015) (emphasis in original).
[320] Executive Order 12,866, Regulatory Planning and Review (Sept. 30, 1993) (emphasis added).
[321] *See*, *e.g.*, *Stewart v. Azar*, 313 F.Supp.3d 237, 243 (D.D.C. 2018) (holding approval of Medicaid waiver invalid due to the "signal omission" that "that the Secretary never adequately considered whether [the waiver] would in fact help the state furnish medical assistance to its citizens, a central objective of Medicaid").

a. The Department completely fails address the costs of increased discrimination on the basis of sex to patients, issuers, and the public health system.

Given that it is the core purpose of the Affordable Care Act as a whole, Section 1557 in particular, and the Department itself, ensuring patients have timely access to quality, affordable health care is undoubtedly "an important aspect of the problem." The Department's analysis, however, makes no effort to "adequately analyze the…consequences" of the Proposed Rule for patients, issuers, and public health systems.[322]

The Proposed Rule expressly states that it is not based on any consideration of the potential costs or harms to transgender patients, explaining: "the Department also lacks the data necessary to estimate the number of individuals who currently benefit from covered entities' policies governing discrimination on the basis of gender identity who would no longer receive those benefits as a consequence of the rule."[323] The Department does not acknowledge even in passing the potential and well-documented economic and non-economic costs to the patients and the public health system of the denial of coverage for medically necessary care on the basis of sex. Nor does the Department refer even fleetingly to the potential for increases in the denial, delay, or substandard delivery of health care services as a result of the Proposed Rule. The Department's failure to even attempt to identify or collect such data on such a manifestly "important aspect of the problem" is plainly unreasonable.

In another recent rulemaking, the Department heavily emphasized that "inadequate enforcement" of certain statutes could impose costs on health care providers, emphasizing that some "may experience real harms that are significant and sometimes devastating psychologically, emotionally, and/or financially."[324] The Department emphasized psychological harms, including "stigmatization, shunning by peers,"[325] and harms "of the psychological trauma that results from moral distress."[326] There, the Department emphasized that its goal was "to decrease unlawful discrimination, thereby permitting greater personal freedom," and "peaceful and fulfilling lives" and "help ensure a society free from discrimination and more respectful of personal freedom and fundamental rights enshrined in the First Amendment and Federal law."[327] The Department assessed as a benefit the potential to "promote a culture of respect for" those rights, in contrast to "a degraded moral culture in health care" that could "jeopardize patients' health."[328] While failing to provide any statistical data on these harms or the extent to which its action would impact them, the Department relied on "anecdotes of the occurrence and nature" of such harms from commenters.[329] The Department also relied on anecdotes from commenters and general surveys of the problem to conclude that its action would prevent covered entities from choosing to forego

[322] *Am. Wild Horse Pres. Campaign v. Perdue*, 837 F.3d 914, 932 (D.C. Cir. 2017).
[323] Proposed Rule, 84 Fed. Reg. at 27876.
[324] Conscience Rule, 84 Fed. Reg. at 23228.
[325] *Id.*
[326] *Id. at* 23248.
[327] *Id.* at 23250.
[328] *Id.* at 23229–30, 23246, 23249.
[329] *Id.* at 23228.

providing health services at all.[330] Here, the Department should give at least as much consideration to the rights, freedoms, and well-being of patients that will be threatened by the Proposed Rule, and should give at least as much weight to similar types of evidence. Unfortunately, in this case the Department has not even "attempted a detailed description of the actual impact expected from the rule on access to care, health outcomes, and associated concerns."[331]

Discrimination against transgender patients has numerous economic and non-economic costs, many of which are described in Part 1. These include:

> **Out-of-pocket costs shifted from issuers to consumers for otherwise-covered services that are denied on the basis of sex because of transgender exclusions.** Because of the widespread compliance with Section 1557's protections for transgender patients, many patients have ordered their personal and financial lives around these protections, relying on their ability to access non-discriminatory coverage for major medical costs in making choices about employment, furthering their education, buying a home, and having children. In some cases, patients are currently in the midst of a multi-part course of treatment that could be interrupted if issuers abruptly reintroduce exclusions in reliance on the Proposed Rule.
>
> **Increased costs to patients, issuers, and the public health system of treating comorbid health conditions such as depression, anxiety, high blood pressure, and other stress-related diseases as a result of the delay or denial of care caused by discriminatory exclusions.** It is axiomatic that patients who do not receive the recommended treatment for a medical condition in a timely fashion will likely require additional treatment for such comorbid conditions, and the medical literature confirms this is true for gender dysphoria.[332] Significantly, the Department makes no effort to dispute its prior determination that such exclusions are "now recognized as outdated and not based on current standards of care," and are therefore necessarily harmful to patients' health.[333] Indeed, the Department could not reasonably dispute this conclusion, as it is based on a half-century of clinical experience and research and has been embraced by every major medical association, as noted in comments on the 2015 Proposed Rule and the current Proposed Rule. As the American Medical Association stated more than a decade ago, these medical needs, "if left untreated, can result in clinically significant psychological distress, dysfunction, debilitating depression and, for some people without access to appropriate medical care and treatment, suicidality and death."[334]
>
> **Increased costs to patients, issuers, and the public health system of delaying or denying coverage for clinically appropriate services based on sex coding.** Because

[330] *Id.* at 23246–47; but *compare id.* at 23253 ("The Department is not aware of any data establishing what, if any, part of this avoidance phenomenon is attributable to the exercise of conscientious objections protected by this rule or by implementation of the enforcement mechanisms of this rule.").
[331] *Id.* at 23252.
[332] *See* supra notes 32–60.
[333] 2016 Rule, 81 Fed. Reg. at 31429.
[334] Am. Medical Ass'n, *AMA Policies on GLBT Issues, Patient-Centered Policy H-185.950, Removing Financial Barriers to Care for Transgender Patients* (2008), http://www.imatyfa.org/assets/ama122.pdf.

patients and covered entities will no longer have guidance from the Department on this issue, it is likely that many patients who continued to face such denials will be discouraged from contesting them, some issuers will fail to make simple changes to their systems to eliminate these problems, and some issuers may reintroduce discriminatory practices. As discussed previously, the improper use of sex coding can delay or prevent the detection and effective treatment of many sexual and reproductive health problems including reproductive cancers. This shifts costs to patients and the public health system, and will also cost issuers more in the long term. As previously discussed, there is abundant evidence that sex discrimination in health care causes these harms, including in reports published by the Department itself.[335]

Increased costs to patients, issuers, and the public health system of denial, delay, or substandard delivery of care on the basis of sex. These include the direct cost of treating medical conditions that are exacerbated by a failure to provide timely, adequate treatment; costs assumed by patients in finding and obtaining care from another provider after facing discrimination; and the costs of increased mental health morbidities caused by experiences of discrimination.

Increased costs to patients, issuers, and the public system of delays in obtaining health care services based on patients' increased fear of discrimination on the basis of sex. As previously discussed, transgender patients frequently delay or avoid seeking preventive, primary, urgent, or even emergency care out of fear of being mistreated on the basis of sex.[336] This well-documented phenomenon will be exacerbated by the Department's declaration that such mistreatment is permitted by federal law.

Decreased respect for personal dignity, freedom, and fundamental rights. "The Constitution promises liberty to all within its reach, a liberty that includes certain specific rights that allow persons, within a lawful realm, to define and express their identity."[337] These rights include the First Amendment right to express one's deeply and sincerely held gender identity through speech and appearance,[338] the right to make deeply personal decisions regarding one's social gender role and one's medical care,[339] and the right to maintain privacy regarding deeply personal information regarding sex characteristics or medical care.[340] By effectively preventing and addressing health care discrimination, the

[335] *See, e.g., supra* notes 32–50.
[336] *See* Sandy E. James et al., *The Report of the 2015 U.S. Transgender Survey* 98 (2016), www.ustranssurvey.org/report (finding that 23% of transgender adults in a national sample avoided seeking care when needed in the past year because of fear of mistreatment).
[337] *Obergefell v. Hodges*, 135 S.Ct. 2584, 2593 (2015). *See also Roberts v. U.S. Jaycees*, 468 U.S. 609, 619 (1984) (due process "safeguards the ability independently to define one's identity that is central to any concept of liberty").
[338] *See, e.g.*, *Zalewska v. County of Sullivan*, 316 F.3d 314, 320 (2d Cir. 2003) (*citing Doe ex rel. Doe v. Yunits*, No. 001060A, 2000 WL 33162199 (Mass.Super.Oct.11, 2000)).
[339] *See, e.g., Karnoki*, No. C17-1297, 2017 WL 6311305, at *8 (holding Due Process Clause protects individual's "ability to define and express their gender identity"); *Doe v. McConn*, 489 F.Supp. 76 S.D. Tex. 1980) (holding application of anti-cross-dressing ordinance to transgender people violated substantive liberty interests); *City of Chicago v. Wilson,* 389 N.E.2d 522 (Ill. 1978) (same).
[340] *See, e.g., Powell v. Schriver*, 175 F.3d 107, 112 (2d Cir. 1999) (holding that individuals have a constitutional right to privacy concerning transgender status); *Love v. Johnson,* 146 F.Supp.3d 848, 855 (E.D. Mich. 2015)

> Department served our society's interest in "protecting the rights of transgender people in public spaces and not forcing them to exist on the margins," and reflected "the simple recognition of their humanity."[341] By withdrawing recognition, notification, and enforcement of protections for transgender patients, intersex patients, those perceived as not conforming to sex stereotypes, and others, the Proposed Rule sends a strong public message of disregard for their rights and dignity, promotes stigmatization, and erodes respect for fundamental rights. The Department must consider and provide a reasoned analysis regarding these intangible but important costs.

The Department has received comments from many individual patients and providers addressing these costs in response to its 2013 Request for Information on Section 1557, its 2015 Proposed Rule, its 2017 Request for Information on ACA regulatory reform, and the current Proposed Rule, and must consider that information in its analysis.

Even if many covered entities continue to make efforts to comply with Section 1557 as interpreted by the 2016 Rule and applicable case law—and even if the number who do so significantly exceeds the 50% estimated by the Department—these costs would likely be significant, and the Regulatory Impact Assessment is incomplete and unreasonable without taking them into account. To the extent that the Department suggests that some transgender-inclusive laws, policies, and practices of covered entities may violate the Proposed Rule or other federal laws,[342] the harms and costs to patients and the health care system could be even greater.

b. The Proposed Rule could cause billions of dollars in costs through missed cancer screenings alone.

To attempt to quantify just one way in which the Proposed Rule could impact health care outcomes and costs, researchers from Johns Hopkins University modeled the impact of this regulation on incidence and mortality among LGBT people of colorectal, breast, prostate, and lung cancers, which are four of the most common—and most preventable—cancers.[343] Using data from the Centers for Disease Control's (CDC) Surveillance, Epidemiology, and End Results (SEER) Cancer Registry, they calculated the decrease in incidence and mortality of each cancer that is achievable through timely screening per the US Preventive Services Task Force guidelines. According to a study by Harvard University and National Public Radio (NPR), 18% of LGBT people report foregoing care that they need, including preventive care, due to fears of or experiences of discrimination.[344] This number is conservative for transgender people: in the Harvard/NPR study,

(holding privacy concerns regarding transgender status "cut at the 'very essence of personhood' protected under the substantive component of the Due Process Clause"); *Arroyo Gonzalez v. Rossello Nevares*, 305 F.Supp.3d 327, 333 (D.P.R. 2018) ("there are few areas which more closely intimate facts of a personal nature than one's transgender status").

[341] *G. G.*, 853 F.3d at 730 (Davis, J., concurring).

[342] *See supra* notes 309–311.

[343] Kellan Baker, Personal correspondence (Aug. 13, 2019). This analysis is currently being finalized to submit for publication.

[344] Nat'l Public Radio & Harvard T.H. Chan School of Public Health, *Discrimination in America: Experiences and Views of LGBTQ Americans* 12 (Nov. 2017), https://cdn1.sph.harvard.edu/wp-content/uploads/sites/94/2017/11/NPR-RWJF-HSPH-Discrimination-LGBTQ-Final-Report.pdf

22% of transgender people reported foregoing care,[345] and in the 2015 US Transgender Survey, 23% of transgender people reported foregoing care in the previous year.[346]

The Johns Hopkins researchers stratified the total US LGBT population of 11.3 million[347] into gender- and age-appropriate strata for colorectal, breast, prostate, and lung cancer screenings. They then estimated the number of LGBT people in the screening-eligible populations who would be expected to forego these screenings due to discrimination or fear of discrimination, and calculated the resulting excess mortality and excess treatment costs that will be due to the proposed regulation. They estimated that this regulation will cost $1.4 billion in excess costs over the next ten years to treat cases of these four cancers alone that would have been detected and prevented by screening, and that there will be an 18% increase in preventable mortality from these four cancers among LGBT people. According to the 2016 value of a statistical life (VSL) used by the US Department of Transportation, these preventable deaths are worth $39 billion to the US economy over the next ten years.[348]

This analysis assumes that 18% rate of foregoing care as a baseline of what would occur if the 2016 Rule were not maintained and fully enforced, and that over a period of ten years maintaining and enforcing the 2016 Rule would largely eliminate this effect. However, even assuming a much smaller effect of maintaining and enforcing the 2016 Rule, the findings are dramatic. Assuming that the 2016 Rule would only be 25% effective over ten years in eliminating missed screenings due to discrimination or fear of discrimination, this would still produce a 4.5% change in excess mortality among the LGBT population, saving $354 million in excess treatment costs and $9.8 billion in excess mortality costs. Assuming only a 10% effect, this would produce a 1.8% reduction in excess mortality, and save $141 million in excess treatment costs and $3.9 billion in excess mortality costs. Even assuming only an extremely conservative 5% effect, there would still be a 0.9% reduction in excess mortality, and a savings of $70.7 million in excess treatment costs and $2 billion in excess mortality costs over ten years.

Considering outcomes for transgender individuals alone, this analysis estimates that the 2016 Rule would prevent 543 cancer deaths and save $207 million in treatment costs if it were 100% effective over ten-year period in eliminating missed screenings. An assumption of 25% efficacy yields an estimate of 136 fewer cancer deaths and a savings of $51.9 million in treatment costs over ten years. An assumption of 10% efficacy in preventing missed screenings for transgender people yields an estimate of 54 fewer cancer deaths and $20.7 in treatment costs saved over ten years. Even assuming only 5% efficacy, this analysis yields an estimated 27 cancer deaths prevented and $10.4 million in treatments costs saved over ten years.

[345] *Id.* at 2.
[346] James et al., *supra* note 336 at 98.
[347] Williams Inst., *Adult LGBT Population in the United States* (Mar. 2019), https://williamsinstitute.law.ucla.edu/wp-content/uploads/LGBT-Population-Estimates-March-2019.pdf.
[348] U.S. Dep't of Transp. *Guidance on Treatment of the Economic Value of a Statistical Life (VSL) in U.S. Department of Transportation Analyses – 2016 Adjustment* (Aug. 8, 2016) https://www.transportation.gov/sites/dot.gov/files/docs/2016%20Revised%20Value%20of%20a%20Statistical%20Life%20Guidance.pdf.

In health care, civil rights protections save lives. Even when looking only at transgender people, only at missed screenings for four of the most common cancers, and only assuming an extremely low 5% efficacy of fully implementing the 2016 Rule, the economic costs in combined morbidity and mortality of the Proposed Rule would be in the hundreds of millions of dollars. The non-economic and intangible costs of this excess morbidity and mortality are also enormous. Given the evidence presented throughout this comment, similar effects for other medical and mental health conditions are likely. The Department has not, and cannot, identify benefits that outweigh such grave costs to patients, their families, the health care system, and the wider economy and society.

c. The Department ignores costs it creates by withdrawing clear federal guidance and by eliminating means for administratively resolving issues of discrimination.

Despite the Department's claim that the Proposed Rule adds clarity and uniformity to the interpretation of Section 1557, the Proposed Rule in fact withdraws the explicit and detailed guidance provided by the 2016 Rule, leaving covered entities in the dark about how Section 1557 is to be interpreted and applied with regard to anti-transgender discrimination. By failing to set a federal standard that complies with applicable case law, the Proposed rule will increase rather than decrease costs. Covered entities will need expend resources to obtain legal advice regarding their own obligations under federal law as interpreted by the courts, assess their liability, and respond to any ensuing litigation, as well as to determine their obligations under state and local laws that may conflict or be in tension with the Proposed Rule. Since the passage of the ACA, many of these costs were offset by the Department's technical support to covered entities on how to comply with their obligations when it came to LGBT patients.[349] In the absence of this assistance and of clear guidance from department regulations, entities will have to bear these burdens themselves or else risk litigation. The Department's withdrawal from its role in resolving sex discrimination complaints administrative—a practice that decreases legal costs for all parties involved[350]—would further increase the burdens on covered entities as well as on patients. Even though the Department itself admits that incidents of discrimination based on gender identity will now have to be settled in court,[351] the Propose Rule's cost analysis fails to consider the resultant costs.

d. The Department ignores widespread reliance on and compliance with Section 1557.

The Department falsely claims that the prohibition on discriminating against transgender consumers in health insurance never went into effect. The Department concluded that transgender patients "could not have developed a reliance interest" on these protections, and therefore repealing them is cost-free.[352] Here, the Department has "offered an explanation for its decision that runs counter to the evidence before the agency."[353] Specifically, the Department's contention ignores statutory protections and the history of regulatory policy on this issue.

[349] *See, e.g.,* Gruberg & Bewkes, *supra* at 197.
[350] *See, e.g., id.* ("Most of the closed complaints resulted in the subject of the complaint taking voluntary corrective action.")
[351] Proposed Rule, 84 Fed. Reg. at 27873.
[352] *Id.* at 27886.
[353] *State Farm*, 463 U.S. at 43.

The civil rights protections outlined in Section 1557 were one of few parts of the Affordable Care Act to become effective on the day it became law in 2010, and was not dependent implementing rules. In 2012, the Department released an opinion letter clarifying that Section 1557's sex discrimination provisions included discrimination based on gender identity and sex stereotyping, in accordance with precedents of the Supreme Court and the Courts of Appeals.[354] In some cases, federal courts accorded some deference to the Department's reasonable interpretation,[355] while in others courts reached the same conclusion based solely on the plain statutory text.[356] Patients and covered entities alike have relied on this position since that time in seeking coverage and care and evaluating plan designs.

Over the last nine years, countless private insurance plans have updated their policies to comply with the law by removing blanket exclusions that single out transgender consumers and clarifying their coverage policies. Many public and private plans implemented these actions long before the 2016 rule was adopted, considering their statutory obligations under the ACA as well as applicable case law the Department's 2012 guidance. Many others did so based on the additional clarity provided by the 2016 Rule. That rule did not *create* the obligation for payers to provide access to nondiscriminatory coverage for transgender patients. Rather, the 2016 Rule provided clear guidance for covered entities regarding their existing obligations under the statute. The Department gave plans advance notice in the 2016 Rule that it would enforce these obligations starting in the 2017 plan year. Insurance companies filed their 2017 plans accordingly shortly thereafter, and the government approved plans in August 2016.

The Department mentions the preliminary injunction in the *Franciscan Alliance* case as the reason why the 2016 Rule requirements never "went into effect." However, Section 1557's nondiscrimination protections on the basis of sex, including gender identity and sex stereotyping, have been in place since the passage of the ACA, as recognized by the Department's 2012 guidance and the overwhelming majority of federal courts to consider the issue. Even if the Department believed that these protections were first established by the 2016 Rule, the *Franciscan Alliance* court did not enjoin the 2016 Rule and the underlying statutory obligation it interprets, but rather the Department's ability to administratively enforce it.[357] And even if that were not the case and the 2016 Rule and underlying statutory requirements themselves had been enjoined, by the time that the *Franciscan Alliance* ruling was issued in December 2016, covered entities had already long since filed their 2017 health plan documents.[358]

In fact, since at least the start of the 2017 plan year, the vast majority of Marketplace plans have come into compliance with Section 1557, as interpreted by section 92.207(b)(3)–(5). A study of 866 2017 Marketplace Silver plans from 81 issuers across 16 states found that the vast majority (95%) had eliminated transgender-specific exclusions, with only four plans from four issuers

[354] Department of Health and Human Services, OCR Transaction Number 12-000800 (July 12, 2012).
[355] *See, e.g., G.G.*, 822 F.3d at 721.
[356] *See, e.g., Prescott,* 265 F.Supp.3d at 1105.
[357] *Franciscan Alliance*, 227 F. Supp. 3d at 696.
[358] *See, e.g.,* Ctr. for Consumer Info. & Ins. Oversight (CCIIO), *2017 Letter to Issuers in the Federally-facilitated Marketplaces* (Feb. 29, 2016); 45 C.F.R. § 156.210(b).

retaining such exclusions.[359] A similar analysis found that of 548 2018 Marketplace Silver plans from 71 issuers in 18 states, 90% did not include exclusions. Only a handful of plans from seven issuers maintained such exclusions.[360] Most recently, an analysis of 622 2019 Marketplace Silver plans from 129 issuers in 38 states found that 94% did not contain transgender-specific exclusions. Only a small number of plans from eight issuers contained such exclusions.[361] This represents a dramatic change from the years prior to the ACA's enactment, when such exclusions were commonplace in both the individual and group markets.

State insurance commissioners have continued to enforce Section 1557 with respect to discrimination against transgender consumers. For example, in 2018, the New Mexico Superintendent of Insurance issued a bulletin outlining plan obligations under the ACA and federal court rulings to provide coverage for medically necessary care for transgender beneficiaries.[362] A comment submitted on the current Proposed Rule by 18 state insurance commissioners states:

> The vast majority of regulated entities across the country, including those we regulate, have already come into compliance with Section 1557. … Our collective experience in implementing these protections has been that the fiscal and regulatory impact of ensuring nondiscriminatory treatment of insurance claims, including claims for medical care related to gender transition, are negligible. We have been able to consider and resolve the consumer complaints that we have received under Section 1557.[363]

Similarly, the use of exclusions for transition-related care has decreased dramatically in large employer plans since the passage of Section 1557 and the issuance of the 2012 guidance and the 2016 Rule. For example, while only 9% of employers surveyed in the Human Rights Campaign's Corporate Equality Index in 2010 had transgender-inclusive plans, that rate rose to 42% by 2013 and 83% by 2019.[364]

Currently, only eight states still have exclusions of transition-related care in their Medicaid programs, some of which are currently being challenged in court.[365] Several states have had

[359] Out2Enroll, *Summary of Findings: 2017 Marketplace Plan Compliance with Section 1557* (2016), https://out2enroll.org/out2enroll/wp-content/uploads/2015/10/Report-on-Trans-Exclusions-in-2017-Marketplace-Plans.pdf.

[360] Out2Enroll, *Summary of Findings: 2018 Marketplace Plan Compliance with Section 1557* (2017), https://out2enroll.org/out2enroll/wp-content/uploads/2017/11/Overview-of-Trans-Exclusions-in-2018-Marketplace-Plans-1.pdf.

[361] Out2Enroll, *Summary of Findings: 2019 Marketplace Plan Compliance with Section 1557*. https://out2enroll.org/out2enroll/wp-content/uploads/2018/11/Report-on-Trans-Exclusions-in-2019-Marketplace-Plans.pdf.

[362] Office of the Superintendent of Insurance. Bulletin 2018-031. August 23, 2018, https://www.osi.state.nm.us/wp-content/uploads/2019/06/Bulletin2018-013.pdf.

[363] Comment from insurance commissioners of California, Connecticut, Colorado, Delaware, District of Columbia, Illinois, Michigan, Minnesota, Nevada, New Jersey, New Mexico, New York, Oregon, Pennsylvania, Rhode Island, Vermont, Washington, and Wisconsin, Re: Proposed rule RIN 0945-AAll, (Aug. 5, 2019), https://www.insurance.ca.gov/0400-news/0100-press-releases/2019/upload/nr057LtrToAzarSec1557-080519.pdf.

[364] Human Rights Campaign, *Corporate Equality Index 2019* 14–15 (2019), https://www.hrc.org/campaigns/corporate-equality-index.

[365] These states are Alaska, Georgia, Missouri, Nebraska, Ohio, Tennessee, Wisconsin, and Wyoming.

exclusions of transition-related care in their programs successfully challenged in federal court, including decisions in Wisconsin and New York based on Section 1557.[366] Other states have voluntarily removed Medicaid exclusions, citing, among other reasons, their obligations under Section 1557.[367]

A similar trend has emerged in state employee plans. Wisconsin had removed its blanket exclusion of transition-related care in its state employee plan following the publication of the 2016 Rule, but chose to reinstate it based on the *Franciscan Alliance* injunction. A federal court found that the exclusion violated Section 1557,[368] and the state reversed its decision and removed the exclusion.[369] Only twelve states maintain such exclusions in state employee plans, some of which are also being challenged in court.[370]

At the federal level, the Medicare program eliminated a national exclusion for transition-related surgeries in 2014,[371] and the Office of Personnel Management directed Federal Employee Health Benefit eliminated blanket exclusions for transition-related care in 2015.[372] Based on this history, it is apparent that the Department has both undervalues the reliance interests of patients and providers with respect to these protections, and overestimates the potential "regulatory relief" that the Proposed Rule provides.

The fact that a handful of states and issuers have interpreted the *Franciscan Alliance* preliminary injunction and the Department's embrace of it as authorizing them to reinstate such exclusions underscores the confusion that the Proposed Rule is likely to cause, with resulting burdens on patients and covered entities. In addition to Wisconsin, North Carolina has recently reinstated an exclusion in its state employee plan,[373] as did Oscar health plans sold in marketplace states such as Tennessee and Texas,[374] and plans sold by Medical Mutual of Ohio.[375] These entities attributed their rollbacks directly to the Department's refusal to defend the 2016 Rule and its public announcement that it would instead seek to rescind it—even as the majority of states and issuers continued to abide by the ACA's protections for transgender consumers. This confusion underscores the importance of the clarity provided by the 2016 Rule, and previews the wider

[366] *See Flack*, 328 F.Supp.3d at 950; *Cruz*, 195 F.Supp.3d at 579.
[367] *See, e.g.*, Me. Dep't of Health & Human Servs., Emergency Adoption: Chapter 101, MaineCare Benefits Manual, Section 90, Chapter II, Physician Services (June 18, 2019), https://www.mainepublic.org/sites/mpbn/files/201906/mainecare_benefits_manual__section_90__chapter_ii__physician_services_emerg_.pdf.
[368] *Boyden,* 341 F.Supp.3d at 997.
[369] Shamane Mills, *Board Approves Transgender Health Benefits For State Of Wisconsin Workers*, WISCONSIN PUBLIC RADIO (August 22, 2018), https://www.wpr.org/board-approves-transgender-health-benefits-state-wisconsin-workers.
[370] LGBT Movement Advancement Project, *Equality Maps: State Employee Benefits* (updated Aug. 7, 2019), http://www.lgbtmap.org/equality-maps/healthcare_laws_and_policies/state_employees.
[371] Dep't of Health & Human Services, NCD 140.3, Transsexual Surgery, 12 (2014).
[372] FEHB Program Carrier Letter No. 2015-12, Covered Benefits for Gender Transition Services, (June 24, 2015).
[373] Jonathan Drew, *North Carolina Sued Again over Transgender Rights*, A.P. NEWS (March 11, 2019), https://www.apnews.com/a725c74b9f074bd2a81fb4e9b1cda375.
[374] National Center for Transgender Equality. An Open Letter to Oscar Health Insurance (June 21, 2018), https://medium.com/transequalitynow/an-open-letter-to-oscar-health-insurance-3fdf865d11
[375] Nicole Pasulka, *Within Reach: The Transgender Community Fights for Health Care*, HARPER'S MAGAZINE (Feb. 2018), https://harpers.org/archive/2018/02/within-reach.

confusion that would follow the adoption of this Proposed Rule, particularly if a fraction of these covered entities misunderstand the Proposed Rule to *require* them to reinstate discriminatory practices in coverage or care.

e. The Department fails to acknowledge the negligible cost of prohibiting sex-based discrimination against transgender people in health insurance coverage.

The Department reasonably concluded in the 2016 Rule that prohibiting discrimination against transgender consumers in health insurance "will have de minimis impact on the overall cost of care and on health insurance premiums."[376] In fact, studies have found that providing access to coverage of transition-related care is extremely cost effective, and leads to cost savings in the long term.[377] A 2013 survey of employers by the Williams Institute at the UCLA School of Law found that transition-related health care benefits have "zero or very low costs" and low utilization, with utilization rates estimated at 1 per 10,000 to 20,000 employees.[378] The report concludes: "Overall, we find that transition-related health care benefits have very low costs, have low utilization rates by employees, and yet can provide benefits for employers and employees alike."[379] A 2016 study in the *Journal of General Internal Medicine* estimated the cost of providing coverage for medical and surgical treatment of gender dysphoria at $0.016 per member per month, and that this minimal cost "hold good value for reducing the risk of negative endpoints [such as] depression, suicidality, and drug abuse."[380] As noted above, 18 state insurance commissioners have submitted comments on the Proposed Rule stating that, "Our collective experience in implementing these protections has been that the fiscal and regulatory impact of ensuring nondiscriminatory treatment of insurance claims, including claims for medical care related to gender transition, are negligible."[381]

In fact, leading health insurers and various other stakeholders have welcomed these provisions. Comments on the 2015 rule,[382] comments on the 2017 regulatory reform RFI,[383] and the

[376] 2016 Rule, 81 Fed. Reg. at 31456–57.
[377] *See, e.g.* Aaron Belkin, *Caring for Our Transgender Troops — The Negligible Cost of Transition-Related Care*, 373 NEW ENG. J. MED. 1089 (Sept. 15, 2015); Or. Health Review Comm'n, Value-based Benefits Subcommittee (June 12, 2014), http://www.oregon.gov/oha/herc/CommitteeMeetingMaterials/VbBS%20Materials%206-12-2014.pdf; Jody L. Herman, *Cost and Benefits of Providing Transition-Related Health Care Coverage in Employee Health Benefits Plans* (Sept. 2013), https://williamsinstitute.law.ucla.edu/research/transgender-issues/costs-benefits-providing-transition-related-health-care-coverage-herman-2013; Cal. Dep't of Ins., *Economic Impact Assessment Gender Nondiscrimination in Health Insurance* (Apr. 13, 2012).
[378] Herman, *supra* note 377, at 2.
[379] *Id.* at 17.
[380] 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. INTERN. MED. 394 (Oct. 2016), https://doi.org/10.1007/s11606-015-3529-6.
[381] *See supra* note 363.
[382] Blue Cross and Blue Shield Association, Comment on 2015 Proposed Rule on Nondiscrimination in Health Programs and Activities (Nov. 2015), https://www.regulations.gov/document?D=HHS-OCR-2015-0006-1758. America's Health Insurance Plans, Comment on 2015 Proposed Rule on Nondiscrimination in Health Programs and Activities (Nov. 2015), https://www.regulations.gov/document?D=HHS-OCR-2015-0006-0842.
[383] Blue Cross and Blue Shield Association, *RE: RFI on Reducing Regulatory Burdens Imposed by the PPACA and Improving Healthcare Choices to Empower Patients* (July 2017), https://www.regulations.gov/document?D=CMS-2017-0078-2686. America's Health Insurance Plans, *RE: Reducing Regulatory Burdens Imposed by the Patient Protection and Affordable Care Act and Improving Healthcare Choices to Empower Patients—AHIP Comments* (July 2017), https://www.regulations.gov/document?D=CMS-2017-0078-2544.

"Supporting Documents" posted by OCR in support of the current proposed rule,[384] show that the industry stakeholders have welcomed the guidance these provisions provide. These stakeholders have not said they are burdensome, have not advocated for their repeal, and at most have simply sought more clarity on their implementation. Neither have comments during any of these comment periods from any state officials provided significant evidence of increased cost in this area. Commenting on the current Proposed Rule, America's Health Insurance Plans (AHIP) state strongly that these rescissions provide no meaningful regulatory relief:

> Removing references in the rule to discrimination based on gender identity, sex stereotyping, and pregnancy status is inconsistent with providing access to affordable high-quality care to everyone. Those changes should not be finalized.[385]

Similarly, a public statement from the Association of Community Affiliated Plans (ACAP) in response to the current Proposed Rule stated:

> It's difficult to see what problems these revisions solve.
>
> We believe that keeping open avenues to coverage and health care is the best way to keep people healthy and is the wisest use of resources for government-sponsored programs.
>
> Turning the clock back and allowing health care entities to discriminate on the basis of a person's gender identification, or whether someone has previously sought an abortion, will lead to worse health outcomes and higher health care costs.[386]

f. The Department failed to conduct a cost-benefit assessment of several other rescissions.

The Department did not conduct a Regulatory Impact Analysis, including a cost benefit analysis, for several other changes it is proposing regarding the sex discrimination protections outlined in the 2016 Rule and other CMS regulations.

First, as previously discussed, the Department did not include any meaningful analysis on the consequences of removing all sex stereotyping language from the rule. Costs of this rescission could include increased confusion for patients and covered entities, increased discrimination based on sex stereotyping with attendant economic and non-economic costs to patients and the public health system, increased need for legal advice, and increased litigation. While the Department

[384] *See* Nondiscrimination in Health and Health Education Programs or Activities, Supporting and Related Materials, https://www.regulations.gov/docketBrowser?rpp=25&so=DESC&sb=commentDueDate&po=0&dct=SR%2BO&D=HHS-OCR-2019-0007.
[385] America's Health Insurance Plans (AHIP), RE: NPRM on Nondiscrimination in Health and Health Education Programs or Activities, RIN 0945–AA11 (Aug. 12, 2019), https://www.ahip.org/wp-content/uploads/AHIP-1557-NPRM-Comment-Letter.pdf.
[386] ACAP Statement on Proposed Revisions to Health Care Non-Discrimination Regulations (May 24, 2019), https://www.communityplans.net/acap-statement-on-proposed-revisions-to-health-care-non-discrimination-regulations.

claims savings for covered entities based on not taking steps to prevent or respond to such discrimination, any such savings are unlikely in light of clear Supreme Court precedent that such discrimination is unlawful.

Second, the Department did not include any cost-benefit analysis regarding the rescission of other Section 1557 provisions unrelated to gender identity, including the complete rescission of section 92.206 regarding sex discrimination in health care service delivery; section 92.207 regarding discrimination on the basis of race, color, national origin, age, disability, and sex in insurance; and section 92.209 regarding associational discrimination. As previously discussed, these provisions are not simply duplicative of other regulations but provide important additional clarity on issues clearly covered by the statute. Costs of these rescissions could include increased confusion for patients and covered entities, increased discrimination with attendant economic and non-economic costs to patients and the public health system, increased need for legal advice, and increased litigation.

Third, the Department did not conduct cost-benefit analysis of the proposed changes to remove sexual orientation and gender identity nondiscrimination protections in ten CMS regulations. As previously mentioned, these regulations are independent from and unrelated to Section 1557, with some even predating the Affordable Care Act itself. They affect many different portions of public and private insurance benefits, including the Marketplace exchanges, Medicaid, and the Program for All Include Care for the Elderly (PACE). The changes to these regulations cannot in any way be considered "conforming amendments," and CMS must conduct an adequate cost-benefit analysis prior to any change to these longstanding regulations. Costs of these rescissions could include increased confusion for patients and covered entities, increased discrimination on the basis sex with attendant economic and non-economic costs to patients and the public health system, decreased participation in the covered programs, increased need for legal advice, and increased litigation.

Fourth, the Department did not conduct a cost-benefit analysis of the impact, including impact on patients, that the adoption of the Title IX religious exemption in the Proposed Rule would have if applied to a health care setting. As detailed above, the Department failed to specify how this religious exemption would operate and be enforced in practice outside of the education context and how patients would be affected by the reduction of available services. The Department has also failed to provide an analysis of how this new exemption differs from, and would affect patients in light of, the recently finalized rule on "Protecting Statutory Conscience Rights in Health Care," including the delay in the effective date of that rule and the current legal challenges to it.

g. The Department failed to adequately assess administrative and legal costs.

The Department estimates that the rescinding both the gender identity and sex stereotyping provisions, taken together, will result in 50% of covered entities choosing to abandon all efforts to prevent or respond to such discrimination. It estimates that the Proposed Rule will thereby provide an annual 1.5% decrease in grievance caseload across all covered entities (half of an overall 3% reduction), with an annual labor savings of $123.4 million.[387]

[387] Proposed Rule, 84 Fed. Reg. at 27884

This estimate is based on several flawed assumptions. First, it assumes that federal law prior to the 2016 Rule did not cause covered entities to receive or incur costs associated with grievances related to gender identity or sex stereotyping. This assumption is flawed because all covered entities were already subject to Section 1557's statutory requirements, and many patients and covered entities were aware of numerous court rulings and the Department's own 2012 guidance indicating such claims were covered.

Second, this estimate failed to identify or collect any data regarding the number of covered entities, and the market share of those entities, that are covered by state or local laws prohibiting anti-transgender discrimination. These includes the nondiscrimination laws in 20 states, the District of Columbia, and over 300 localities that explicitly enumerating gender identity, which apply to some or all covered entities in the jurisdiction. These also include state laws regarding sex or disability discrimination, mental health parity, and unfair trade practices that have been interpreted by state courts or regulators to prohibit such discrimination. For example, an estimated 52% of the U.S. population lives in states where private insurers are prohibited from maintaining transgender-related exclusions.[388] Estimates for the transgender population in each state have been developed based on a national, state-administered survey.[389] The Department could and should have sought additional information from covered entities or state agencies.

Third, this estimate assumes that covered entities will be free under federal law to ignore discrimination based on both sex stereotypes and gender identity. As previously discussed, this is untrue, because (1) binding Supreme Court precedent prohibits sex stereotyping discrimination, (2) numerous courts have interpreted Section 1557 and similar sex discrimination statutes to prohibit gender identity, and (3) other federal laws such as the Medicaid Act, the Social Security Act, the Americans with Disability Act, the Rehabilitation Act, Title VII, and the Employee Retirement Income Security Act (ERISA), prohibit or limit some covered entities' ability to engage in anti-transgender discrimination.

Fourth, the Department relies on projections about complaints OCR "would have" received, rather than identifying the actual changes in OCR's caseload, based on the apparent assumption that it received no such complains due to the *Franciscan Alliance* preliminary injunction. In fact, OCR has received such complaints, because patients have been aware of their right to complaint since at least the 2012 guidance and the issuance of the 2016 rule in May 2016, well before the injunction. The Department received and acted on such complaints well ahead of the effective date of the rule, and appears to have continued to receive some complaints despite the injunction.[390] While a proper estimate may require some estimate of what would have occurred had the

[388] LGBT Movement Advancement Project, *Equality Maps: Private Insurance* (updated Aug. 7, 2019), http://www.lgbtmap.org/equality-maps/healthcare_laws_and_policies/state_employees.
[389] Andrew R. Flores et al., *How Many Adults Identify as Transgender in the United States?* (2016), http://williamsinstitute.law.ucla.edu/wp-content/uploads/How-Many-Adults-Identify-as-Transgender-in-the-United-States.pdf.
[390] *See, e.g.,* Gruberg & Bewkes, *supra* note 197; Dep't of Health & Human Servs., Office for Civil Rights, *Bulletin: The Brooklyn Hospital Center Implements Non-Discriminatory Practices to Ensure Equal Care for Transgender Patients* (Jul. 14, 2015).

injunction and the Department's embrace of it not occurred, the estimate must start with actual complaint data.

Fifth, the Department the Department assumes that trends in its own OCR complaint data, and assumptions made about those data, are fully applicable to the grievances experienced by covered entities. This is not necessarily true, particularly to the extent that OCR has stated since early 2017 that it would ignore such complaints, while covered entities have been required under statutory requirements and applicable case law to continue to respond to complaints, and have indeed continued to do so.

For all these reasons, the estimate of $123.4 million in cost savings related to these portions of the Proposed Rule is fatally flawed. It is likely that both the estimate of the proportion of entities that will cease to address anti-transgender discrimination and the decrease in complaint volume are too high. The Department could and should have—but failed to—identify or collect data that could have provided a more accurate estimate.

In addition, the Regulatory Impact Estimate wrongly estimates that the Proposed Rule will decrease costs related to litigation risk for covered entities. The Department states that "[t]he existence of lawsuits and court orders blocking enforcement of significant parts of the Final Rule for over two years indicates that changes in the proposed rule may minimize litigation risk."[391] Elsewhere the Department states that its proposal "seeks to avoid further litigation and uncertainty regarding the implementing regulations,"[392] and that the Proposed Rule will prevent future litigation.[393] It is unclear whether each of these passing comments refers to the litigation risk faced by covered entities, or by the Department itself. Litigation risk and cost for the Department itself are not a proper focus of the Regulatory Impact Assessment—particularly here, where the Proposed Rule clearly conflicts with the overwhelming body of federal case law and is therefore virtually certain to be challenged in court itself.[394]

With respect to covered entities, the Department states:

> First, because the proposed rule is simple and easily administrable, it would be less likely that covered entities would need to pay for legal advice or otherwise expend organizational resources to understand their obligations under Section 1557, either in general or with respect to any particular situation that arises. Second, the proposed rule would eliminate the need for covered entities to expend labor and money on an ongoing basis to maintain internal procedures for mitigating the legal risk that persists due to unresolved controversy over the meaning of Section 1557. The Department solicits comment regarding the nature and magnitude of such ongoing costs incurred by covered entities.[395]

[391] Proposed Rule, 84 Fed. Reg. at 27849.
[392] *Id.* at 27850.
[393] *Id.* at 27860, 27870.
[394] *See NAACP v. Trump*, 298 F.Supp.3d at 234–35 (holding agency litigation risk is not a valid independent ground for agency action).
[395] Proposed Rule, 54 Fed. Reg. at 27876.

The Department presents no data or other evidence to suggest that covered entities will see less need to obtain legal advice, assess their internal procedures, or otherwise address legal risks because of the Proposed Rule. In reaching such conclusions, "conclusory statements will not do,"[396] and the Department's assertion of this result in the absence of any evidence is insufficient. This assertion is highly questionable given that the Proposed Rule upsets the Department's settled position since at least 2012, is contrary to a large body of case law, reduces rather than increases the amount of guidance that covered entities have, and does not bind federal courts or insulate entities from private suits. As discussed above, covered entities that changed their practices in reliance on the Department's embrace of the *Franciscan Alliance* injunction and intention to revise the 2016 Rule have in fact faced litigation and in some case have already lost in court. Many covered entities are well aware that their obligations under Section 1557, and the case law recognizing those obligations, do not flow from the 2016 Rule alone but rather from the underlying statute. As the Department itself notes, numerous private suits seeking to enforce Section 1557 with respect to sex stereotyping or gender identity discrimination remain pending, and are not likely be withdrawn or dismissed simply because of the Department's action.[397] In fact, law firms and legal experts advising covered entities on their obligations under Section 1557 and related laws have publicly said as much. For example, one of the largest health care law firms in the country advised employers last fall that "while HHS continues its current policy of non-enforcement of allegations of gender identity discrimination under Section 1557, employers should be aware of provisions in their group health plans that exclude coverage for transgender benefits and litigation risks that these provisions may pose."[398]

Contrary to the Department's assumption, many covered entities have benefited from the clarity and nationwide consistency provided by the 2016 Rule, which has reduced the need for entities to closely study and comply with varying state and local laws and with court rulings. Covered entities, most of whom have already taken substantial steps to comply with Section 1557's sex discrimination requirements, will now have to incur additional costs to reassess their current legal and internal procedures based on that varied state, local, and judicial landscape. Although the Department's estimate that 50% of entities will choose to resume or ignore discriminatory practices is very likely too high, those who do so will continue to face significant litigation risk based on state and local laws, other federal laws, and Section 1557 itself. In sum, the Department unreasonably assumed a decrease, rather than an increase, in cost and risk related to legal advice, compliance, and litigation.

[396] *Amerijet Int'l*, 753 F.3d at 1350 (emphasis in original, internal quotation marks and citations omitted); *see also Getty*, 805 F.2d at 1057.

[397] *See, e.g., Tovar*, 342 F. Supp. 3d 947 (on remand from 8th Circuit); *Boyden*, 341 F. Supp.3d 979 (appealed to 7th Circuit, No. 3:18-3408 and No. 18-3485, on Nov. 9, 2018); *Flack*, 328 F. Supp.3d 931 (pending motion for class certification); *Smith* v. *Highland Hosp. of Rochester*, No. 17-CV-6781-CJS (W.D.N.Y. filed Oct 2, 2018) (appealed to 2d Circuit on Nov. 6, 2018); *Prescott*, 265 F.Supp.3d 1090 (protective order granted on Nov. 6, 2018); *Edmo v. Ida. Dep't of Corr.*, No. 1:17-cv-00151, 2018 WL 2745898 (D. Id. *filed* Oct. 9, 2018) (motion to stay pending Feb. 13, 2019); *Enstad v. Peacehealth*, No. 2:17-cv-01496-RSM (W.D. Wash. *filed* Oct. 5, 2017) (granted stay of litigation on Sept. 24, 2018); *Robinson v. Dignity Health*, No. 16-CV-3035 YGR, (N.D. Cal. *filed* Dec. 6, 2016) (on remand from U.S. Supreme Court).

[398] Nathaniel M. Glasser & Cassandra Labbees, *Group Health Plans Cannot Categorically Exclude Coverage for Gender Dysphoria, Say Two More Federal Courts*, HEALTH EMPLOYMENT AND LABOR LAW BLOG (Oct. 4, 2018), https://www.healthemploymentandlabor.com/2018/10/04/group-health-plans-cannot-categorically-exclude-coverage-for-gender-dysphoria-say-two-more-federal-courts.

PART 5: CONCLUSION

As explained above, the Proposed Rule distorts the text of Section 1557 and applicable case law; would create confusion for patients, state and local governments, and covered entities and inconsistencies with other federal programs and initiative; and would generate tremendous harms and costs to patients and society that overwhelm any benefits.

The Department has failed to provide a reasoned analysis supporting these regulatory rescissions, in some areas providing no analysis at all and depriving the public of an adequate opportunity to comment.

The Proposed Rule should not be finalized. Instead, the Department should maintain and fully enforce the 2016 Rule and associated guidance.

EXHIBIT 12

Comments by The California Endowment

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August 12, 2019

Roger Severino, Director
Office for Civil Rights
U.S. Department of Health and Human Services
200 Independence Avenue SW Room 509F
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RIN 0945-AA11: Nondiscrimination in Health and Health Education Programs and Activities, Proposed Rule

Mr. Severino:

The California Endowment strongly opposes the above-referenced proposed rule[1] that arbitrarily and unjustifiably weakens Section 1557 of the Patient Protection and Affordable Care Act (ACA), contrary to the ACA's underlying legislative purpose to expand access to affordable, quality, health insurance coverage for all Americans, especially the most historically excluded and medically underserved.

Mission of the Office of Civil Rights and Statutory Intent of ACA Section 1557

The mission of U.S. Department of Health and Human Services (HHS) Office of Civil Rights (OCR) is to protect of the civil rights of all Americans, not issue administrative rules that limit its own authority, and narrows the scope of protections against discrimination for entire classes of Americans. We are deeply disappointed that OCR has proposed this rule repealing and otherwise weakening significant sections of its own prior final regulation - which went through detailed administrative development and extensive public comment - and that implemented the ACA's statutory intent to ensure that all Americans are protected against unlawful discrimination in health care insurance and all of HHS's funded programs and services.

We are particularly disturbed that, throughout this proposed rule, OCR repeatedly references the unsubstantiated and self-proffered burdens on covered entities such as large national and multi-state health insurance plans and pharmacy benefit management companies, but barely mentions the real harms that past and ongoing discrimination by health insurance plans and other federally-funded health care providers and systems experienced by tax-paying women, individuals who are limited English proficient, and sexual and gender minorities, especially transgender individuals. Indeed, OCR acknowledges that its proposed rule will

[1] 84 Fed. Reg. 27846-27895, June 14, 2019.

primarily benefit 180 health insurance plans, 84 Fed. Reg. at 27877.[2] In contrast, OCR states that:

> Continued enforcement of Section 1557 includes *vindication of legal rights, the benefits of which are difficult to quantify*…OCR will continue to vigorously enforce civil rights in order to help guarantee more access to health care and concomitant improved health outcomes – but *those benefits are difficult to estimate* given that many of the prohibitions encompassed by the proposed rule, as with the Final Rule, have been in place at the Federal level for many years or have been otherwise required by State or local law. 84 Fed. Reg. at 27886 (emphasis added).

It is unconscionable that a taxpayer-funded federal agency charged with enforcing civil rights laws is unable to describe the real harms experienced by victims of discrimination when OCR itself receives countless discrimination complaints every day, every month, and every year. If there is any issue that OCR should have expertise and experience about, it is the devastating consequences of discrimination on individuals and their families and communities, especially when it occurs in the provision of health care. The mission of the OCR - and the appropriate use of its rulemaking authority - should be to protect the civil rights of all Americans against discrimination, rather than protecting the self-interests of 180 health insurance plans, pharmacy benefit management companies, and other recipients of millions of dollars of federal funding.

About The California Endowment

The California Endowment (The Endowment) is a statewide health foundation, with a mission and charitable purpose to expand access to affordable, quality health care for underserved individuals and communities, and to promote fundamental improvements in the health status of all Californians. For over the past two decades, The Endowment has supported expanding access to health insurance coverage, nutrition, physical activity, housing, and other supports for healthy living and optimal health. For example, The Endowment has invested significantly in supporting the implementation of the ACA in California. Due to the collaborative efforts of community members and organizations, the California Department of Health Care Services, Covered California (California's ACA health insurance marketplace), and many other stakeholders, the rate of uninsured

[2] OCR reveals its motivations for the proposed rule: "The proposed rule would particularly reduce the economic burden imposed on health care providers and insurers required to provide taglines under the Final Rule…eliminating the taglines requirement wil alleviate burdens on patients and insurance beneficiaries that neither need nor want to receive repeated tagline mailings." 84 Fed. Reg. at 27887. On the other hand, OCR neglects to mention, let alone balance, the real and ongoing harms from discrimination experienced by limited English proficient Americans.

persons in California has been reduced from 17 percent in 2013 to 7 percent in 2017.[3]

Impact of Proposed Regulation on Californians
Since California is the state with the highest overall population, and one of the most demographically diverse populations in the nation, the harmful impacts of the proposed rule will be disproportionately experienced by Californians. Our comments will highlight the adverse impacts of the proposed rule on four classes of Californians that have historically experienced discrimination by health insurance plans and providers: women, individuals who are limited English proficient, individuals with disabilities, and transgender people:

- Using the latest available American Community Survey (ACS) data from 2017, there are over 8.7 million women in the child-bearing ages of 16 to 49[4] residing in California (ACS, 1-year estimates, Table B01001).[5]
- 44% of the 37 million Californians ages 5 years and older - nearly 16.5 million individuals - speak a language other than English at home, and that 40% of those individuals - over 6.6 million Californians - do not speak English "very well" and are limited English proficient (LEP) individuals (ACS, 1-year estimates, Table S1601).
- The 2017 ACS also reports that 10.6% of the 39 million Californians (total non-institutionalized population) - or over 4.1 million individuals, are individuals with disabilities; including over 295,000 children under age 18, and over 1.8 million seniors ages 65 and older (ACS, 1-year estimates, Table DP02).
- The Williams Institute at the University of California Los Angeles estimates that there are 218,400 transgender adults (ages 18 and older)[6] and another 22,200 transgender youth (ages 13-17) residing in California.[7]

Purpose of ACA Section 1557
ACA Section 1557 prohibits discrimination on the basis of race, color, national origin, sex, age, and disability, referencing and codifying prohibitions against discrimination from Title VII of the 1964 Civil Rights, Title IX of the Education Amendments of 1972, Section 504 of the 1973 Rehabilitation Act, and the 1972 Age Discrimination Act. In enacting those successive laws, Congress clearly

[3] Berchick ER, Hood E, Barnett JC. Health Insurance Coverage in the U.S., U.S. Census Bureau, 2018, https://www.census.gov/content/dam/Census/library/publications/2018/demo/p60-264.pdf
[4] CDC Definition of Childbearing Age, https://www.cdc.gov/biomonitoring/glossary.html
[5] American Community Survey, https://factfinder.census.gov/faces/nav/jsf/pages/searchresults.xhtml?refresh=t
[6] Flores AR, Herman JL Gates GJ, Brown TNT. How Many Adults Identify as Transgender in the United States, Williams Institute, 2016, https://williamsinstitute.law.ucla.edu/wp-content/uploads/How-Many-Adults-Identify-as-Transgender-in-the-United-States.pdf
[7] Herman JL, Flores AR, Brown TNT, Wilson BDM, Conron KJ. Age of Individuals Who Identify as Transgender in the United States, Williams Institute, 2017, https://williamsinstitute.law.ucla.edu/wp-content/uploads/TransAgeReport.pdf

intended these protections against discrimination to be expanded to ever larger numbers of Americans, i.e. based on disability through the enactment of the Rehabilitation Act, and based on age through the enactment of the Age Discrimination Act. By referencing and codifying these prior laws, the clear intent of ACA Section 1557 was to continue to expand these protections against discrimination to more, not fewer, Americans, e.g., on the basis of sex.

Accordingly, we strongly oppose the proposed changes in 45 Code of Federal Regulations (CFR) Section 92.3 that would narrow the scope of application of ACA Section 1557, 84 Fed. Reg. at 27862-27863. Section 1557 applies to 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 Title I of the ACA. Thus, Section 1557 applies to *all* health programs or activities administered by the Department (as well as other federal Departments) *in addition to* those established under Title I. Further, similar to Title VI, Section 1557 applies to *all* parts of the covered entity, not only the portion of the covered entity receiving federal financial assistance.

We also strongly oppose the proposed amendment to 45 CFR Section 92.3(c) that would create an unprecedented and irrational exemption for health insurance plans from ACA Section 1557's prohibitions against discrimination. Given that the majority of Americans access health care through insurance plans, the provision of health insurance is a "health program or activity" and thus Section 1557 applies to it. The proposed changes run counter to the statutory text and intent of Section 1557 to broaden, not limit, protections against discrimination as health insurance coverage is expanded to more Americans under the ACA.

We also oppose the proposed changes that would limit private rights of action and give OCR the sole authority to enforce ACA Section 1557, proposed 45 CFR Section 92.5. Given this proposed rule severely limiting OCR's civil rights mandate, preserving a private right of action is even more urgent. Moreover, the numerous lawsuits regarding the protections against discrimination based on gender identity have all been brought as private rights of action by victims of such discrimination. OCR is being disingenuous by proposing to restrict the rights of victims of discrimination to be able to pursue legal remedies under ACA Section 1557.

Finally, we oppose the proposed repeal of requirements for a designated compliance coordinator at each covered entity with 15 or more employees, who would be responsible for responding to grievances and complaints related to ACA Section 1557, and a written grievance procedure, 84 Fed. Reg. at 27883. Assigning a designated staff person to this task and requiring a written grievance procedure are not burdensome on covered entities, would ensure that covered entity's familiarity with its obligations not to discriminate under ACA Section 1557, and is highly likely to decrease the number of complaints made to OCR, when grievances and complaints are resolved through internal procedures at the covered entity.

Importance of Prohibiting Discrimination Against American Women

Prior to the enactment of the ACA, it was lawful to deny women health insurance based solely on their sex, for being of child-bearing age, being pregnant, having a prior pregnancy, being survivors of domestic violence, or being treated after a sexual assault. It also was lawful to charge women more for health insurance than men, and to impose different annual or lifetime limits on how much coverage health insurers would provide based on sex. For example, a pre-ACA survey conducted in 2008 reported that health insurers charged up to 48% higher premiums for a 40-year old woman than a 40-year old man.[8] Health insurers also could outright deny any pregnancy-related or maternity-related coverage. The ACA explicitly and intentionally ended these sex-based exclusions, denials, and differential treatment of women. Unfortunately, even with the ACA, women still face exclusions and differential treatment from health insurers and often have to challenge these unlawful practices to ensure equal access.[9]

Under the unjustified pretext of protecting religious freedom, the proposed rule would severely undermine the clear statutory intent of ACA Section 1557 by carving out an open-ended exemption in 45 CFR Section 92.6 for any federally-funded health insurer or provider to once again discriminate against women on the basis of sex, including a prior termination of pregnancy, 84 Fed. Reg. at 27864. We urge the restoration of the clear definitions and examples in the 2016 final rule of the types of sex-based discrimination prohibited by Section 1557, including a prior termination of pregnancy or refusal to provide reproductive health services including birth control, and that OCR continue to interpret and enforce the statute accordingly.

Importance of Prohibiting Discrimination Against Transgender Americans
Transgender Americans continue to experience persistent health disparities, including exclusion and stigmatization by health insurance plans and health care providers.[10] More alarmingly, transgender Americans are one of the few populations that experience outright denials of care, and even physical harm, from health care providers.[11] For example, the National Center for Transgender Equality reported these results from its 2015 U.S. Transgender Survey:

[8] National Women's Law Center, Nowhere to Turn: How the Individual Health Insurance Market Fails Women, 2008, https://nwlc-ciw49tixgw5lbab.stackpathdns.com/wp-content/uploads/2015/08/NWLCReport-NowhereToTurn-81309w.pdf
[9] Palankar D, Davenport K. Women's Health Coverage Since the ACA: Improvements for Most, But Insurer Exclusions Put Many At Risk, The Commonwealth Fund, 2016, https://www.commonwealthfund.org/publications/issue-briefs/2016/aug/womens-health-coverage-aca-improvements-most-insurer-exclusions
[10] Institute of Medicine, The Health of Lesbian, Gay, Bisexual, and Transgender People: Building a Foundation for Better Understanding, 2011, http://www.nationalacademies.org/hmd/Reports/2011/The-Health-of-Lesbian-Gay-Bisexual-and-Transgender-People.aspx
[11] Lambda Legal, When Health Care Isn't Caring, 2010, http://www.lambdalegal.org/publications/when-health-care-isnt-caring; National Gay and Lesbian Task Force and National Center for Transgender Equality, Injustice at Every Turn: A Report of the National Transgender Discrimination Survey, 2011, http://www.thetaskforce.org/reports_and_research/ntds

- One in four (25%) respondents experienced a problem in the past year with their insurance related to being transgender, such as being denied coverage for care related to gender transition or being denied coverage for routine care because they were transgender.
- More than half (55%) of those who sought coverage for transition-related surgery in the past year were denied, and 25% of those who sought coverage for hormones in the past year were denied.
- One-third (33%) of those who saw a health care provider in the past year reported having at least one negative experience related to being transgender, with higher rates for people of color and people with disabilities. This included being refused treatment, verbally harassed, or physically or sexually assaulted, or having to teach the provider about transgender people in order to get appropriate care.[12]

More recently, the Center for American Progress reported that in 2017, transgender Americans continued to experience denials of access to health care based on gender identity:

- 29 percent said a doctor or other health care provider refused to see them because of their actual or perceived gender identity
- 29 percent said that they experienced unwanted physical contact from a doctor or other health care provider (such as fondling, sexual assault, or rape)
- 21 percent said a doctor or other health care provider used harsh or abusive language when treating them
- 23 percent said a doctor or other health care provider intentionally misgendered them or used the wrong name
- 12 percent said a doctor or other health care provider refused to give them health care related to gender transition.[13]

HHS continues to acknowledge the ongoing widespread discrimination against transgender Americans and the need for protections against such discrimination. On the current healthcare.gov website, HHS states:

> Many health plans are still using exclusions such as "services related to sex change" or "sex reassignment surgery" to deny coverage to transgender people for certain health care services…. Plans might use different language to describe these kinds of exclusions. Look for language like "All procedures related to being transgender are not covered." Other terms to look for include "gender change,"

[12] National Center for Transgender Equality, U.S. Transgender Survey, 2015, http://www.ustranssurvey.org/reports#USTS

[13] Mirza SA, Rooney C. Discrimination Prevents LGBTQ People from Accessing Health Care, Center for American Progress, January 18, 2018, https://www.americanprogress.org/issues/lgbt/news/2018/01/18/445130/discrimination-prevents-lgbtq-people-accessing-health-care/

> "transsexualism," "gender identity disorder," and "gender identity dysphoria."…These transgender health insurance exclusions may be unlawful sex discrimination. The health care law prohibits discrimination on the basis of sex, among other bases, in certain health programs and activities.[14]

OCR even admits in the proposed rule that the 2016 final regulation would have resulted in an increase in discrimination complaints brought by transgender Americans, 84 Fed. Reg. at 27883. It is the mission of OCR of protect Americans against discrimination, not issue administrative interpretations that limit such protections.

Despite significant legislative and policy advances for the LGBTQ communities here in California, many LGBTQ Californians still face discrimination, bullying, stigma, and barriers to accessing services and otherwise fully participating in all aspects of life.[15] The California Endowment has proudly defended the rights of LGBTQ Californians and supported community-based organizations that are providing health and other services that address the needs of LGBTQ Californians.

There is a clear consensus among medical experts that gender-affirming care is medically necessary for transgender patients.[16] These medical experts note that ending discrimination based on gender identity in both health insurance coverage and in the provision of health care is essential to improving the health of transgender Americans.[17]

Yet despite the overwhelming evidence of significant and ongoing discrimination against transgender Americans, the proposed rule would arbitrarily and unjustifiably repeal any protections against such discrimination based on gender identity, using the pretext of one lawsuit that has been filed against OCR's administrative interpretation of ACA Section 1557. 84 Fed. Reg. at 27848. While OCR references other lawsuits regarding Section 1557 in its proposed rule, 84 Fed. Reg. at 27855, it fails to acknowledge that in those lawsuits, four federal

[14] https://www.healthcare.gov/transgender-health-care/
[15] Equality California Institute, Fair Share for Equality, 2017, https://www.eqca.org/wp-content/uploads/Fair-Share-for-Equality-Report-2017.pdf; Equality California Institute and Mental Health America of Northern California, First Do No Harm: California Reducing Disparities Project, 2013, http://www.eqcai.org/atf/cf/{8cca0e2f-faec-46c1-8727-cb02a7d1b3cc}/FIRST_DO_NO_HARM-LGBTQ_REPORT.PDF
[16] Eckstrand KL, Ng H, Potter J. Affirmative and responsible health care for people with nonconforming gender identities and expressions. AMA J. Ethics. 2016;18(11):1107-1118; Padula WV, Baker K. Coverage for gender-affirming care: making health insurance work for transgender Americans. LGBT Health. 2017;4(4):224-247
[17] Bakko M, Katari SK. Differential access to transgender inclusive insurance and healthcare in the United States: challlenges to health across life course. J. Aging Soc Policy. 2019 Jun 23, [Epub ahead of print]

courts have ruled that, regardless of any administrative interpretation by OCR, ACA Section 1557 does protect transgender Americans against discrimination.[18]

OCR references related pending litigation whether Title VII of the 1964 Civil Rights prohibits employment discrimination based on gender identity and sexual orientation. However, rather than maintaining a consistent position on these issues, OCR actually adds to the confusion by arbitrarily reversing its prior administrative interpretation and proposing to repeal Section 1557's prohibitions against discrimination based on gender identity. Moreover, OCR takes the unjustifiable and irrational position that individual states should be free to prohibit such gender identity-based discrimination on a state-by-state basis, 84 Fed. Reg. at 27874 and 27886, which would result in a patchwork of inconsistent protections. The very purpose of ACA Section 1557 was to accompany the expansion of health insurance coverage and other health care delivery system and payment reforms throughout the nation with national and uniform prohibitions against discrimination.

We also oppose the proposed overbroad repeal of ten other prohibitions against discrimination based on gender identity and sexual orientation based in other HHS statutes and regulations, 84 Fed. Reg. at 27870-27871; these are not incidental or technical "conforming amendments". Any proposed repeal of these unrelated regulations should proceed through separate and independent rulemaking that allows for additional public comment. In summary, we strongly oppose the repeal of these essential, life-saving prohibitions against discrimination against transgender Americans in the definitions and other text in the 2016 final rule, and throughout other unrelated HHS regulations.

Importance of Prohibiting Discrimination Against Limited English Proficient Americans

The Institute of Medicine has documented the importance of ensuring language access for LEP Americans, finding that without language access, LEP patients:

- Have a decreased likelihood of having a usual source of care (Kirkman-Liff and Mondragon, 1991; Weinick and Krauss, 2000)
- Have an increased probability of receiving unnecessary diagnostic tests (Hampers,
1999)
- Experience more serious adverse events (Divi, 2007)
- Experience more medication complications (Gandhi, 2000)

[18] Keith K. Section 1557 Lawsuit Over Transgender and Abortion Protections Will Proceed, Health Affairs Blog, December 19, 2018, https://www.healthaffairs.org/do/10.1377/hblog20181219.113331/full/; Keith K. HHS Proposes to Strip Gender Identity, Language Access Protections from ACA Anti-Discrimination Rule, Health Affairs Blog, May 25, 2019, https://www.healthaffairs.org/do/10.1377/hblog20190525.831858/full/

- Experience delays in pre-hospital care (Grow, 2008)
- Experience lower health care quality (Pippins, 2007, Woloshin, 1995)
- Receive less information about end-of-life care (Thornton, 2009)
- Feel more dissatisfied with health care services (Carrasquillo, 1999; Weech-Maldanado, 2003; Baker, 1998; Hampers, 1999)[19]

The California Endowment has been a leading funder supporting the expansion of language access in health care for LEP individuals. For example, our foundation has supported the development of standards of ethics and standards of practice for health care interpreters,[20] which led to the development of national certification programs for health care interpreters.[21] We also have supported the training of health care interpreters, and increased awareness among health care providers of the importance of language access for limited English proficient patients.[22] Despite these efforts, the availability of qualified, trained health care interpreters is still uneven throughout California.[23]

Accordingly, we strongly oppose the repeal of the requirement that covered entities provide a notice of nondiscrimination that informs the public of their legal rights. The notice requirement is consistent with the long history of civil rights regulations requiring the posting of notice of rights, including Title VII of the 1964 Civil Rights, Title IX of the Education Amendments of 1972, Section 504 of the 1973 Rehabilitation Act, and the 1972 Age Discrimination Act, which all require that recipients of federal financial assistance notify recipients that they do not discriminate. Without requiring such notices, members of the public will have limited means of knowing that language services are available, how to request

[19] Institute of Medicine, Race, Ethnicity, and Language Data: Standardization for Health Care Quality Improvement (2009), http://www.nationalacademies.org/hmd/Reports/2009/RaceEthnicityData.aspx
[20] National Council on Interpreting in Health Care, A National Code of Ethics for Healthcare Interpreters, 2004, https://www.ncihc.org/assets/documents/publications/NCIHC%20National%20Code%20of%20Ethics.pdf; National Council on Interpreting in Health Care, National Standards of Practice for Interpreters in Health Care, 2005, https://www.ncihc.org/assets/documents/publications/NCIHC%20National%20Standards%20of%20Practice.pdf
[21] Certification Commission for Healthcare Interpreters, http://cchicertification.org/certifications/; National Board of Certification of Medical Interpreters, https://www.certifiedmedicalinterpreters.org/overview
[22] Dignity Health, Catholic Healthcare West expands language access initiative, January 30, 2008, https://www.dignityhealth.org/about-us/press-center/press-releases/catholic-healthcare-west-expands-language-access-initiative; Bau I. Creating a culturally competent health system: cultural competency essential to reform June 4, 2012, https://californiahealthline.org/news/creating-a-culturally-competent-health-care-system/; California Pan-Ethnic Health Network, Building Quality & Equitable Health Systems, 2010, https://cpehn.org/sites/default/files/resource_files/buildingqualityandequitablehealthcaresystems10-10.pdf
[23] Gonzalez JM. Medical interpreters in short supply as coverage grows, San Francisco Chronicle, April 26, 2015, https://www.sfchronicle.com/health/article/Medical-interpreters-in-short-supply-as-health-6225291.php?psid=gj197

them, what to do if they face discrimination, that they have the right to file a complaint, and how to file such a complaint.

We also oppose the repeal of the requirement for covered entities to provide in-language taglines informing recipients of the availability of language assistance on significant documents. The inclusion of taglines is well-supported by long-standing federal and state regulations, guidance and practice.[24] OCR acknowledges that such taglines will continue to be required by other provisions of the ACA, as well as other statutory requirements for recipients of federal financial assistance. 84 Fed. Reg. at 27887. The use of taglines is a cost-effective approach to ensuring that covered entities are not overly burdened, while maintaining access for LEP individuals.

We also oppose removing the references to and requirements for language access plans because they have long been recognized as a way for covered entities to ensure they are compliant with the language access requirement of Title VI of the 1964 Civil Rights Act. OCR itself has required language access plans from covered entities as a key component of Title VI enforcement actions involving LEP individuals. Moreover, Executive Order 13166 required HHS to create and implement its own language access plan for its federally conducted programs and activities. Based on that Executive Order, HHS issued guidance for covered entities, which included the importance of adopting and implementing language access plans. The proposed rule's repeal of requirements for language access plans would eliminate an essential tool for OCR's enforcement of prohibitions against discrimination against LEP Americans.

Importance of Prohibiting Discrimination Against Americans with Disabilities

In 2005, the U.S. Surgeon General issued a national call to action to improve the health and well-being of Americans with disabilities.[25] Among the improvements needed are eliminating physical and other access to health care.[26] Unfortunately, Americans with disabilities continue to face barriers to full access to the health care they need, beginning with continued barriers to physical access and mobility,[27] and including barriers to effective communication.[28] Lack of health

[24] See Title VI Coordination Regulations, 29 C.F.R. § 42.405(d)(1); Marketplace and QHP issuer requirements, 45 C.F.R. § 155.205(c)(2)(iii); Medicaid Managed care plans, 42 C.F.R. § 438.10(d)(3); DOL WIOA Nondiscrimination requirements, 29 C.F.R. § 38.9(g)(3); USDA SNAP Bilingual Requirements, 7 C.F.R. § 272.4(b); and the 2003 HHS LEP Guidance.

[25] U.S. Surgeon General, A Call to Action To Improve the Health and Wellness of Persons with Disabilities, 2005, http://www.ncbi.nlm.nih.gov/books/NBK44667/pdf/TOC.pdf

[26] Institute of Medicine, Future of Disability in America, 2007, http://www.nationalacademies.org/hmd/reports/2007/the-future-of-disability-in-america.aspx

[27] Wong JL, Alschuler KN, Mroz TM, Hreha KP, Molton Ir. Identification of targets for improving access to care in persons with long term physical disabilities. Disabil Health J. 2019;12(3):363-374

[28] Sharby N, Martiire K, Iversen MD. Decreasing health disparities for people with disabilities through improved communication strategies and awareness. Int J Environ Res

care provider knowledge about the legal rights, including prohibitions against discrimination, for their patients with disabilities, contributes to these barriers.[29] Uninsured persons with disability experience greater barriers to accessing health care than do non-disabled uninsured persons.[30] The legislative purpose of the ACA, including the prohibitions against discrimination under Section 1557, was to decrease these barriers for all Americans, including Americans with disabilities.

Accordingly, we oppose the proposed "undue financial and administrative burden" exemption in 45 CFR Section 92.104 to the requirement that covered entities ensure that federally-funded programs and activities are accessible to Americans with disabilities. We also oppose the proposed exemption of covered entities with fewer than 15 employees from being required to meaningfully communicate with Americans with disabilities, i.e., through auxiliary aids and services, 84 Fed. Reg. 27867. If a federally funded covered entity is providing services to an American with a disability, Section 1557 unequivocally requires that service to be accessible; it is irrelevant how large or small that covered entity is, or how many employees it has.

Finally, we also oppose the elimination of the prohibition against discriminatory health insurance marketing and benefit design in proposed 45 CFR Section 147.104, which would allow health insurers to exclude benefits, or design their prescription drug formularies in a way that would limit access to medically necessary care for Americans living with disabilities and other chronic conditions such as HIV, diabetes, and cardiovascular disease.

For all the above reasons, we strongly oppose this proposed rule. We urge OCR to immediately withdraw the proposed rule, and instead, re-commit itself to its mission to protect all Americans from discrimination in the provision health care, health insurance, and all other HHS programs and services, by continuing to enforce the 2016 final rule implementing Section 1557 of the ACA.

Sincerely,

Robert K. Ross, MD
President and CEO

Public Health. 2015;12(3):3301-3316; Iezzoni LI. Make no assumptions: communication between persons with disabilities and clinicians. Assist Technol. 2006;18(2):212-219
[29] Agaronnik ND, Pendo E, Campbell EG, Ressalam J, Iezzoni LI. Knowledge of practicing physicians about their legal obligations when caring for persons with disability. Health Aff. 2019;38(4):545-553; Agaronnik ND, Campbell EG, Ressalam J, Iezzoni LI. Communicating with patients with disability: perspectives of practicing physicians. J Gen Intern Med. 2019;34(7):1139-1145
[30] Iezzoni LI, frakt AB, Pizer SD. Uninsured persons with disability confront substantial barriers to health care services. Disabil Health J. 2011;4(4):238-244

EXHIBIT 13

Comments by the American Psychological Association

July 12, 2017

Seema Verma, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
CMS-9928-NC
200 Independence Avenue, SW
Washington, DC 20201

Dear Administrator Verma:

The American Psychological Association (APA) appreciates this opportunity to respond to a request for information published in the *Federal Register* on June 12, 2017 (Docket No. CMS-9928-NC), "Reducing Regulatory Burdens Imposed by the Patient Protection and Affordable Care Act & Improving Healthcare Choices to Empower Patients."

The American Psychological Association, in Washington, D.C., is the largest scientific and professional organization representing psychology in the United States. APA's membership includes nearly 115,700 researchers, educators, clinicians, consultants and students. Through its divisions in 54 subfields of psychology and affiliations with 60 state, territorial and Canadian provincial associations, APA works to advance the creation, communication and application of psychological knowledge to benefit society and improve people's lives. The final rule implementing Section 1557 of the Affordable Care Act (ACA) empowers patients, promotes consumer choice, and in some cases, enhances affordability - this response focuses on those areas of the request for information. We have previously submitted comments supporting the proposed regulation implementing Section 1557, and we strongly support the final rule, which prohibits discrimination on the basis of race, color, national origin, sex, age, or disability in certain health programs or activities. At this point, we would like to comment specifically on the importance of provisions protecting non-discrimination based on sex - specifically gender identity and termination of pregnancy - as they relate to empowering patients, promoting consumer choice, and enhancing affordability.

In our 2008 *Policy on Transgender, Gender Identity & Gender Expression Non-Discrimination,* APA recognized the efficacy, benefit, and medical necessity of transition related treatments – which may include psychotherapy, hormone therapy, and a variety of surgical treatments - for appropriately evaluated individuals.[i] The Affordable Care Act and its implementing regulations - including those implementing Section 1557 - have been essential in empowering transgender patients and promoting consumer choice. While the uninsured rate among transgender people remains higher than that in the general population,[ii] research indicates that the uninsured rate among transgender people has dropped dramatically.[iii] Additionally, after publication of the rule implementing Section 1557, one study showed

that over 95% of insurers removed exclusions for gender dysphoria treatments from their 2017 plans, ensuring that a greater number of transgender consumers can have access to treatment.[iv]

Despite these improvements, many transgender people experience other forms of discrimination in the health system. For example, the 2015 U.S. Transgender Survey found that in the year prior to taking the survey, 33% of respondents who saw a health care provider faced one or more form of mistreatment or discrimination due to being transgender. This discrimination likely contributes to health disparities. Respondents were approximately five times more likely than the general population to have been diagnosed with HIV, eight times more likely to have experienced serious psychological distress in the month prior to taking the survey, and nearly twelve times more likely to have attempted suicide.[v]

Moreover, repealing the nondiscrimination protections for transgender people would not make health plans more affordable. Contrarily, studies have shown that eliminating transgender exclusions has no significant effect on medical expenditures or premiums[vi] and that covering medically necessary services for the U.S. transgender population is affordable and cost effective.[vii]

The rule implementing Section 1557 also prohibits covered entities from discrimination based on pregnancy, false pregnancy, termination of pregnancy or recovery therefrom, childbirth or related medical conditions. However, the regulation does not compel organizations that would otherwise be exempt from performing abortion or abortion-related services to provide or pay for those services, in accordance with provider conscience laws[viii], the Religious Freedom Restoration Act[ix], or provisions in the ACA related to abortion services and preventive health services.[x]

Current HHS regulations pertaining to Section 1557 of the ACA protect women who have had an abortion at any point in their lives from being denied medical treatment by a covered entity based on that procedure. APA supports pregnancy termination as the civil right of the pregnant woman, and concludes that the preponderance of scientific data also supports the conclusion that freedom of choice and a woman's control over her critical life decisions promotes psychological health. [xi] These choices should not affect any woman's future access to vital health services. Otherwise women who have terminated a pregnancy would experience reduced options in insurers and providers – potentially leading to tremendous financial burdens.

Repealing consumer protections, such as the rule implementing 1557 of the ACA, would undermine affordability for consumers when their needs are excluded under discriminatory benefit designs, or if they face other discriminatory treatment. Thus, APA supports maintaining the implementation of Section 1557 in its current form. The protections afforded under this rule respond directly to this request for information: They empower patients, promote consumer choice, and enhance affordability. Please contact Gabriel Twose, Ph.D. (202-336-5931; gtwose@apa.org) in our Public Interest Government Relations Office if we can provide any further information.

Sincerely,

Clinton W. Anderson

Clinton W. Anderson, Ph.D.
Interim Executive Director
Public Interest Directorate

[i] American Psychological Association. (2008) *Policy on Transgender, Gender Identity & Gender Expression Non-Discrimination.* Retrieved from http://www.apa.org/about/policy/transgender.aspx

[ii] Mayer, I. H., Brown, T. N. T., Herman, J. L., Reisner, S. L., & Bockting, W. O. (2017). Demographic characteristics and health status of transgender adults in select U.S. regions: Behavioral risk factor surveillance system, 2014. *American Journal of Public Health 107*(4), 582-589.

[iii] Baker, K., Durso, L. E., & Cray, A. (2014) *Moving the Needle: The Impact of the Affordable Care Act on LGBT Communities*. Retrieved from., https://cdn.americanprogress.org/wp-content/uploads/2014/11/LGBTandACA-report.pdf

[iv] Out2Enroll. (2017). *Summary of Findings: 2017 Marketplace Plan Compliance with Section 1557*. Retrieved from https://out2enroll.org/out2enroll/wp-content/uploads/2015/10/Report-on-Trans-Exclusions-in-2017-Marketplace-Plans.pdf.

[v] James, S. E., Herman, J. L., Rankin, S., Keisling, M., Mottet, L., & Anafi, M. (2016). *The Report of the U.S. Transgender Survey*. Retrieved from www.ustranssurvey.org/report.

[vi] California Department of Insurance. (2012). *Economic Impact Assessment: Gender Nondiscrimination in Health Insurance.* Retrieved from http://transgenderlawcenter.org/wp-content/uploads/2013/04/Economic-Impact-Assessment-Gender-Nondiscrimination-In-Health-Insurance.pdf.

[vii] Padula, W. V., Heru, S., & Campbell, J. D. (2016). *Journal of General Internal Medicine 31*(4), 394-401.

[viii] See, e.g. , 42 U.S.C. 300a-7; 42 U.S.C. 238n; Consolidated and Further Continuing Appropriations Act 2015, Public Law 114-53, Div. G, § 507(d) (Dec. 16, 2015).

[ix] 42 U.S.C. 2000bb-1.

[x] See, e.g. , 42 U.S.C. 18023, 45 CFR 147.131.

[xi] American Psychological Association (1969, 1980, 1989, 1992). *Resolutions on Abortion.* Retrieved from http://www.apa.org/about/policy/abortion.aspx.

EXHIBIT 14

Letter of James L. Madara, MD, Executive Vice President and CEO of the American Medical Association

JAMES L. MADARA, MD
EXECUTIVE VICE PRESIDENT, CEO

ama-assn.org
t (312) 464-5000

September 1, 2017

Roger Severino
Director
Office of Civil Rights
U.S. Department of Health & Human Services
220 Independence Avenue, SW
Washington, DC 20201

Dear Director Severino:

It is our understanding that the administration may be reevaluating current policy addressing discrimination in health care programs on the basis of sex as outlined in the final rule implementing Section 1557 of the Affordable Care Act ("Section 1557"). We strongly urge your office to reconsider. Since 2012, the Office of Civil Rights has interpreted Section 1557 of the Affordable Care Act's sex discrimination prohibition to extend to claims of discrimination based on gender identity or sex stereotypes and accepted such complaints for investigation. Numerous federal agencies, including the U.S. Department of Justice, U.S. Department of Labor, U.S. Department of Education, and the U.S. Department of Housing and Urban Development, have previously interpreted sex discrimination to include discrimination on the basis of gender identity. Further, the rule's inclusion of sex stereotyping reflects the Supreme Court's holding in *Price Waterhouse v. Hopkins* (1989), which stated that discrimination based on stereotypical notions of appropriate behavior, appearance or mannerisms for each gender constitutes sex discrimination. Lower courts, including in the context of Section 1557, have recognized that sex discrimination includes discrimination based on gender identity.[1]

Based on longstanding policy, the American Medical Association (AMA) opposes any discrimination based on an individual's sex, sexual orientation, gender identity, race, religion, disability, ethnic origin, national origin, or age. AMA policy also supports public and private health insurance coverage for treatment of gender dysphoria as recommended by the patient's physician. Section 1557's protections assist some of the populations that have been most vulnerable to discrimination, such as lesbian, gay, bisexual, and transgender individuals and those suffering from mental illness, including substance use disorders, and help provide those

[1] *See, e.g., Rumble v. Fairview Heath Servs.*, Civ. No. 14–cv–2037, 2015 WL 1197415 (D. Minn. Mar. 16, 2015) (Section 1557) (order denying motion to dismiss); *Barnes v. City of Cincinnati*, 401 F.3d 729, 737 (6th Cir.), cert. denied, 546 U.S. 1003 (2005)(Title VII); *Smith v. City of Salem, Ohio*, 378 F.3d 566, 575 (6th Cir. 2004) (Title VII); *Schroer v. Billington*, 577 F.Supp.2d 293, 304 (D.D.C. 2008) (Title VII).

populations equal access to health care and health coverage. We also note that Section 1557 does not force physicians to violate their medical judgment. Rather, covered entities, including insurers, must "apply the same neutral, nondiscriminatory criteria [used] for other conditions when the coverage determination is related to gender transition."[2]

In sum, the AMA stands behind Section 1557's gender identity protections and opposes any modifications to the rule that would jeopardize the health and wellbeing of vulnerable populations. We urge the U.S. Department of Health & Human Services (HHS) to seek input from stakeholders about whether informal guidance may help to clarify misunderstandings of the existing rule. If HHS determines that rule changes are necessary, it should undertake the same process used previously to develop the rule, including a formal Request for Information and public comment period.

Thank you for your consideration. We would be happy to meet with you in person to discuss this matter. If you have any questions or concerns, please feel free to contact Laura Hoffman, Assistant Director, Federal Affairs, at laura.hoffman@ama-assn.org or (202)789-7414.

Sincerely,

James L. Madara, MD

[2] 81 Fed. Reg. 31435 (May 18, 2016).

EXHIBIT 15

Comments by the New York Legal Assistance Group

August 13, 2019

Via Electronic Submission

Office of the Secretary
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Re: Docket No.: HHS-OCR-2019-0007; RIN:0945-AA11

Comments in Opposition to Proposed Changes to "Nondiscrimination in Health and Health Education Programs or Activities" Rule

The New York Legal Assistance Group (NYLAG) submits these comments to express its strong objection to the proposed rule regarding 'Nondiscrimination in Health and Health Education Programs or Activities' (Proposed Rule) published by the Department of Health and Human Services (HHS) on June 14, 2019.[1] The Proposed Rule substantially alters the 'Nondiscrimination in Health Programs and Activities' rule (Final Rule) finalized on July 18, 2016.[2] The proposed regulation is unlawful, arbitrary and capricious, costly, and a disaster for transgender patients seeking healthcare.

I. Introduction

A. About NYLAG

NYLAG is a not-for-profit legal services organization located in New York City. NYLAG uses the power of the law to help New Yorkers in need combat social and economic injustice. We address emerging and urgent legal needs with comprehensive, free civil legal services, impact litigation, policy advocacy, and community education. NYLAG serves immigrants, veterans, seniors, the homebound, families facing foreclosure, renters facing eviction, low-income consumers, those in need of government assistance, children in need of special education, domestic violence victims, people with disabilities, patients with chronic illness or disease, low-wage workers, low-income members of the LGBTQ community, Holocaust survivors, as well as others in need of free legal services.

NYLAG provides a variety of services to those seeking healthcare through providers. NYLAG's LGBTQ Law Project provides low-income LGBTQ+ communities with comprehensive legal services for civil issues including family law, name changes, immigration,

[1] *See* Notice of Proposed Rulemaking, Fed. Reg. 27846-27895; HHS Docket No. HHS-OCR-2019-0007; RIN 0945-AA11 (June 14, 2019).
[2] *See* Nondiscrimination in Health Programs and Activities, 81 FR 31375, July 18, 2016.

and civil rights protections. In addition, we run a legal clinic in conjunction with Mount Sinai's Center for Transgender Medicine and Surgery, one of the first medical programs exclusively dedicated to comprehensive care for transgender patients. This legal clinic provides a unique ability to address the needs of transgender patients. Through this work, NYLAG as a whole has represented hundreds of transgender, non-binary, and gender non-conforming clients (TGNC) over the past year. NYLAG works to ensure that low-income TGNC clients and their families, including children, the elderly, and those with disabilities, have access to the medical care that is critical to their survival. TGNC patients confronting illness are some of New York's most vulnerable populations and they struggle to maintain their livelihoods and access to medical care. Compounding the difficulties of access to care is systemic discrimination and a lack of knowledge and understanding within the broader medical community of transgender healthcare and the needs of transgender patients

LegalHealth, created as a division of NYLAG in 2001, is the nation's largest Medical-Legal Partnership, with clinics at 35 hospitals and community health organizations throughout New York City and Long Island, and partnerships with 5 Providing Performer Systems through New York State's DSRIP Program. LegalHealth complements health care with legal care by providing free civil legal assistance to patients in the healthcare setting, serving out-patients, in-patients, and the homebound. The majority of LegalHealth's clients are individuals with chronic and serious illnesses, including cancer, end-stage renal disease, high blood pressure, diabetes, HIV, asthma and heart disease. When social conditions pose a barrier to improved health, the LegalHealth team can use the law to ensure a patient's right to access care, stable housing, and income maximization and immigration remedies. These services are often the determining factor in whether patients will receive the life changing treatment they need. The overall health care system benefits as well: by helping our clients find stability in their lives, our legal services facilitate good health, prevent unnecessary hospital admission and readmission, and lead to a decrease in healthcare spending. Last year, LegalHealth's staff improved the lives of over 7,210 low-income New Yorkers with serious health needs.

B. Summary of NYLAG's Opposition to the Proposed Rule

NYLAG strongly objects to the proposed regulation in every aspect. In particular, NYLAG believes that the following substantive changes proposed in the rule will lead to particularly devastating consequences. Our clients at the New York Legal Assistance Group have experienced the types of discrimination in New York City hospitals that are prohibited under the Final Rule. One client presented in 2014 at an emergency room suffering from kidney stones requiring surgery. Although she identifies as female, staff at the hospital repeatedly misgendered her, identified her sex assigned and birth and by her birth name, claimed she provided false identification, called security and told her to leave. Another client went to a VA hospital after he was assaulted in his car in 2011. The physician did not perform the rape kit or a psychological evaluation. The doctor told the client and wrote in her discharge notes that she did not feel comfortable or qualified to treat him and did not want to continue working with him because he was transgender. She told the client who had just been sexually assaulted to go to a public hospital instead. The client left the hospital and returned the next day, but could not receive a rape kit because he had showered. He has since had several psychiatric hospitalizations as a result of his assault and subsequent experiences.

NYLAG opposes the proposed regulation for numerous reasons, as set forth in more detail below. First, the regulation is unlawful. It arbitrarily and capriciously makes substantial changes to the definitions and scope of several provisions required by the Section 1557 of the Affordable Care Act. It also impermissibly conflicts with the plain meaning of the statute it seeks to effectuate through this regulation. The proposed rule's removal of gender identity protections ignores the plain meaning of "on the basis of sex" discrimination. It strips the protection of rights of vulnerable populations including; transgender, intersex, and disabled patients, or anyone who does not fit a strict definition of white, Christian, heteronormativity.

Second, the interpretation promulgated by HHS relating to the definition of "on the basis of sex" discrimination is a radical departure from settled case law and precedent in the federal system, the common law history of the definition of sex, and the unified consensus of medical professionals and scientists.

Third, and relatedly, the regulation would *not* accomplish its intended purposes. Critically, the oxymoronic title of this proposed rule would serve to severely rollback existing civil rights protections with no proper justification other than inaccurate cost savings borne by those who require language access materials. The citation of pending litigation in *Franciscan Alliance v. Burwell* as the impetus to rollback protections is a preliminary conclusion wanting of a substantive decision. The preliminary injunction issued by Judge Reed O'Connor is not based on a reasoned interpretation of the law and rests on the bigoted assertions of the plaintiffs. The basis promulgated by HHS for repealing gender identity protections have been contradicted throughout the intervening years by several Federal District and Circuit Courts.

Fourth, the proposed regulation could prompt a public health crisis of disastrous proportions, among both TGNC patients and other communities. A rollback of access to care after years of expansion could lead to an increased suicide rate among TGNC patients as they lose their access to care. Public health could also be harmed as the loss of access to care could increase the infection rate of HIV.

Fifth, the proposed regulation would not meet its stated purpose of providing "much needed finality, predictability, administrability, consistency, relief of burdens, and clarity [.]"[3] This is especially true regarding the redefinition of covered entities such as "health program or activity". The result will be arbitrary, inconsistent, and unfair application that results from litigation over this pending rule. In addition, the vague nature of the proposed regulation will make it impossible for healthcare providers to reasonably conform their behavior to the rule, which is unfair and unlawful.

Sixth, the proposed regulation would *cost* more money, not save it. It will increase costs for health care and other public-health related costs, and will discourage or preclude TGNC patients from vital access to care. The resulting loss of access will increase overall costs borne by hospitals by increasing costs associated with care for acute medical crises resulting from preventable conditions. Lack of care will be costly in human lives as TGNC patients could be denied urgent lifesaving care and result in costly wrongful death litigation. Additionally, the cited removal of language access requirements will burden immigrants and non-English speakers

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[3] Proposed Rule, *supra at note* 1

by removing vital requirements to have medical information provided in the most common languages.

Seventh, at a basic human level, the proposed regulation is cruel. It would place countless patients—parents, providers, children, the elderly, those with disabilities—in impossible positions. We should seek to expand access to care as broadly as possible and provide protections to all marginalized communities rather than target them through unlawful regulations that strip them of civil rights protections.

II. A Brief History of Gender Identity in Society and the Common Law

Contrary to the assertions of the Department of Health and Human Services, the definition of sex has always included those who do not identify as the gender they were assigned at birth as well as intersex individuals. The recognition of transgender and intersex people is not a recent development. The history of the common law recognition of multiple sexes and gender expression is wide and varied.

English common law has always recognized that there were more than two sexes. Henry of Bratton, an English judge, was quoted as saying in the 13th century that "[m]ankind may also be classified in another way: male, female, or hermaphrodite."[4] While the term of hermaphrodite may be outdated, this shows from the earliest development of the common law, there has been recognition for those that do not neatly fit within the gender binary. Going even further in history shows a direct lineage to Roman, Greek, and Semitic thought on the matter.[5] What we know now as transgender individuals were "then described as hermaphrodites (or, androgynos) and persons 'of doubtful sex.' The Mishnahs, Translated Into English With Notes, Glossary and Indicies, Vol. 2. (1982), Tractate Bikkurim, Chapter 4 (Bikkurim dates back beyond 1500 B.C.E., the time period at which it was first reduced to written form)."[6]

From the earliest years of colonial America, courts and society have grappled with those who do not fit within the binary definition of sex nor the strict imposition of sex based on physical characteristics. For example, on April 8, 1629, a person named T. Hall appeared before the General Court of the colony of Virginia.[7] This peculiar and complicated case dealt with the determination of the sex of T. Hall who lived as a woman and a man throughout their life and went by both the name of Thomas and Thomasina at various times.[8] T was initially determined to be female by the court and was ordered to wear women's clothing; however, confusion ensued when those who had seen T's body attested to the court that T was a man. A subsequent inspection of T's body by other men resulted in a determination of T being a man. Ultimately,

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[4] Bracton*: De Legibus Et Consuetudinibus Anglae, Bracton, On the Laws and Customs of England* (attributed to Henry of Bratton, c. 1210-1268).

[5] Theodore F.T. Plucknett, *A Concise History of the Common Law*, 5th Ed., Little, Brown & Co. (1956) (ISBN: 0-316-71083-0): ("However remote the date at which we start, it will always be necessary to admit that much of the still remoter past that lies behind [the Common Law of England] will have to be considered as directly bearing upon the later history. … But behind the Roman system were others still more ancient—Greek, Semitic[.])"

[6] Causes of Action 2d 135

[7] Mary Beth Norton, *"Founding Mothers & Fathers—Gendered Power and the Forming of American Society,* p. 183-197. Alfred A. Knopf (1996).

[8] *Id.*

the court composed of the Virginia Governor and council, the highest judicial authority in the colony, accepted T's self-identification as both a man and a woman and that T may wear male clothes but for T to also wear other feminine clothing such as an apron and a coyfe on their head.[9]

In a later case dating to 1878, the Supreme Court of Illinois presided over a case where the validity of a marriage between a cis-man and an intersex person was in dispute.[10] While the underlying matter of the defendant's intersex condition was not factored in to the final decision, it shows additional evidence of courts grappling with the elusive definition of sex.

Outside of the common law, religions have also needed to grapple with those who did not conform to the prevailing understanding of sex. For example, various texts in the Mishna and Talmud recognize six distinct genders of varying physical characteristics: Zachar, Nekeivah, Androgynos, Tumtum, Ay'lonit, and Saris.[11] Shi'a Islam has a rich history of debate among Islamic scholars discussing "Mukhannathun," those born male with indeterminate gender, and their interactions with Mohammed in the Hadiths.[12] As a result, transgender individuals are acknowledged and legally recognized by the government of Iran.[13] In addition, Hijras are recognized as a third gender in Pakistan and they are distinct and relatively large community.[14]

All of this history is just a brief sample of the countless times, prior to the modern era, that society and the courts have had to come to terms with the complex nature of human biology and the determination of the definition of sex to include those who don't fit typical notions of male and female. For HHS to state that the Final Rule's definition of sex discrimination to include gender identity as erroneous is itself mistaken.[15] Title IX and other relevant Civil Rights Titles cannot "unambiguously" define sex as the "biological and anatomical differences between male and female" just as the court in colonial Virginia could not define T's gender.[16] The rationale established by HHS is unworkable and will lead to similar cases where a legal gender cannot be determined by an agency. It is best to defer to the patient's gender identity rather than go through pained deliberations to fit patients into two arbitrary categories that they cannot accurately be defined by.

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[9] *Id.*
[10] *Peipho v. Peipho*, 88 Ill. 438, 1878 WL 9902 (1878)
[11] *"Terms for Gender Diversity in Classical Jewish Texts,"* Transtorah.org, *Available at* http://transtorah.org/PDFs/Classical_Jewish_Terms_for_Gender_Diversity.pdf.
[12] Hendricks, Muhsin *Islam and Homosexuality). ILGA's preconference on religions July 2006). Available at* http://doc.ilga.org/content/download/4522/27322/version/1/file/ILGA-July06-Religions.pdf
[13] Alipour, M (2016). "*Islamic shari'a law, neotraditionalist Muslim scholars and transgender sex-reassignment surgery: A case study of Ayatollah Khomeini's and Sheikh al-Tantawi's fatwas"*. International Journal of Transgenderism. 17:1: 91–103.
[14] Stephen O. Murray and Will Roscoe *"Conclusion". Islamic Homosexualities: Culture, History, and Literature*. NYU Press. p. 305 (1997).
[15] Proposed Rule, *supra at note 1,* at 27848 ("The district court held that the Department had adopted an erroneous interpretation of ''sex'' under Title IX, and that the regulation was also arbitrary and capricious for failing to incorporate Title IX's religious and abortion exemptions.")
[16] *Id.*

III. The Proposed Rule Ignores Substantial Case Law Establishing Sex Discrimination to Inherently Include Gender Identity and Sex Stereotypes

Section 1557 of the Affordable Care Act inherently prohibits sex discrimination, including discrimination based on sex stereotypes, gender expression, or gender identity. Section 1557 expressly incorporates four federal civil rights statutes, which outline the protected grounds of discrimination: race, color, and national origin (under Title VI); sex (under Title IX); age (under the ADEA); and disability (under the Rehabilitation act). Several courts have concurred that the statutory Section 1557 protections for "on the basis of sex" logically encompass protections for gender identity.[17]

A. The Interpretation of Title IX in Constructing the Interpretation of Sex Discrimination in the Current Regulation is Valid

The proposed rule stated that "Interpreting Section 1557, through Title IX, to prohibit gender identity discrimination was a relatively novel legal theory when HHS adopted the Final Rule."[18] This is an invalid determination of the Final Rule's reasoning, as it is not a novel legal theory, neither at the time nor currently. Title IX had already been found to include protections for sex stereotypes and logically included those and gender identity in its rule.[19] Agencies may look to a variety of sources such as the legislative record, other agency determinations, court precedent, and policy experts in its construction of a statute when faced with an ambiguous term.[20] Since the rule was first promulgated, Title IX has been shown to explicitly encompass gender identity protections.[21] This is particularly so in the interpretation of Section 1557 by other courts. Subsequent litigation has completely affirmed this that Title IX protects transgender people. In the recent decision granting summary judgement in *Grimm v. Gloucester County School Board,* on August 9, 2019, the court found that:

> "[E}very court to consider the issue [Title IX transgender protections] since May 22,2018 has agreed with the analysis relied

[17] *Tovar v. Essentia Health*, 342 F. Supp. 3d 947, 952 (D. Minn. 2018) (Holding that ACA Section 1557 prohibits discrimination on the basis of gender identity); *Prescott v. Rady Children's Hosp.-San Diego*, 265 F.Supp.3d 1090, 1098-1100 (S.D. Cal. 2017) (holding that Section 1557 extends to claims of gender identity based on its plain language); *Flack v. Wis. Dep't of Health Servs*., Civ. No. 18-309, 328 F.Supp.3d 931, 940–50, 2018 WL 3574875, at *12-13 (W.D. Wis. July 25, 2018); *Rumble v. Fairview Health Servs*., Civ. No. 14-2037, 2017 WL 401940, at *3 (D. Minn. Jan. 30, 2017); *Cruz v. Zucker*, 195 F. Supp. 3d 554, 581 (S.D.N.Y.),on reconsideration, 218 F. Supp. 3d 246 (S.D.N.Y. 2016)(Holding that Medicaid's categorical exclusion of treatments and procedures for the treatment of gender dysphoria as discriminatory)

[18] Proposed Rule, *supra at note* 1, at 27852-27853

[19] *Miles v. New York Univ*., 979 F.Supp. 248, 250 n.4 (S.D.N.Y. 1997)(It is established that the Title IX term "on the basis of sex" is interpreted in the same manner as similar language in Title VII. *See, e.g., Murray v. New York University College of Dentistry* (2d Cir.1995) 57 F.3d 243, 249 ("in a Title IX suit for gender discrimination based on sexual harassment of a student, an educational institution may be held liable under standards similar to those applied in cases under Title VII").); *See also Kenosha Unified Sch. Dist. No. 1 Bd. of Educ. v. Whitaker ex rel. Whitaker*, 138 S. Ct. 1260, 200 L. Ed. 2d 415 (2018) at 1048; *Grimm v. Gloucester Cty. Sch. Bd*., (E.D. Va. 2019);

[20] *Chevron, U.S.A., Inc. v. Nat. Res. Def. Council, Inc*., 467 U.S. 837, 843, 104 S. Ct. 2778, 2782, 81 L. Ed. 2d 694 (1984)(Holding that "the question for the court is whether the agency's answer is based on a permissible construction of the statute.)

[21] *Grimm v. Gloucester Cty. Sch. Bd*., 302 F. Supp. 3d 730 (E.D. Va. 2018) ("[A]s a matter of first impression, claims of discrimination on the basis of transgender status are per se actionable under a gender stereotyping theory under Title IX").

upon by this Court. *Doe by & through Doe v. Boyertown Area Sch. Dist*., 897 F.3d 518,530 (3d Cir. 2018) (stating that a policy forcing transgender students to use separate facilities "would very publicly brand all transgender students with a scarlet'T,' and they should not have to endure that as the price of attending their public school"); *Adams by & through Kasper v. Sch. Bd.of St. Johns Cty.,* 318 F. Supp. 3d 1293,1325 (M.D. Fla. 2018) (holding that "the meaning of 'sex' in Title DC includes 'gender identity' for purposes of its application to transgender students" and that the transgender student proved a Title DC violation where a school board denied him from using male restrooms, causing him harm) appeal docketed^ No. 18-13592 (11th Cir. Aug. 24,2018); *Parents for Privacy v. Dallas Sch. Dist. No. 2*, 326 F. Supp. 3d 1075, 1106 (D. Or. 2018)("Forcing transgender students to use facilities inconsistent with their gender identity would undoubtedly harm those students and prevent them from equally accessing educational opportunities and resources. Such a... District policy would punish transgender students for their gender nonconformity and constitute a form of sex-stereotyping.") appeal docketed^ 18-35708(9th Cir. Aug. 23,2018). *Grimm v. Gloucester Cty. Sch. Bd*., (E.D. Va. 2019).[22]

HHS's prior reliance on Title IX to establish gender identity as a protected class has been repeatedly affirmed by courts at all levels. HHS properly determined that Title IX jurisprudence and statutory construction should inform the definition of "on the basis of sex" to include gender identity and sex stereotypes in the Final Rule. HHS now contends that such a determination is invalid despite there being clear precedent on the matter to enlighten statutory construction. HHS in its proposed rule instead follows the baseless assertion by Judge O'Connor that HHS was not entitled to Chevron deference. This is a reckless abdication of HHS's responsibility to determine and interpret ambiguous statutes to the judiciary, when no determination has been made on the merits. HHS's present contention that Title IX regulations exclude gender identity and sex stereotypes is a legal conclusion made in ignorance of surrounding court precedent and jurisprudence.

B. The Definition of Sex Discrimination Promulgated by HHS Ignores Other Agency Determinations and Court Precedent of Title VII of the Civil Rights Act

HHS may also look to Title VII to help enlighten the construction of "on the basis of sex." The Supreme Court in *Franklin v. Gwinnet County Public Schools* rejected an argument against the prohibition of using Title VII to apply by analogy to Title IX's antidiscrimination provisions.[23] Since then, courts have commonly looked towards the interpretations of on the "on

[22] *Grimm v. Gloucester Cty. Sch. Bd*., (E.D. Va. 2019) citing *Doe by & through Doe v. Boyertown Area Sch. Dist*., 897 F.3d 518,530 (3d Cir. 2018); *Adams by & through Kasper v. Sch. Bd.of St. Johns Cty.,* 318 F. Supp. 3d 1293,1325 (M.D. Fla. 2018); *Parents for Privacy v. Dallas Sch. Dist. No. 2*, 326 F. Supp. 3d 1075, 1106 (D. Or. 2018).

[23] *Franklin v. Gwinnett Cty. Pub. Sch*., 503 U.S. 60, 65, 112 S. Ct. 1028, 1032, 117 L. Ed. 2d 208 (1992)

the basis of sex" to enlighten their analysis of the term when looking to apply canons of statutory construction towards provisions in the Civil Rights Titles. Prior to the implementation of the Final Rule in 2016, the courts had already established a significant amount of precedent that established transgender status and gender identity as inherently protected by Title VII.[24]

In adding Section 1557 to the Affordable Care Act, Congress intended for relevant agencies to incorporate Titles VI, Title VII, Title VIII, and Title IX into its definitions of discrimination.[25] Title VII has long had a significant role in determining protections for employees against sex discrimination and every court that has examined the issue has found that Title VII protects gender identity.[26] In 2011, the EEOC issued an administrative decision in *Macy v. Holder* finding that a complaint "based on gender identity, change of sex, and/or transgender status is cognizable under Title VII.[27] The Equal Employment Opportunity Commission (EEOC) has subsequently investigated and brought cases on the basis of gender identity.[28] This proposed rule goes even farther than contradicting these precedents, case law, and agency determinations; it ignores the bedrock principle of sex discrimination by removing sex stereotype protections established by the Supreme Court in *Price Waterhouse v. Hopkins*.[29] The Supreme Court affirmed this expansive view of Title VII in *Oncale v. Sundowner Offshore Services, Inc*., in which the court stated that "statutory prohibitions often go beyond the principal evil to cover reasonably comparable evils, and it is ultimately the provisions of our laws rather than the principal concerns of our legislators by which we are governed."[30]

Title VII cases of employment discrimination have offered the clearest examples yet of sex discrimination encompassing gender identity. Multiple circuit courts have weighed in and determined that gender identity and transgender status is explicitly protected under the prohibitions of discrimination on the basis of sex.[31] In *Glenn v. Brumby,* the 11th Circuit found that "[D]iscrimination against a transgender individual because of her gender-nonconformity is sex discrimination, whether it's described as being on the basis of sex or gender."[32] This holding

[24] *Glenn v. Brumby*, 663 F.3d 1312, 1317 (11th Cir. 2011); *Roberts v. Clark Cty. Sch. Dist*., 215 F.Supp.3d 1001, 1014 (D. Nev. 2016), reconsideration denied, No. 2:15-cv-00388-JAD-PAL, 2016 WL 6986346 (D. Nev. Nov. 28, 2016) (Holding that discrimination against a person based on transgender status is discrimination "because of sex" under Title VII.); *Fabian v. Hosp. of Cent*. Conn., 172 F.Supp.3d 509, 527 (D. Conn. 2016); *Lopez v. River Oaks Imaging & Diagnostic Grp., Inc*., 542 F.Supp.2d 653, 660 (S.D. Tex. 2008); *Schroer v. Billington*, 577 F.Supp.2d 293, 305 (D.D.C. 2008).

[25] *Tovar v. Essentia Health*, 342 F. Supp. 3d 947, 952 (D. Minn. 2018) (Holding that ACA Section 1557 prohibits discrimination on the basis of gender identity)

[26] *E.E.O.C. v. R.G. & G.R. Harris Funeral Homes, Inc*., 884 F.3d 560, 572 (6th Cir. 2018) (The court found "an employer cannot discriminate on the basis of transgender status without imposing its stereotypical notions of how sexual organs and gender identity ought to align. There is no way to disaggregate discrimination on the basis of transgender status from discrimination on the basis of gender non-conformity, and we see no reason to try."); *E.E.O.C. v. Rent-A-Center East, Inc*., 264 F.Supp.3d 952, 956 (C.D. Ill. 2017)

[27] *Mia Macy*, EEOC DOC 0120120821, 2012 WL 1435995, at *1 (Apr. 20, 2012)

[28] *Id.*

[29] *Price Waterhouse v. Hopkins*, 490 U.S. 228, 109 S. Ct. 1775, 104 L. Ed. 2d 268 (1989)(Holding that sex stereotypes are a form of sex discrimination).

[30] *Oncale v. Sundowner Offshore Servs., Inc*., 523 U.S. 75, 118 S. Ct. 998, 140 L. Ed. 2d 201 (1998)

[31] *Smith v. City of Salem*, 378 F.3d 566, 575 (6th Cir. 2004) ("[A] label, such as 'transsexual,' is not fatal to a sex discrimination claim where the victim has suffered discrimination because of his or her gender non-conformity."); *Rosa v. Park West Bank & Trust Co.*, 214 F.3d 213, 215–16 (1st Cir. 2000) (holding that a transgender individual stated a claim for sex discrimination under the Equal Credit Opportunity Act)

[32] *Glenn v. Brumby*, 663 F.3d 1312, 1317 (11th Cir. 2011)

by the 11th Circuit was based on the determination of several courts prior to the instant case.[33] The most recent and high profile case is that of the *EEOC v. RG & GR Harris Funeral Homes.*[34] The 6th Circuit held that "discrimination on the basis of transgender and transitioning status violates Title VII."[35]

Even more directly, courts have addressed the construction of the term "on the basis of sex" under Section 1557 in the course of Title VII litigation.[36] The most instructive of these cases was *Tovar v. Essentia Health* which found that the ACA prohibits discrimination on the basis of gender identity.[37] The District Court found that the employer, Essentia Health, and the third party administrator, Health Partners, violated Section 1557 for denying coverage of treatments and procedures for gender dysphoria. The insurance plan in Tovar excluded coverage for treatments and procedures for gender dysphoria. The court found that the categorical exclusions were discriminatory on the basis of gender identity. In its reasoning, the district court stated:

> *"***By definition, a transgender individual does not conform to the sex-based stereotypes of the sex that he or she was assigned at birth.***" Whitaker,* 858 F.3d at 1048*; see also Glenn v. Brumby,* 663 F.3d 1312, 1316 (11th Cir. 2011) ("A person is defined as transgender precisely because of the perception that his or her behavior transgresses gender stereotypes."). Courts have therefore recognized a cause of action under Title VII for sex discrimination based on gender identity and gender-transition status, e.g., male-to-female, female-to-male." [Emphasis added][38]

Again and again, courts have looked to the issue to construct the term "on the basis of sex" and repeatedly concluded that it implicitly encompasses protections for gender identity and transgender status as an extension of the sex stereotyping doctrine.

IV. The Proposed Rule Violates the Administrative Procedures Act

Under the Administrative Procedure Act §706(2)(A), a court shall determine an agency's policy change unlawfully arbitrary and capricious when an agency does not provide "the relevant data and articulate a satisfactory explanation for its action including a 'rational connection between the facts found and the choices made.'"[39] Under this standard, interpreted by the Supreme Court in *Motor Vehicle Manufacturers Association v. State Farm* and employed by the Court again in its 2019 term, an agency's cogent and reasoned analysis must: 1) sufficiently

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[33] *Id.*
[34] *E.E.O.C. v. R.G. & G.R. Harris Funeral Homes, Inc*., 884 F.3d 560, 574-575 (6th Cir. 2018) cert. granted in part sub nom. *R.G. & G.R. Harris Funeral Homes, Inc. v. E.E.O.C*., 139 S. Ct. 1599, 203 L. Ed. 2d 754 (2019)
[35] *Id.*
[36] *Tovar v. Essentia Health, supra at note* 23.
[37] *Id. at 952.*
[38] *Id.*
[39] *Dept. Comm. v. New York,* 139 S.Ct. 2551, 2569 (2019) quoting *Motor Vehicle Mfrs. Assn. of US Inc. v. State Farm Mut. Automobile Ins. Co.,* 463 U.S. 29, 43 (1983).

explain factual findings on which it relied to make its policy change; 2) sufficiently explain the connection between factual findings and the policy decision; and 3) explain pre-existing policy alternatives and reasons the agency, following an examination of evidence, decided against these alternatives.[40]

A. The Proposed Rule Unlawfully Ignores the Impact on Transgender Individuals, Who Have Developed a Serious Reliance Interest On Section 1557 of the Affordable Care Act

The agency erroneously finds that serious reliance interests do not exist for transgender individuals whose health care provisions were regulated by the Final Rule, because the Northern District of Texas enjoined enforcement of the Final Rule before the first plan year in which it would have applied.[41] The relevant part of the Proposed Rule states that:

> "The Department does not know what effect the Final Rule, in conjunction with the court injunction, has had on benefit design with respect to coverage of gender identity-related treatments. It, therefore, does not have enough information to estimate effects from the proposal to repeal of the Final Rule's benefit design requirements. The Department believes, however, that because a Federal court enjoined enforcement of the Section 1557 Regulation before the start of the first plan year in which the Final Rule would have applied, that beneficiaries of the expanded gender identity provisions could not have developed a reliance interest on the enjoined parts of the rule." [42]

Ignorance of the Proposed Rule's impact against the reliance interest of transgender patients is not an excuse for ignoring the impact that the Proposed Rule would have. The assumption that the enjoined Final Rule had no effect is woefully misinformed and ignorant of the current realities of transgender care. HHS made no meaningful attempt to inquire and analyze the changes in coverage for transgender patients and the implementation of non-discrimination policies. Most egregiously, the Proposed Rule redefines a covered entity to exclude private insurance providers, as well as federally funded exchange insurance plans.

1. Transgender Patients Are Disproportionately Discriminated Against In Medical Settings and Suffer Adverse Outcomes as a Result

There are an estimated 1.4 million Americans who identify as transgender.[43] All of these individuals will need health care at some point in their lives.[44] Many trans identified people will

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[40] (*State Farm, Independent US Tanker Committee v. Dole*).
[41] Proposed Rule, *supra at note 1,* at 27886
[42] *Id.* at 27886.
[43] Andrew R. Flores et al., The Williams Institute, *How Many Adults Identify as Transgender in the United States?* (June 2016). https://williamsinstitute.law.ucla.edu/wp-content/uploads/How-Many-Adults-Identify-as-

be more likely to need care than the average of the United States population, due to a need for life-saving medical attention such as hormone therapy or surgery, gender affirming care and heightened experiences of violence, clinical depression, anxiety, and suicidality.[45]

Transgender people require routine and life-saving care as much, if not more, than other portions of the United States. As a result of social and economic marginalization, transgender people experience clinical depression, anxiety, and serious psychological distress at significantly higher rates (39%) than the United States population average (5%).[46] Forty percent (40%) of transgender individuals have attempted suicide in their lifetime and seven percent (7%) have attempted suicide in the past year, nearly nine and twelve times the national averages (4.6% and 0.6%), respectively.[47] Nearly five times the number of transgender individuals than the national average are living with HIV (1.4% compared with 0.3%).[48] These rates are higher among transgender women (3.4%) especially transgender women of color; nearly one in five (19%) black transgender women surveyed by one analysis was living with HIV.[49]

Transgender people regularly experience discrimination while attempting to obtain routine and life-saving care related to the conditions above, their gender transitions, and other health care needs. In the 2015 U.S. Transgender Survey (conducted prior to the 2016 Regulation), one-third (33%) of transgender individuals reported at least one negative experience related to being transgender in health care, such as being verbally harassed, sexually or physically assaulted, or refused treatment.[50]

Trans and gender-non conforming (TGNC) people are regularly denied access to health care or provided substandard health services due to discrimination by health care providers and insurance policies.[51] The 2011 National Transgender Discrimination Survey found that at least 19% of individuals were refused care altogether due to their transgender or gender non-conforming identity (with higher rates among people of color).[52] Nearly thirty percent (28%) were subjected to harassment in medicals settings, and 2% were victims of violence in a doctor's office.[53] Denials and instances of discrimination occurred in doctor's offices, hospitals, emergency rooms, mental health clinics, by EMTs, and in drug treatment programs.[54] Twenty-

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Transgender-in-the-United-States.pdf.

[44] **S**ee *NFIB v. Sebelius*, 567 U.S. 519, 591-592 (2012), Ginsberg dissenting.

[45] James, S. E., Herman, J. L., Rankin, S., Keisling, M., Mottet, L., & Anafi, M., *The Report of the 2015 U.S. Transgender Survey. Washington, DC: National Center for Transgender Equality* (2016). https://transequality.org/sites /default/files/docs/usts/USTS-Full-Report-Dec17.pdf.

[46] The National Center for Transgender Equality (NCTE), *The Report of the 2015 US Transgender Survey,* at p. 5, *Available at* https://transequality.org/sites/default/files/docs/usts/USTS-Full-Report-Dec17.pdf

[47] *Id.*

[48] *Id. at* p. 6

[49] *Id. at* p. 10

[50] *Id.*

[51] Center for American Progress, "Discrimination Prevents LGBTQ People from Accessing Health Care," January 18, 2018. https://www.americanprogress.org/issues/lgbt/news/2018/01/18/445130/discrimination-prevents-lgbtq-people-accessing-health-care/

[52] The National Center for Transgender Equality (NCTE), *Injustice at Every Turn: A Report of the National Transgender Discrimination Survey,* at p. 6, *Available at* https://www.transequality.org/sites/default/files/docs/resources/NTDS_Report.pdf

[53] *Id.* at p 72.

[54] *Id. at* p. 73.

eight percent (28%) of individuals postponed needed medical care due to discrimination.[55] A 2018 study found that being denied a greater number of services and being discriminated against in more settings was associated with lower levels of treatment in transgender adults.[56] A quarter of respondents in a 2017 study reporting that they have avoided doctors or health care due to concern they would be discriminated against.[57]

Health service denials for transgender patients correlated with increased rates of coping-motivated substance use and elevated rates of attempted suicide.[58] Transgender and GNC adults face barriers to health care that may be due to a variety of reasons, including discrimination in health care, health insurance policies, employment, and public policy or lack of awareness among health care providers on transgender-related health issues.[59] Such barriers to health care would only increase with the elimination of protections against gender based discrimination in health care.

The implementation of these anti-discrimination standards by HHS is essential to the lives and wellbeing of TGNC communities. Currently, discrimination in health care prevents TGNC patients from receiving the healthcare they desperately need or care that would keep them healthy.[60] In 2010, prior to the implementation of section 1557 of the ACA barring discrimination due to gender identity in health care, 70% of TGNC patients reported experiencing some type of discrimination while seeking health care services.[61] HHS should be increasing and protecting transgender and gender non-conforming people's access to healthcare and while widening providers' ability to provide such care. In order to do this successfully,HHS must fully enforce Section 1557, the anti-discrimination provision of the ACA to include gender identity and sex stereotype protections.

2. HHS Arbitrarily and Capriciously Ignored the Proposed Rule's Impact on Transgender Patient's Serious Reliance Interest

HHS relies on a flawed interpretation of the necessary standard of review for determining when citing *FCC v. Fox,* which held that an agency changing its existing position "need not always provide a more detailed justification than what would suffice for a new policy created on

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[55] *Id. at* p. 6

[56] Administration and Policy in Mental Health, "*Examining Mechanisms and Moderators of the Relationship between Discriminatory Health Care Encounters and Attempted Suicide Among U.S. Transgender Help-Seekers,*" November 2018. https://www.ncbi.nlm.nih.gov/pubmed/29574543

[57] National Public Radio, Robert Wood Johnson Foundation, Harvard T.H. Chan School of Public Health, "Discrimination in America: Experiences and Views of LGBTQ Americans," November, 2017. https://www.npr.org/documents/2017/nov/npr-discrimination-lgbtq-final.pdf

[58] Administration and Policy in Mental Health, *"Examining Mechanisms and Moderators of the Relationship between Discriminatory Health Care Encounters and Attempted Suicide Among U.S. Transgender Help-Seekers,"* November 2018. https://www.ncbi.nlm.nih.gov/pubmed/29574543

[59] Gilbert Gonzalez, Carrie Henning-Smith, "*Barriers to Care Among Transgender and Gender Nonconforming Adults*," December 11, 2017. Available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5723709/

[60] Center for American Progress, "Discrimination Prevents LGBTQ People from Accessing Health Care," January 18, 2018. https://www.americanprogress.org/issues/lgbt/news/2018/01/18/445130/discrimination-prevents-lgbtq-people-accessing-health-care/

[61] Lamda Legal's Survey on Discrimination against LGBT People and People Living with HIV, "When Health Care isn't Caring," 2010. https://www.lambdalegal.org/sites/default/files/publications/downloads/whcic-report_when-health-care-isnt-caring_1.pdf

a blank slate." HHS does not complete the full analysis required.[62] In *Fox,* in the sentence following that which the agency cited, the Supreme Court held that an agency must provide a more detailed justification for its change in policy when its prior policy has resulted in serious reliance interests.[63] The court noted that "[i]t would be arbitrary or capricious to ignore such matters. In such cases it is not that further justification is demanded by the mere fact of policy change; but that a reasoned explanation is needed for disregarding facts and circumstances that underlay or were engendered by the prior policy.

Several organizations such as Mt. Sinai's Center for Transgender Medicine, with whom we partner with to provide legal services for transgender patients, have relied on the expansion of coverage for transgender individuals under Section 1557 to provide services for transgender patients. Several hospitals could lose significant revenue and potentially be forced to shutter programs if coverage is once again restricted for transgender individuals under the proposed rule.

Data suggests health care providers and insurers have adapted their policies to the explicit anti-discrimination provisions of the Final Rule prior to the injunction. Additionally, several court cases, such as *Cruz v. Zucker*, and *Tovar v. Essentia Health* have expanded access using the Section 1557 statute as a basis.[64] There would be a catastrophic and detrimental impact on the health and well-being of transgender patients as a direct result of the Proposed Rule. An analysis of discrimination complaints received by CMS prior to the Texas injunction found that the majority of trans patients filing complaints had been discriminated against or denied routine care, solely because of their gender identity.[65] A later analysis of ACA individual market plans for 2017-2019 found that 90% of plans did not include exclusions of transgender related care or gender dysphoria.[66] The high number of plans without exclusions is a rapid change from the time before the ACA when gender dysphoria treatment was routinely excluded. Additionally, the Final Rule went into effect in July 18, 2016 and was only enjoined in December 31, 2016. Nearly every plan has open enrollment prior to this date and the plans must be designed prior to this time. In 2016, NYLAG's own health insurance coverage through Oxford removed the requirement of supplemental coverage for gender dysphoria and implemented standard coverage for gender dysphoria, although with some exclusions still in place.

At the same time these protections are still necessary. At least 19% of individuals were refused care altogether due to their trans or gender non-conforming status and almost thirty percent of these individuals (28%) were subjected to harassment in medical settings.[67] Taken

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[62] Proposed Rule, *supra at note 1,* at 27850 citing *F.C.C. v. Fox Television Stations, Inc.*, 556 U.S. 502, 129 S. Ct. 1800, 173 L. Ed. 2d 738 (2009).
[63] *F.C.C. v. Fox Television Stations, Inc.*, 556 U.S. 502, 129 S. Ct. 1800, 173 L. Ed. 2d 738 (2009).
[64] *Cruz v. Zucker*, 195 F. Supp. 3d 554, 581 (S.D.N.Y.),on reconsideration, 218 F. Supp. 3d 246 (S.D.N.Y. 2016)(Holding that Medicaid's categorical exclusion of treatments and procedures for the treatment of gender dysphoria as discriminatory)
[65] Sharita Gruberg, *The ACA's LGBTQ Nondiscrimination Regulations Prove Crucial*, Center for American Progress (March 7, 2018). https://www.americanprogress.org/issues/lgbt/reports/2018/03/07/447414/acas-lgbtq-nondiscrimination-regulations-prove-crucial/
[66] Katie Keith, *HHS Proposes To Strip Gender Identity, Language Access Protections From ACA Anti-Discrimination Rule Health Affairs*, (May 25, 2019). https://www.healthaffairs.org/do/10.1377/hblog20190525.831858/full/.
[67] Grant, Jaime M., Lisa A. Mottet, Justin Tanis, Jack Harrison, Jody L. Herman, and Mara Keisling. *Injustice at Every Turn: A Report of the National Transgender Discrimination Survey.* Washington: National Center for

together, this data indicates trans individuals have been regularly discriminated in and barred from general provisions of health care. Accordingly, as physicians and payers have adapted their policies to conform to the Final Rule, transgender patients have developed serious reliance interests on the explicit gender identity protections which protect them from discrimination in accessing health care.[68]

The Final Rule sets out procedural and substantive protections against discrimination on the basis of protected classes by health care programs receiving federal assistance, administered by the Department of Health and Human Services (HHS), or established by the Affordable Care Act (ACA).[69] Currently, such "covered entities," such as hospitals and State Medicare providers, and insurers must treat individuals consistently with their gender identity and cannot categorically deny them access to health services, facilities, or coverage because of their gender.[70]

HHS must provide sufficient factual findings and a sufficient explanation of its rational for removing explicit protections of gender identity, which would reduce transgender, gender non-conforming, and intersex individuals' access to health care. As written, the Proposed Rule does not provide sufficient factual bases or explanations for its policy change. Without administratively sufficient factual or policy explanation, the Proposed Rule is an arbitrary and capricious regulatory change that harms the serious reliance interests of transgender patients. The Proposed Rule will open the door for continued discrimination of trans identified people as well as confusion as to which standard prevails in the state and local municipalities that have developed their own protections.

3. HHS Ignores the Significant Costs That Will Be Incurred by Healthcare Providers and Transgender Patients

Conflicting rules will increase cost to providers and increase private litigation. Failure to provide a proper standard of care is malpractice regardless of whether the health care provider denied care due to one's gender identity. Currently 19 states and Washington D.C. ban insurance exclusions for transgender healthcare.[71] The American Medical Association ethics rules clearly state that, "Physicians who offer their services to the public may not decline to accept patients because of race, color, religion, national origin, sexual orientation, gender identity or any other

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Transgender Equality and National Gay and Lesbian Task Force, (2011). https://www.transequality.org/sites/default/files/docs/resources/NTDS_Report.pdf.

[68] Katie Keith, *HHS Proposes To Strip Gender Identity, Language Access Protections From ACA Anti-Discrimination Rule Health Affairs*, (May 25, 2019). https://www.healthaffairs.org/do/10.1377/hblog20190525.831858/full/.

[69] *Nondiscrimination in Health Programs or Activities*, 81 FR 31375 (Proposed on May 18, 2016). https://www.federalregister.gov/documents/2016/05/18/2016-11458/nondiscrimination-in-health-programs-and-activities?utm_campaign=subscription+mailing+list&utm_medium=email&utm_source=federalregister.gov.

[70] Katie Keith, *HHS Proposes To Strip Gender Identity, Language Access Protections From ACA Anti-Discrimination Rule Health Affairs*, (May 25, 2019). https://www.healthaffairs.org/do/10.1377/hblog20190525.831858/full/.

[71] Human Rights Campaign, *"State Maps of Laws and Policies: Transgender Healthcare,"* January 15, 2019. https://www.hrc.org/state-maps/transgender-healthcare

basis that would constitute invidious discrimination."[72] Many states and localities explicitly prohibit discrimination based on gender identity and sexual orientation in public accommodations, which includes health services provided by physicians, hospitals, and other health service providers. The following 17 states have explicit protections: California, Connecticut, Colorado, Delaware, Hawaii, Illinois, Iowa, Maryland, Maine, Minnesota, Nevada, New Jersey, New Mexico, Oregon, Rhode Island, Vermont, and Washington State, as well as the District of Columbia.[73] More than 200 cities and counties also explicitly prohibit gender identity discrimination even if their state does not.[74]

Private medical malpractice suits are expensive for practitioners which is a cost passed down to patients. More than a third of physicians have had a claim filed against them at some point in their careers and the average expense incurred on medical liability claims that closed in 2015 was $54,165.[75] In 2015, 68.2 percent of all closed claims were dropped, dismissed, or withdrawn; however, each of these claims costs an average of $30,475 to defend.[76] Eliminating gender discrimination protections from section 1557 conflicts with many state and local laws, and will put providers at greater risk for medical malpractice and discrimination litigation which overrides any miniscule cost benefit from eliminating the current protections.

The Proposed Rule states their novel definition of sex discrimination would allow for efficiency, flexibility, and cost-effectiveness, but does not account for increased litigation in its analysis. Additionally, the private right of action for specific instances of discrimination is still reserved by patients. As a result, patients who experience discrimination will be able to engage in federal litigation against providers that discriminate regardless of the Proposed Rule. As a result, medical providers will be liable for costly federal litigation due to conflicting liability under HHS' proposed rule. Instead of providing a more expedient and efficient manner of dispute resolution through administrative complaints with the Office of Civil Rights, HHS instead shifts the burden back to the courts where significant case law has developed showing a private right of action under Section 1557.

One such example occurred in 2015, where a 14 year old transgender boy admitted to the hospital with suicidal ideations was repeatedly misgendered and harassed by hospital staff and eventually released early without proper treatment.[77] The boy subsequently committed suicide as a direct result of the treatment he received.[78] A court found that the hospital was liable under Section 1557 for discriminating on the basis of gender identity.[79] Litigation such as this could

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[72] American Medical Association, Code of Medical Ethics, "*Chapter 8: Opinions on Physicians & the Health of the Community: Disparities in Health Care*" https://www.ama-assn.org/sites/ama-assn.org/files/corp/media-browser/code-of-medical-ethics-chapter-8.pdf

[73] Trans Equality, "Know Your Rights: Public Accomodations," 2019. https://transequality.org/know-your-rights/public-accommodations

[74] *Id.*

[75] American Medical Association, Jose R Guardado, PhD, Policy Research Perspectives, "Medical Liability Insurance Indemnity Payments, Expenses and Claim Disposition, 2006-2015," 2018 https://www.ama-assn.org/sites/ama-assn.org/files/corp/media-browser/public/government/advocacy/policy-research-perspective-liability-insurance-claim.pdf

[76] *Id.*

[77] *Prescott v. Rady Children's Hospital-San Diego*, 2017 U.S. Dist. LEXIS 160259 (S.D. Cal. Sept. 27, 2017).

[78] *Id.*

[79] *Id.*

continue under the current interpretation of Section 1557 by the courts. The Proposed Rule ignores this possibility and the removal of explicit protections creates confusion that will place providers in greater legal liability while also diminishing the immediate remedies available to transgender patients.

B. The Proposed Rule Radically Redefines 'Covered Entities' and 'Principally Engaged in the Business of Providing Healthcare' To Exclude Health Insurers

The Final Rule sets out procedural and substantive protections against discrimination on the basis of protected classes by health care programs receiving federal assistance, administered by the Department of Health and Human Services (HHS), or established by the Affordable Care Act (ACA). Currently, such "covered entities," such as hospitals and State Medicare providers, and insurers must treat individuals consistently with their gender identity and cannot categorically deny them access to health services, facilities, or coverage because of their gender.

Section 1557 states in 42 U.S. Code 18116 (a), that "any health program or activity" is covered by anti-discrimination portion of the statute. The Proposed Rule inexplicably incorporates the standard of determining covered entities from the Civil Rights Restoration Act of 1987 (CRRA) without any basis to do so.[80] This results in defining health insurance companies as not being primarily in the business of healthcare which ignores the plain meaning of the statute. As quoted above, the relevant portion states "any health program or activity." A textualism analysis and the plain meaning of the term would immediately show that health insurance companies would constitute a health program or activity. Additionally, there is no indication that Congress intended for the CRRA to apply to Section 1557 as there would be no need to include Section 1557 in the first place if Title VI protections, as amended by the CRRA, already existed. HHS has impermissibly abrogated Section 1557 by bringing in the CRRA standard to a statute that was designed to expand civil rights protections.

C. The Proposed Rule Arbitrarily and Capriciously Redefines the Definition of Discrimination on the Basis of Sex

The Proposed Rule eliminates explicit definitions of discrimination on the basis of sex, including the Final Rule's distinction of gender identity as a category of sex protected against discrimination.[81] This change removes the legal protected classes, specific protections of benefits, and specific protections against discrimination by health care providers on the basis of gender identity.

The Proposed Rule erases the identities of intersex and transgender people. It substitutes an irrational unsubstantiated, and erroneous view that sex is solely based on biological and anatomical differences but fails to state what exactly those differences are. As noted previously in the case of T. Hall, determining sex is anything but unambiguous and simple. The Proposed rule cited that "sex and sexual refer to the biological indicators of male and female (understood in the context of reproductive capacity), such as in sex chromosomes, gonads, sex hormones, and

[80] Proposed Rule, *supra at note 1,* at 27862
[81] *Id.* at 27846

nonambiguous internal and external genitalia," and stated that any "differences between males and females [are] binary and biological."[82] However, this fails to capture the complexity of sex within a biological construct. By referring to sex as binary and biological, the Proposed Rule has created an impossible and unworkable standard. Even at a biological standpoint, there is no neat definition of what constitutes a man or a woman.

If one were to look solely towards the factors cited by HHS, this would be entirely reductive and unmanageable. It is taken for granted by HHS that sex can solely be determined on genetics, genitalia, and sex hormones. For instance, many intersex individuals are born with genitalia inconsistent with their genetics such as those with XX Male Syndrome who are genotypically women but are phenotypically male.[83] How would HHS characterize sex discrimination against such an individual? Another example would be those with Swyer Syndrome where they have XY chromosomes and an SRY deletion which results in phenotypical female features. One woman with Swyer Syndrome was able to give birth to a healthy baby girl.[84] Again, how would HHS characterize sex discrimination against such an individual? Sex hormones can oftentimes fail to distinguish sex characteristics due to Androgen Insensitivity Syndrome. Finally, there is recent research showing that the neurological configuration of transgender brains match not of their birth sex but of the gender they identify as.[85] Even with all of these examples, each individual born intersex often identify with a different gender than what either their genetics, genitalia, or sex hormones would indicate. Reliance on these factors to determine sex when analyzing a case of discrimination is in and of itself, an impermissible use of sex stereotypes which is prohibited under current Supreme Court precedent.

Each and every factor listed by HHS fails and has significant exceptions due to genetic and biological diversity among the population which results in a model of sex being closer to a bimodal distribution rather than a simple binary. HHS lays out no manner of dealing with discrimination on the basis of sex when someone's sex is indeterminable according to the factors cited. It would just be easier and far less intrusive to the privacy of patients if they can just simply self-attest their gender identity than to deal with the layered and extremely complex nature of sex. HHS believes that by citing biological sex in its Proposed Rule from miscellaneous research guidelines, it is being backed up by science in its prejudiced view that transgender individuals should not enjoy federal civil rights protections. However, at every turn, the medical science contradicts and indicates that the term "biological sex" is unambiguous and workable as a definition for discrimination protections.

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[82] Proposed Rule, *supra at note 1,* at 27854

[83] Parada-Bustamante, Alexis; Ríos, Rafael; Ebensperger, Mauricio; Lardone, María Cecilia; Piottante, Antonio; Castro, Andrea (2010-11-01). "*46,XX/SRY-negative true hermaphrodite*". Fertility and Sterility. 94 (6): 2330.e13–2330.e16. doi:10.1016/j.fertnstert.2010.03.066. ISSN 0015-0282. PMID 20451191

[84] Jyoti Taneja, David Ogutu, and Michael Ah-Moye, "Rare Successful Pregnancy In A Patient With Swyer Syndrome." Case Rep Womens Health. 2016 Oct; 12: 1–2. Published online 2016 Oct 18. doi: 10.1016/j.crwh.2016.10.001

[85] Mohammadi MR, Khaleghi A. "Transsexualism: A Different Viewpoint to Brain Changes". Clin Psychopharmacol Neurosci. 2018;16(2):136–143. doi:10.9758/cpn.2018.16.2.136

V. Health and Human Services is Impermissibly and Unconstitutionally Motivated by Hatred and Animus Towards Transgender People

Agencies are given wide latitude to construct interpretations of ambiguous statutes as long as they are not arbitrary and capricious under the Administrative Procedures Act. Additionally, agencies are cannot promulgate rules where the pretext for the change is animus towards a protected group. As courts have noted, transgender individuals are protected under the Equal Protection Clause of the 14th amendment and are due intermediate scrutiny when assessing actions that harm them.[86]

It cannot be emphasized enough how much of an outlier the decision to grant a nationwide preliminary injunction in *Franciscan Alliance* v. *Burwell* is. As previously detailed above, several federal circuit and district courts have established that gender identity is inherently protected under provisions prohibiting discrimination on the basis of sex. However, HHS is seemingly obsessed with adhering to the preliminary and non-substantive determinations of Judge O'Connor in the Northern District of Texas rather than its own reasoned interpretation established in 2016. This is a complete abdication of HHS' authority and independence to implement administrative regulations based on reasoned statutory construction. It begs the question as to why HHS would defer to an outlier decision to inform the entire basis of its proposed rule.

HHS claims that the Final Rule somehow superseded its authority in making that determination despite well-developed precedent determining that indeed, Title VII and Title IX's protections include gender identity and transgender status.[87] HHS consistently and repeatedly cites the *Franciscan Alliance v. Burwell* case as the sole basis for determining that HHS superseded its authority.[88] This is no accident as HHS is desperate to point towards favorable precedent and yet can only find one case, the alleged impetus for rewriting this rule. This is because HHS chose not to defend the rule and appeal to the 5th Circuit. Due to the unique nature of the preliminary injunction, intervenors on the case have not been joined while HHS considers a new rule.[89] This entire basis for rulemaking process for the proposed rule relies on a flimsy pretext created by the HHS' own decision to not defend the Final Rule.

The only change since the Final Rule was finalized was a change of administration and the inauguration of President Trump. The current administration has consistently shown animus towards transgender individuals and believes they do not deserve civil rights protections. The stated purpose of resolving the *Franciscan Alliance* case is a pretext to obscure the real motivations of HHS, particularly those of Director of the Office of Civil Rights Roger Severino,

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[86] *Supra* Note 20, at p. 749 (Finding that intermediate scrutiny applies under the Equal Protection Clause); *See* also *Whitaker*, 858 F.3d at 1051; *Glenn*, 663 F.3d at 1321.
[87] *Proposed Rule, Supra note 37, at* 27848.
[88] *Id.*
[89] *Franciscan Alliance, INC.; v. Burwell*, Secretary of the United States Department of Health and Human Services; and United States Department of Health and Human Services, Defendants., 2016 WL 5934533 (N.D.Tex.) Proposed Intervenors' Reply In Further Support Of Motion To Bifurcate Intervention And Suspend Briefing on the Merits. *Available at* https://www.aclu.org/legal-document/franciscan-alliance-v-price-proposed-intervenors-reply-motion-bifurcate-intervention

which is a deep seated animus and hatred of the transgender community.[90] Director Severino has repeatedly harnessed hateful and harmful rhetoric against the transgender community by misgendering transgender individuals and promoting prejudiced tropes.[91] Such rhetoric in New York State in the course of practicing law would subject Director Severino to ethical rules violations.[92] It is clear from this record that HHS cannot promulgate new rules stripping transgender individuals of civil rights protections when its own director has shown such blatant disdain and disregard for transgender individuals.

VI. Conclusion

For all the reasons cited above, NYLAG vehemently opposes the Proposed Rule.

Respectfully Submitted,

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[90] Roger Severino, *Pentagon's Radical New Transgender Policy Defies Common Sense*, July 1, 2016. (Mr. Severino used bigoted tropes against transgender service members by stating "biological men should not be allowed into the same barracks and showers as women."). *Available at* https://www.cnsnews.com/commentary/roger-severino/pentagons-radical-new-transgender-policy-defies-common-sense; Roger Severino, *Commentary: Court should reject Obama's radical social experiment,* November 7, 2016. (Purposely misgendered Gavin Grim, a transgender man as "a gender-dysphoric teen girl in Virginia sued her school district to get full access to the boys'athrooms.") *Available at* https://www.inquirer.com/philly/opinion/20161107_Commentary__Court_should_reject_Obama_s_radical_social_experiment.html; Roger Severino, *Pentagon's Radical New Transgender Policy Defies Common Sense*, July 1, 2016. (Mr. Severino used bigoted tropes against transgender service members by stating "biological men should not be allowed into the same barracks and showers as women."). *Available at* https://www.cnsnews.com/commentary/roger-severino/pentagons-radical-new-transgender-policy-defies-common-sense

[91] *Id.*

[92] 22 NYCRR Part 1200, Rule 8.4 (g) ("A lawyer or law firm shall not. . . .unlawfully discriminate in the practice of law, including in hiring, promoting or otherwise determining conditions of employment on the basis of age, race, creed, color, national origin, sex, gender identity, gender expression, disability, marital status or sexual orientation.

CERTIFICATE OF SERVICE

I hereby certify that on January 19, 2021, I electronically filed the foregoing brief with the Clerk of the Court for the United States Court of Appeals for the District of Columbia Circuit by using the appellate CM/ECF system. Participants in the case are registered CM/ECF users, and service will be accomplished by the appellate CM/ECF system.

/s/ Joshua Dos Santos
JOSHUA DOS SANTOS

[ORAL ARGUMENT NOT SCHEDULED]

No. 20-5331

IN THE UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

WHITMAN-WALKER CLINIC, INC., et al.,

Plaintiff-Appellees,

v.

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, et al.,

Defendants-Appellants.

On Appeal from the United States District Court
for the District of Columbia

JOINT APPENDIX
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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

WHITMAN-WALKER CLINIC, INC., *et al.*, **Plaintiffs,** **v.** **U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, *et al.*,** **Defendants.**	**Civil Action No. 20-1630 (JEB)**

ORDER

For the reasons set forth in the accompanying Memorandum Opinion, the Court ORDERS that:

1. Plaintiffs' Motion for a Preliminary Injunction or, in the Alternative, a Stay Pending Judicial Review is GRANTED IN PART and DENIED IN PART;
2. Defendants are preliminarily ENJOINED from enforcing the repeal of the definition of discrimination "[o]n the basis of sex" insofar as it includes "discrimination on the basis of . . . sex stereotyping," as previously set forth in 45 C.F.R. § 92.4;
3. Defendants are preliminarily ENJOINED from enforcing the 2020 Rule's incorporation of the religious exemption contained in Title IX, see 45 C.F.R. § 92.6(b); and
4. Plaintiffs' Motion is DENIED in all other respects.

IT IS SO ORDERED.

/s/ *James E. Boasberg*
JAMES E. BOASBERG
United States District Judge

Date: September 2, 2020

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

WHITMAN-WALKER CLINIC, INC., *et al.*, **Plaintiffs,** **v.** **U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, *et al.*,** **Defendants.**	**Civil Action No. 20-1630 (JEB)**

MEMORANDUM OPINION

In an effort to improve access to health care for LGBTQ individuals, the Department of Health and Human Services in 2016 promulgated a Rule that offered a bevy of protections for such patients. Those included explicit prohibitions on discrimination on the basis of gender identity or sex stereotyping, limits on exemptions from providing treatment that certain religious entities could invoke, proscriptions of categorical coverage exclusions, and a number of others. Believing that many of these protections were either unnecessary or misguided, the current administration has recently issued a Rule that revises or repeals the 2016 Rule in significant respects.

Concerned by this change in policy, private health-care facilities that provide services to LGBTQ people, LGBTQ-services organizations, national associations of health professionals, and individual physicians and behavioral-health providers have joined forces to bring suit challenging the new Rule under both the Administrative Procedure Act and various constitutional provisions. They now ask this Court to preliminarily enjoin the measure while this litigation proceeds.

As the daunting length of this Opinion suggests, the multiple issues they raise and their ability to do so pose myriad thorny questions that require extensive analysis. The Court ultimately concludes that Plaintiffs have standing to level challenges to certain provisions of the 2020 Rule, but not others, and that they are likely to succeed (and will suffer irreparable harm) on two central claims: first, that the 2020 Rule arbitrarily and capriciously eliminated "sex stereotyping" from the prior Rule's definition of "discrimination on the basis of sex"; and second, that it improperly incorporated Title IX's exemption of certain religious organizations from the statute's nondiscrimination mandate. The Court, consequently, will grant Plaintiffs' Motion in part and enjoin HHS from implementing these two provisions during the pendency of this case.

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I. Background

The Court begins with a brief overview of the relevant statutory background, then turns to the various regulatory actions at issue, and concludes with a history of the current litigation.

A. Statutory Background

Passed in 2010, the Patient Protection and Affordable Care Act (ACA) is "a comprehensive national plan to provide universal health insurance coverage" across the nation. Nat'l Fed'n of Indep. Bus. v. Sebelius, 567 U.S. 519, 583 (2012). It adopted a series of reforms to "expand coverage in the individual health insurance market," many of which were designed to protect consumers and make quality health care more broadly accessible. King v. Burwell, 135 S. Ct. 2480, 2485 (2015). An important component of the ACA's effort to ensure the prompt and effective provision of health care to all individuals — and of particular relevance for the present case — is the statute's express anti-discrimination mandate, which draws from protections embodied in four longstanding civil-rights laws. Section 1557 provides, as pertinent here:

> Except as otherwise provided for in this title (or an amendment made by this title), an individual shall not, on the ground prohibited under title VI of the Civil Rights Act of 1964 (42 U.S.C. 2000d et seq.), title IX of the Education Amendments of 1972 (20 U.S.C. 1681 et seq.), the Age Discrimination Act of 1975 (42 U.S.C. 6101 et seq.), or section [504 of the Rehabilitation Act of 1973 (29 U.S.C. 794)], 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] (or amendments). The enforcement mechanisms provided for and available under such title VI, title IX, section [504], or such Age Discrimination Act shall apply for purposes of violations of this subsection.

42 U.S.C. § 18116(a).

By outlawing discrimination "on the ground prohibited" by Title IX, Section 1557 bars discrimination "on the basis of sex." See 20 U.S.C. § 1681(a) (Title IX). It also forbids discrimination based on race, color, national origin, age, and disability. See 42 U.S.C. § 2000d (Title VI); id. § 6102 (Age Discrimination Act); 29 U.S.C. § 794 (Rehabilitation Act). These prohibitions sweep broadly, applying to "any health program or activity" receiving federal funding, as well as to "any program or activity that is administered by an Executive Agency or any entity established under [Title I of the ACA]." 42 U.S.C. § 18116(a). Section 1557 likewise adopts the "enforcement mechanisms" available under the four incorporated statutes, instructing that they "shall apply for purposes of violations." Id. Finally, it provides that the Secretary of HHS "may" promulgate implementing regulations. Id. § 18116(c).

B. Regulatory Background

1. *2016 Rule*

Exercising that delegation of authority, HHS published a rule on May 18, 2016, to "clarif[y] and codif[y] existing nondiscrimination requirements and set[] forth new standards to implement Section 1557." Nondiscrimination in Health Programs and Activities, 81 Fed. Reg. 31,375, 31,376 (May 18, 2016). In doing so, the agency devoted particular attention to the statute's prohibition on discrimination based on sex and well-documented challenges experienced by LGBTQ individuals seeking access to health care. The agency reported that for "transgender individuals, a major barrier to receiving care is a concern over being refused medical treatment based on bias against them." Id. at 31,460. In one study, approximately 27% of transgender respondents reported that they had been refused needed health care. Id. A 2011 survey likewise revealed that 25% of transgender individuals had experienced harassment in medical settings. Id. These findings supported the belief that transgender individuals who have

suffered such discriminatory treatment "often postpone or do not seek needed health care, which may lead to negative health consequences." Id. HHS also noted that many insurance or other health-care providers maintained explicit exclusions of coverage for all care related to gender dysphoria — a condition characterized by distress arising from a conflict between one's birth-assigned gender and gender identity — or associated with gender transition. Id. at 31,429.

The 2016 Rule thus introduced a host of measures in response to these and other perceived barriers to accessing quality and necessary health care. Several are of particular relevance to the present litigation.

First, the 2016 Rule defined its prohibition on sex discrimination — as incorporated by way of Title IX — to include "discrimination on the basis of . . . sex stereotyping, and gender identity." 81 Fed. Reg. at 31,467 (formerly codified at 45 C.F.R. § 92.4). The Rule explained that "gender identity" is "an individual's internal sense of gender, . . . which may be different from an individual's sex assigned at birth." Id. It defined "sex stereotypes," in turn, to include "stereotypical notions of masculinity or femininity," as well as "the expectation that individuals will consistently identify with only one gender and that they will act in conformity with the gender-related expressions stereotypically associated with that gender." Id. at 31,468 (formerly codified at 45 C.F.R. § 92.4). HHS explained that such "clarification" regarding the scope of Section 1557's sex-discrimination prohibition was consistent with prior agency and judicial interpretation, and was necessary to combat continued discrimination experienced by transgender individuals seeking access to health care. Id. at 31,388, 31,460.

In addition, the 2016 Rule declined to expressly incorporate Title IX's exemption of certain religious entities from its prohibition on sex discrimination in the event of a conflict between such prohibition and the entity's religious tenets. As HHS explained, "Section 1557

itself contains no religious exemption." Id. at 31,380. The agency also cited concerns surrounding wholesale importation of Title IX's exemption into the broader health-care context, worrying that an exemption could "result in a denial or delay in the provision of health care to individuals" and "discourag[e] [them] from seeking necessary care." Id. While the Rule made clear that it did not incorporate Title IX's religious exemption, it nonetheless instructed that Section 1557's nondiscrimination mandate would not apply in the event of a conflict with federal statutory protections for religious freedom and conscience. Id. at 31,466 (formerly codified at 45 C.F.R. § 92.2(b)(2)).

Several other provisions warrant brief mention, as they also appear in this litigation. The 2016 Rule prohibited insurers from having or implementing "categorical coverage exclusion[s] or limitation[s] for all health services related to gender transition." Id. at 31,471–72 (formerly codified at 45 C.F.R. § 92.207(b)(4)). It also required health-care providers and other covered entities to post notices and short, written "taglines" — in fifteen different languages in certain significant publications and in conspicuous physical locations — informing patients of their nondiscrimination rights and the availability of language-assistance services. Id. at 31,469 (formerly codified at 45 C.F.R. § 92.8). Finally, the Rule clarified the scope of entities to which Section 1557 applied — namely, every health program or activity that receives federal funding, is administered by HHS, or is administered by an entity established under Title I of the ACA. Id. at 31,466 (formerly codified at 45 C.F.R. 92.2(a)).

One additional piece of background regarding the 2016 Rule merits mention. In December 2016, several months after the Rule's promulgation, a federal court in the Northern District of Texas issued a nationwide preliminary injunction barring HHS from enforcing its definition of sex discrimination insofar as it included "gender identity" (but not sex

stereotyping). Franciscan Alliance, Inc. v. Burwell, 227 F. Supp. 3d 660, 695–96 (N.D. Tex. 2016). The court reasoned that the statutory term "sex," as deployed in Title IX and incorporated into Section 1557, "refer[red] to the biological differences between males and females" and thus did not encompass gender identity. Id. at 688–89. It went a step further in October 2019 when it vacated that portion of the 2016 Rule and remanded it for "further consideration." Franciscan Alliance, Inc. v. Azar, 414 F. Supp. 3d 928, 945 (N.D. Tex. 2019). Critically, as the court subsequently clarified, such vacatur applied only "insofar as the Rule defines 'On the basis of sex' to include gender identity . . . ." ECF No. 43 (Pl. Reply), Exh. 4 (Franciscan Alliance Order) at ECF p. 3. "The remainder of 45 C.F.R. § 92," it made clear, "remains in effect." Id.

2. *2020 Rule*

The Obama administration having departed, in June 2019, HHS issued a notice of proposed rulemaking that suggested "substantial revisions" to the 2016 Rule. See Nondiscrimination in Health and Health Education Programs or Activities, 84 Fed. Reg. 27,846, 27,848 (June 14, 2019). Many of the agency's proposed changes became reality when it promulgated the final 2020 Rule just over a year later. See Nondiscrimination in Health and Health Education Programs or Activities, Delegation of Authority, 85 Fed. Reg. 37,160 (June 19, 2020). Because the Court explains each challenged provision in additional detail when considering the merits of Plaintiffs' various claims, the briefest of discussions of the relevant specific changes will suffice for present purposes.

First, the 2020 Rule "repeal[ed] the 2016 Rule's definition of 'on the basis of sex,'" which — as a reminder — explicitly prohibited discrimination based on sex stereotyping and gender identity. Id. at 37,178. HHS did so on the belief that the prior definition "exceeded the scope of the authority delegated by Congress in Section 1557," imposing legal requirements

"that cannot be justified by the text of Title IX." Id. at 37,161–62; see also, e.g., id. at 37,191 (explaining that "the term 'on the basis of . . . sex' in Section 1557 does not encompass discrimination on the basis of gender identity"). As a result of this wholesale reversal in the agency's legal interpretation, no provision of the 2020 Rule contains any reference to "sex stereotyping" or "gender identity." Indeed, the regulation carries no definitional provision at all, and instead simply explains that Section 1557 prohibits discrimination on the grounds barred in the four civil-rights statutes it incorporates. Id. at 37,244 (to be codified at 45 C.F.R. § 92.2).

In another policy reversal, the 2020 Rule expressly incorporated Title IX's religious exemption into Section 1557. See 45 C.F.R. § 92.6(b) (incorporating "exemptions" contained in various statutes, including Title IX). As HHS explained, "Any educational operation of an entity may be exempt from Title IX due to control by a religious organization." 85 Fed. Reg. at 37,207–08. The agency made clear that such exemption applied in whole to Section 1557, thereby excepting applicable operations from the statute's prohibition on sex discrimination if inconsistent with the organization's religious tenets. Id. at 37,207–08 & n.267. According to HHS, these and other safeguards "will protect both providers' medical judgment and their consciences, thus helping to ensure that patients receive the high-quality and conscientious care that they deserve." Id. at 37,206.

HHS similarly eliminated the 2016 Rule's prohibition on insurers' having or implementing categorical coverage exclusions for gender-affirming care. In doing so, the agency contended that no statutory authority existed for such a prohibition in the first place, and it pointed to evidence indicating division among the medical community "on many issues related to gender identity, including the value of various 'gender-affirming' treatments for gender dysphoria." Id. at 37,187, 37,198.

Next, HHS repealed the 2016 Rule's requirements that covered entities provide various notices and taglines informing individuals of Section 1557's prohibited grounds of discrimination and the availability of language-assistance services. The agency justified that action by emphasizing the significant costs of providing such notices in covered communications and physical locations, as well as limited evidence of their leading to increased access to care. Id. at 37,224, 37,232–33.

The 2020 Rule also narrowed the scope of entities covered under Section 1557 in two distinct ways. First, HHS interpreted the statute's nondiscrimination protections to apply only to health programs or activities receiving federal funding, programs or activities administered by HHS under Title I of the ACA, or programs or activities administered by entities established under Title I. See 45 C.F.R. § 92.3(a). As relevant here, this regulatory action restricted the statute's coverage to HHS programs administered under Title I of the ACA, as opposed to all of the agency's health programs and activities (as provided by the 2016 Rule). See 85 Fed. Reg. at 37,170–71. The effect of this change would likely be to exclude certain programs administered by the Centers for Medicare & Medicaid Services and the Centers for Disease Control and Prevention, among other HHS components, from Section 1557's reach. Id. In addition, the 2020 Rule interpreted Section 1557's reference to "any health program or activity" receiving federal funding, see 42 U.S.C. § 18116(a), as excluding entities "principally or otherwise engaged in the business of providing health insurance." 45 C.F.R. § 92.3(b), (c).

Finally, the 2020 Rule requires would-be plaintiffs to employ the particular enforcement mechanism and accompanying legal standard available under each of Section 1557's incorporated statutes, depending on the precise ground of discrimination asserted. See 45 C.F.R. § 92.5; 85 Fed. Reg. at 37,202. In other words, a litigant bringing a discrimination claim on a

ground prohibited by Title VI — *e.g.*, race — cannot invoke the enforcement mechanisms available under Title IX. See 85 Fed. Reg. at 37,202.

3. Bostock

Just four days before HHS published the 2020 Rule, the Supreme Court issued its decision in Bostock v. Clayton County, 140 S. Ct. 1731 (2020), a case involving Title VII's prohibition on discrimination "because of . . . sex." 42 U.S.C. § 2000e–2(a)(1). The Court held that discrimination based on transgender status or sexual orientation "necessarily entails discrimination based on sex," and accordingly falls within Title VII's sweep. Bostock, 140 S. Ct. at 1747. In reaching that conclusion, the Court expressly assumed that "sex" "refer[red] only to biological distinctions between male and female." Id. at 1739. Nothing turned on the original meaning of that statutory term, the Court explained, because a "straightforward" application of Title VII's text confirmed that "it is impossible to discriminate against a person for being homosexual or transgender without discriminating against that individual based on sex." Id. at 1741, 1743.

In the 2020 Rule, HHS acknowledged that the Court's forthcoming decision in Bostock "will likely have ramifications" for Title IX's similarly worded prohibition on sex discrimination. See 85 Fed. Reg. at 37,168. That was especially so, the agency admitted, because "Title VII case law has often informed Title IX case law with respect to the meaning of discrimination 'on the basis of sex.'" Id. HHS nevertheless pushed ahead, publishing the 2020 Rule shortly after Bostock was decided. Nowhere did the agency mention the case's holding, let alone analyze the implications of its reasoning for HHS's determination that "the term 'on the basis of . . . sex' in Section 1557 does not encompass discrimination on the basis of gender identity." Id. at 37,191. Indeed, the final Rule suggests that HHS simply thought Bostock would

come out differently than it ultimately did. See id. at 37,168 (stating that "the reasons why 'on the basis of sex' . . . does not encompass sexual orientation or gender identity under Title VII have similar force for the interpretation of Title IX").

C. The Instant Litigation

Three days after HHS finalized the 2020 Rule — but before its provisions went into effect — Plaintiffs filed this suit against the agency under the Administrative Procedure Act, 5 U.S.C. § 701 *et seq*. Among the current Plaintiffs are two private health-care facilities that provide services to LGBTQ people (Whitman-Walker Clinic, Inc. and Los Angeles LGBT Center) (the "health-provider Plaintiffs"); two LGBTQ-services organizations (TransLatin@ Coalition and Bradbury-Sullivan LGBT Community Center); two national associations of health professionals (American Association of Physicians for Human Rights, Inc. (GLMA) and AGLP: The Association of LGBTQ+ Psychiatrists); and four individual physicians and behavioral-health providers who work for the health-provider Plaintiffs. See ECF No. 1 (Complaint), ¶¶ 31–46. Their Complaint asserts various claims against HHS, all pertaining to the 2020 Rule. Id., ¶¶ 225–307.

Soon thereafter, Plaintiffs filed this Motion for Preliminary Injunction or, in the Alternative, a Stay Pending Judicial Review. See ECF No. 29, Exh. 1 (Pl. Mot.). Much like their Complaint, the Motion asserts a congeries of claims against HHS, which run together at certain points. Stated broadly, Plaintiffs seek an order from this Court enjoining the agency from carrying out each of the aforementioned regulatory repeals and barring it from enforcing several of the newly promulgated provisions. They chiefly contend that these actions were arbitrary and capricious or otherwise foreclosed by Section 1557. In addition, Plaintiffs argue that select provisions of the 2020 Rule conflict with Section 1554, which prohibits regulations that create

unreasonable barriers and impede access to health-care services. See 42 U.S.C. § 18114. Finally, Plaintiffs maintain that the 2020 Rule runs afoul of the Fifth Amendment's guarantees of equal protection and substantive due process, infringes their right to free speech under the First Amendment, and violates the Establishment Clause.

Following a hearing on the Motion, the Court provided Defendants an opportunity to submit a surreply on questions relating to standing and irreparable harm, as Plaintiffs had declined to discuss the former in their opening brief. On August 17, 2020 — one week after Defendants' supplemental filing, and one day before the 2020 Rule was scheduled to go into effect — a federal court in the Eastern District of New York "preliminarily enjoin[ed] [HHS] from enforcing the repeal" of the 2016 Rule's definition of discrimination on the basis of sex. Walker v. Azar, No. 20-2834, 2020 WL 4749859, at *10 (E.D.N.Y. Aug. 17, 2020). Walker endorsed essentially the very argument that Plaintiffs make here — namely, that HHS's repeal of the 2016 Rule's definition was arbitrary and capricious in light of the agency's failure to consider the implications of the Supreme Court's decision in Bostock. Id. at *9–10. Because the court's injunction remains in effect, HHS's repeal of that definitional provision has not yet occurred. Walker, however, considered only that sole provision of the 2020 Rule; it did not decide any of the additional issues Plaintiffs raise before this Court. As a result, with the one exception, each of the 2020 Rule's new provisions are now in effect.

II. Legal Standard

"A preliminary injunction is an extraordinary remedy never awarded as of right." Winter v. Nat. Res. Def. Council, Inc., 555 U.S. 7, 24 (2008). "A plaintiff seeking a preliminary injunction must establish [1] that he is likely to succeed on the merits, [2] that he is likely to suffer irreparable harm in the absence of preliminary relief, [3] that the balance of equities tips in

his favor, and [4] that an injunction is in the public interest." Sherley v. Sebelius, 644 F.3d 388, 392 (D.C. Cir. 2011) (alterations in original) (quoting Winter, 555 U.S. at 20). "The moving party bears the burden of persuasion and must demonstrate, 'by a clear showing,' that the requested relief is warranted." Hospitality Staffing Solutions, LLC v. Reyes, 736 F. Supp. 2d 192, 197 (D.D.C. 2010) (quoting Chaplaincy of Full Gospel Churches v. England, 454 F.3d 290, 297 (D.C. Cir. 2006)).

Historically, these factors have "been evaluated on a 'sliding scale.'" Davis v. Pension Ben. Guar. Corp., 571 F.3d 1288, 1291 (D.C. Cir. 2009) (quoting Davenport v. Int'l Bhd. of Teamsters, 166 F.3d 356, 361 (D.C. Cir. 1999)). In other words, if the movant makes an "unusually strong showing on one of the factors, then it does not necessarily have to make as strong a showing on another factor." Id. at 1291–92. This Circuit has hinted, though not held, that Winter — which overturned the Ninth Circuit's "possibility of irreparable harm" standard — establishes that "likelihood of irreparable harm" and "likelihood of success" are "'independent, free-standing requirement[s].'" Sherley, 644 F.3d at 392–93 (quoting Davis, 571 F.3d at 1296 (Kavanaugh, J., concurring)); see League of Women Voters v. Newby, 838 F.3d 1, 7 (D.C. Cir. 2016) (declining to address whether "sliding scale" approach is valid after Winter). Unresolved, too, is the related question of "whether, in cases where the other three factors strongly favor issuing an injunction, a plaintiff need only raise a serious legal question on the merits." Aamer v. Obama, 742 F.3d 1023, 1043 (D.C. Cir. 2014) (internal quotation and citation omitted).

III. Standing

Perhaps overconfident of their standing to bring this suit, Plaintiffs, as mentioned before, never even discussed this question in their original Motion. This threshold issue, however, is

quite involved, given all of the discrete challenges Plaintiffs assert here. The Court, as it must, thus begins by addressing its own jurisdiction.

Article III of the Constitution limits the power of the federal judiciary to the resolution of "cases and controversies," a phrase given meaning by the doctrine of "standing." Whitmore v. Arkansas, 495 U.S. 149, 154–55 (1990); see U.S. Const. art. III, § 2, cl. 1. "[S]tanding is an essential and unchanging part of the case-or-controversy requirement of Article III." Lujan v. Defs. of Wildlife, 504 U.S. 555, 560 (1992). For that reason, finding that a plaintiff has standing is a necessary "predicate to any exercise of [the Court's] jurisdiction." Fla. Audubon Soc'y v. Bentsen, 94 F.3d 658, 663 (D.C. Cir. 1996) (*en banc*).

"Every plaintiff in federal court bears the burden of establishing the three elements that make up the 'irreducible constitutional minimum' of Article III standing: injury-in-fact, causation, and redressability." Dominguez v. UAL Corp., 666 F.3d 1359, 1362 (D.C. Cir. 2012) (quoting Lujan, 504 U.S. at 560–61). First, the plaintiff "must have suffered an 'injury in fact' — an invasion of a legally protected interest which is (a) concrete and particularized . . . and (b) actual or imminent, not conjectural or hypothetical." Lujan, 504 U.S. at 560 (internal quotation marks and citations omitted). Second, "there must be a causal connection between the injury and the conduct complained of — the injury has to be 'fairly . . . trace[able] to the challenged action of the defendant, and not . . . th[e] result [of] the independent action of some third party not before the court.'" Id. (alterations in original) (citation omitted). Third, "it must be 'likely,' as opposed to merely 'speculative,' that the injury will be 'redressed by a favorable decision.'" Id. at 561 (citation omitted). A "deficiency on any one of the three prongs suffices to defeat standing." U.S. Ecology, Inc. v. U.S. Dep't of Interior, 231 F.3d 20, 24 (D.C. Cir. 2000).

While the plaintiff "bears the burden of establishing" all three elements of standing, the "manner and degree of evidence required" to do so varies according to the "stage[] of the litigation." Lujan, 504 U.S. at 561. "In the context of a preliminary injunction motion," the plaintiff must "'show a substantial likelihood of standing' 'under the heightened standard for evaluating a motion for summary judgment.'" Electronic Privacy Info. Ctr. v. Presidential Advisory Comm'n on Election Integrity, 878 F.3d 371, 377 (D.C. Cir. 2017) (quoting Food & Water Watch, Inc. v. Vilsack, 808 F.3d 905, 912–13 (D.C. Cir. 2015)). "Thus, the plaintiff cannot 'rest on . . . mere allegations, but must set forth by affidavit or other evidence specific facts' that, if 'taken to be true,' demonstrate a substantial likelihood of standing." Id. (alteration in original) (quoting Lujan, 504 U.S. at 561); see also Electronic Privacy Info. Ctr. v. U.S. Dep't of Commerce, 928 F.3d 95, 104 (D.C. Cir. 2019). "[I]n assessing plaintiffs' standing, [the Court] must assume they will prevail on the merits of their . . . claims." LaRoque v. Holder, 650 F.3d 777, 785 (D.C. Cir. 2011).

Because "standing is not dispensed in gross," but instead may differ claim by claim, Davis v. FEC, 554 U.S. 724, 734 (2008) (internal quotation and alteration omitted), a plaintiff "must demonstrate standing for each claim he seeks to press." DaimlerChrysler Corp. v. Cuno, 547 U.S. 332, 352 (2006). Only one plaintiff, however, needs standing in order for a particular claim to go forward. Comcast Corp. v. FCC, 579 F.3d 1, 6 (D.C. Cir. 2009). That is, if constitutional standing "can be shown for at least one plaintiff, we need not consider the standing of the other plaintiffs to raise that claim." Carpenters Indus. Council v. Zinke, 854 F.3d 1, 9 (D.C. Cir. 2017) (quoting Mountain States Legal Found. v. Glickman, 92 F.3d 1228, 1232 (D.C. Cir. 1996)); see also *In re* Navy Chaplaincy, 697 F.3d 1171, 1176–1178 (D.C. Cir. 2012) (concluding that plaintiffs had standing because "at least some plaintiffs" would suffer injury).

While an "inability to establish a substantial likelihood of standing" on a particular claim "requires denial of the motion for preliminary injunction," it does not warrant outright dismissal. Food & Water Watch, 808 F.3d at 913.

The Court will first assess nine of Plaintiffs' claims under the rubric of organizational standing. It will then consider whether they can assert the rights of third-party LGBTQ patients to bring the three remaining constitutional counts.

A. Organizational Standing

1. *Legal Standard*

Organizations can sue either on their own behalf ("organizational standing") or on behalf of their members ("representational" or "associational standing"). See Ctr. for Responsible Sci. v. Gottlieb, 311 F. Supp. 3d 5, 9 (D.D.C. 2018). For reasons that will become evident, the Court largely focuses on the former theory with respect to the health-provider Plaintiffs (Whitman-Walker and LA LGBT). To establish organizational standing, Plaintiffs must show that the organization itself, like any individual plaintiff, satisfies the three familiar elements of standing — (1) injury, (2) causation, and (3) redressability. See Equal Rights Ctr. v. Post Props., 633 F.3d 1136, 1138 (D.C. Cir. 2011).

To satisfy the injury-in-fact requirement, an organization must allege a "concrete and demonstrable injury to [its] activities." Food & Water Watch, 808 F.3d at 919 (alteration in original) (quoting PETA v. USDA (PETA II), 797 F.3d 1087, 1093 (D.C. Cir. 2015)). Conversely, "a mere 'setback'" to the organization's "'abstract social interests' is not sufficient." Equal Rights Ctr., 633 F.3d at 1138 (quoting Spann v. Colonial Vill., Inc., 899 F.2d 24, 27 (D.C. Cir. 1990)). Our Circuit memorializes this distinction in a two-part test: the Court must ask first "whether the agency's action or omission to act 'injured the [organization's] interest'"; then, if

satisfied, it inquires whether "the organization 'used its resources to counteract that harm.'" PETA II, 797 F.3d at 1094 (alteration in original) (quoting Equal Rights Ctr., 633 F.3d at 1140); accord Food & Water Watch, 808 F.3d at 919 (employing same test); see also Havens Realty Corp. v. Coleman, 455 U.S. 363, 379 (1982) (finding organizational injury based on an "injury to the organization's activities" followed by "the consequent drain on the organization's resources").

Regarding the first prong: to qualify as an injury to the organization's interest, the challenged activity must "perceptibly impair[] the organization's ability to provide services." Food & Water Watch, 808 F.3d at 919 (quoting Turlock Irrigation Dist. v. FERC, 786 F.3d 18, 24 (D.C. Cir. 2015)). Put otherwise, it must "inhibit[]" the organization's "daily operations" in a concrete way, PETA II, 797 F.3d at 1094 (citation omitted), such as by "undermin[ing] the organization's ability to perform its fundamental programmatic services." Nat'l Veterans Legal Servs. Program v. U.S. Dep't of Def., No. 14-1915, 2016 WL 4435175, at *6 (D.D.C. Aug. 19, 2016). A necessary aspect of this requirement is that there be a "direct conflict between the defendant's conduct and the organization's mission." Abigail All. v. Eschenbach, 469 F.3d 129, 133 (D.C. Cir. 2006).

Once this first prong is met, the Court moves on to the second and asks whether the organization will "use[] its resources to counteract that harm." Food & Water Watch, 808 F.3d at 919 (quoting PETA II, 797 F.3d at 1094). While "self-inflicted" injuries do not count, Abigail All., 469 F.3d at 133, an injury is not a "self-inflicted . . . budgetary choice[]" merely by having been made willfully or voluntarily. Equal Rights Ctr., 633 F.3d at 1139 (quoting Fair Emp't Council of Greater Washington, Inc. v. BMC Mktg. Corp., 28 F.3d 1268, 1276 (D.C. Cir. 1994)). Rather, as long as the organization will expend resources "to counteract[] the effects of the

defendant['s]" challenged conduct, that diversion can suffice for Article III purposes. Id. at 1140.

In a suit for preliminary injunctive relief, "past harm is not sufficient to establish an injury in fact." Nat'l Whistleblower Ctr. v. HHS, 839 F. Supp. 2d 40, 45–46 (D.D.C. 2012). The plaintiff, rather, must show "a real and immediate — as opposed to merely conjectural or hypothetical — threat of future injury." Nat. Res. Def. Council v. Pena, 147 F.3d 1012, 1022 (D.C. Cir. 1998) (quoting Church v. City of Huntsville, 30 F.3d 1332, 1337 (11th Cir. 1994)); see also City of Los Angeles v. Lyons, 461 U.S. 95, 105 (1983); Attias v. Carefirst, Inc., 865 F.3d 620, 627 (D.C. Cir. 2017) ("[W]e have frequently upheld claims of standing based on allegations of a 'substantial risk' of future injury.").

The tests for causation and redressability "mirror, with little added gloss, the requirements for a non-organizational plaintiff who attempts to invoke the jurisdiction of the federal courts." Citizens for Responsibility and Ethics in Washington v. U.S. Office of Special Counsel, No. 19-3757, 2020 WL 4530647, at *6 (D.D.C. Aug. 6, 2020). In other words, an organizational plaintiff must show that its injury is "fairly traceable to the defendant's allegedly unlawful conduct." Am. Soc. for Prevention of Cruelty to Animals v. Feld Ent. Inc., 659 F.3d 13, 24 (D.C. Cir. 2011). It must also be "likely" that the injury would be "redressed by a favorable court decision." Id.

2. *Application to Claims*

Mindful of its obligation to ensure that standing exists for every count asserted, the Court will "address seriatim" Plaintiffs' allegations with respect to each claim. West v. Lynch, 845 F.3d 1228, 1235 (D.C. Cir. 2017). For ease of explanation, however, it will begin by describing several organizational injuries alleged by the health-provider Plaintiffs, as these asserted harms

have consequences for several of their counts. Specifically, such harms satisfy the injury-in-fact requirement for Plaintiffs' claims that HHS: 1) improperly eliminated the 2016 Rule's definition of sex discrimination; 2) erred by incorporating Title IX's religious exemption into Section 1557; 3) violated Section 1554; and 4) ran afoul of the Establishment Clause. After surveying these "common injuries," the Court will separately address causation and redressability for all four claims. It will then separately consider standing for the five additional claims that rely on alleged organizational injury but do not share common injuries with the first four claims. Finally, as previously mentioned, the Court will analyze Plaintiffs' remaining three constitutional counts in a separate sub-section, as they do not raise issues of organizational standing.

a. Common-Injury Claims

i. Injury-in-Fact

The Court begins by laying out several organizational injuries that underlie four of Plaintiffs' claims.

First, both Whitman-Walker and LA LGBT — *i.e.*, the health-provider Plaintiffs — profess financial and operational injuries as a result of increased patient demand spurred by the new Rule. Specifically, they contend that growing numbers of LGBTQ patients are likely to turn to their organizations for health-care services given the patients' augmented fear of discrimination at the hands of external providers. See Pl. Mot., Exh. 9 (Declaration of Robert Bolan), ¶¶ 11, 13, 18 (explaining that 2020 Rule is "likely to cause an increase in demand for my health care services" because "patients will come to us seeking affirming health care out of fear of discrimination elsewhere"); Exh. 3 (Declaration of Naseema Shafi), ¶ 34 (explaining that "fear of discrimination, resulting from the [2020] Rule, is likely to result in increased demand for Whitman-Walker's health care services"); Exh. 4 (Declaration of Sarah Henn), ¶¶ 19, 29; Exh. 5

(Declaration of Randy Pumphrey), ¶¶ 9, 14–15; Exh. 8 (Declaration of Darrel Cummings), ¶¶ 12, 18, 20; Exh. 9 (Declaration of Ward Carpenter), ¶¶ 12, 16. That increased demand, in turn, will necessarily generate "considerable operational and financial challenges." Shafi Decl., ¶ 34; Carpenter Decl., ¶ 12. On the financial side, a larger pool of patients demanding the organizations' services will force them to provide care on a broader scale, and the resulting expenditures will exacerbate pressure on already constrained budgets. See Shafi Decl., ¶ 34; Henn Decl., ¶ 29; Cummings Decl., ¶ 20. Operations will also suffer, as fear of discrimination will likely cause an "increase in demand for [LA LGBT's] services," which will "increase wait times" and "limit [LA LGBT's] ability to provide adequate care and time to [its] patients." Carpenter Decl., ¶¶ 12, 16. LA LGBT has likewise indicated the need to hire additional mental-health staff to contend with "increase[d] patient trauma" that the 2020 Rule has and will allegedly continue to cause. Id., ¶ 12.

In addition, the health-provider Plaintiffs assert a related but distinct injury: having to provide costlier and more involved treatment. According to the organizations, heightened fears of discrimination on account of the 2020 Rule will cause patients to refrain from being fully transparent with external providers regarding their LGBTQ identities and unique medical histories. See Bolan Decl., ¶ 17 ("The [2020] Rule will cause LGBTQ patients to attempt to hide their LGBTQ identities to an even greater degree when seeking health care services, especially from religiously-affiliated health care organizations, in order to avoid discrimination."); Shafi Decl., ¶ 21 (contending that 2020 Rule will "encourage LGBTQ patients to remain closeted to the extent possible when seeking medical care"); Henn Decl., ¶¶ 19–20; Pumphrey Decl., ¶ 12; Cummings Decl., ¶¶ 18–19; Carpenter Decl., ¶ 15. Other patients will delay seeking necessary care entirely — even, at times, in cases of emergency. See Pl. Mot., Exh. 6 (Declaration of

Bamby Salcedo), ¶ 33 (stating that "[t]ransgender and gender nonconforming people will likely delay necessary health care and preventative screenings due to fear of discrimination"); Carpenter Decl., ¶ 20; Cummings Decl., ¶ 18.

In either case, patients expose themselves to "significant adverse health consequences" and undercut the effectiveness of their eventual treatment. See Shafi Decl., ¶ 21; see also Pumphrey Decl., ¶ 12; Cummings Decl., ¶ 24. For instance, patients who conceal a same-sex sexual history may not be screened for HIV or other relevant diseases, and they may not be prescribed necessary preventive medications on account of misdiagnoses. See Shafi Decl., ¶ 21; Henn Decl., ¶ 16; Bolan Decl., ¶¶ 13–15. The consequences for the health-provider Plaintiffs are evident: a patient pool with conditions that are increasingly advanced at diagnosis and less responsive to treatment, thus requiring the organizations to expend resources on costlier and more challenging care, especially when administered in cases of emergency. See Cummings Decl., ¶¶ 9, 16 (explaining that 2020 Rule "increases patients' reluctance to seek care for both minor and serious conditions" and "exacerbate[s]" number of patients who arrive at LA LGBT "with acute medical conditions that could have been avoided but-for the[ir] reluctance to seek routine and necessary medical care for fear of discrimination"); Henn Decl., ¶¶ 18–21 (describing how deferral of care "strain[s] Whitman-Walker's resources," "increase[s] costs," and "make[s] it harder for our health care providers to treat the patients"); Bolan Decl., ¶ 11; Carpenter Decl., ¶¶ 11–12, 15.

Each of these qualifies as an injury to the health-provider Plaintiffs' interests. Increased demand and fear of discrimination "perceptibly impair [their] ability to provide services," Food & Water Watch, 808 F.3d at 919 (citation omitted), thus "inhibit[ing]" their "daily operations" by forcing them to deliver costlier and more difficult treatment to a growing number of patients.

PETA II, 797 F.3d at 1094. "These are real, concrete obstacles to [Plaintiffs'] work, rather than the kind of 'abstract concern that does not impart standing.'" PETA v. USDA, 7 F. Supp. 3d 1, 8 (D.D.C. 2013) (quoting Nat'l Taxpayers Union, Inc. v. United States, 68 F.3d 1428, 1433 (D.C. Cir. 1995)), aff'd, 797 F.3d at 1089; see also Dist. of Columbia v. USDA, 444 F. Supp. 3d 1, 40–42 (D.D.C. 2020) (determining that plaintiff organization suffered injury-in-fact by showing that agency action would cause individuals to turn to organization's programs, thereby "increasing demand and forcing [the organization] to divert resources" away from other programs in order to service such demand); Fair Emp't Council of Greater Wash., Inc. v. BMC Mktg. Corp., 28 F.3d 1268, 1276 (D.C. Cir. 1994) (finding organizational standing satisfied where protested action "might increase the number of people in need of counseling . . . [and] reduce[ ] the effectiveness of any given level of [the organization's] outreach efforts").

These harms, moreover, directly frustrate Plaintiffs' missions "to offer affirming community-based health and wellness services to all." Shafi Decl., ¶¶ 3, 40; see also Cummings Decl., ¶¶ 3–4, 33 (similar). And it is evident that the organizations will "use[] [their] resources to counteract" such injury, spending more money and exerting more manpower at a time when resources are already stretched thin. Food & Water Watch, 808 F.3d at 919 (quoting PETA II, 797 F.3d at 1093).

Resisting such a conclusion, Defendants first assert that Plaintiffs "cannot explain how the 2020 Rule might injure them as opposed to others not before the Court." ECF No. 42 (Def. Opp.) at 11–12. On the contrary, far from asserting a mere "generalized grievance," Plaintiffs have alleged concrete and particularized financial and programmatic injuries affecting them uniquely as health-care providers. See Duke Power Co. v. Carolina Envt'l Study Grp., Inc., 438 U.S. 59, 80 (1978).

Next, Defendants characterize Plaintiffs' alleged "financial harm" as "fatally unspecific." ECF No. 48 (Def. Surreply) at 10. To the extent the Government suggests that Plaintiffs need provide a greater accounting of their alleged financial injury than they already have, see ECF No. 46 (Aug. 3, 2020, Hearing Transcript) at 32, they are mistaken. The precise amount of economic harm a plaintiff suffers is "irrelevant," as even "[a] dollar . . . is still an injury-in-fact for standing purposes." Carpenters Indus. Council, 854 F.3d at 5–6; see also Czyzewski v. Jevic Holding Corp., 137 S. Ct. 973, 983 (2017) ("For standing purposes, a loss of even a small amount of money is ordinarily an 'injury.'"). And although Defendants attack Plaintiffs' allegations as "amorphous," they never engage with them specifically, instead opting to rely on non-binding authority that is far afield. See Def. Surreply at 10. In International Academy of Oral Medicine & Toxicology v. U.S. Food & Drug Administration, 195 F. Supp. 3d 243 (D.D.C. 2016), for instance, the court rejected the plaintiff organization's standing argument on the unremarkable ground that it had not specifically identified a member who claimed she would suffer future injury, as required to assert representational — as opposed to organizational — standing. Id. at 264–65. And in Freedom Watch, Inc. v. McAleenan, 442 F. Supp. 3d 180 (D.D.C. 2020), the plaintiff organization offered only "bare assertions" devoid of any "factual allegations to establish, with any level of clarity," how the Government's refusal to conduct a criminal investigation of a third party would generate a "downturn in financial support" for the organization. Id. at 187, 191–92.

Defendants finally argue that Plaintiffs' alleged harm is "conjectural." Def. Opp. at 12 (citing Clapper v. Amnesty Int'l USA, 568 U.S. 398, 401 (2013)). Specifically, they contend that Plaintiffs' claim is premised on a "risk of discrimination in health care" — namely, the belief that third-party medical providers "may choose to deny individuals certain procedures or

coverage" or otherwise engage in discrimination against LGBTQ patients. Id. That outcome, Defendants insist, is "far from inevitable." Id. Another court just last week endorsed this reasoning, holding that the State of Washington lacked standing to challenge the 2020 Rule because it had not demonstrated that the Rule would "yield an increase in discrimination against LGBTQ individuals or a decrease in available healthcare or health coverage." Washington v. HHS, No. 20-1105, slip op. at 19 (W.D. Wash. Aug. 28, 2020).

The health-provider Plaintiffs, however, do not stake their primary injury-in-fact claim on this potentiality. Instead, they assert that LGBTQ patients' fear of discrimination at the hands of third parties — regardless of whether such discrimination ultimately occurs — will cause individuals to turn to Plaintiff organizations for care, thereby necessarily generating financial and operational burdens that "impair[] [Plaintiffs'] ability to provide services." Food & Water Watch, 808 F.3d at 919 (citation omitted). That result is far from "conjectural"; as demonstrated above, anxiety surrounding the possibility of discrimination and denial of treatment is substantially likely to provoke such behavior. See *supra* at 21–23. The result, similarly, is easily distinguished from the highly attenuated chain of possibilities deemed insufficient in Clapper, where the harm "would not have arisen unless a series of independent actors, including intelligence officials and Article III judges, exercised their independent judgment in a specific way." Attias, 865 F.3d at 628 (citing Clapper, 568 U.S. at 410–14). Plaintiffs, accordingly, have demonstrated a "substantial risk" that the alleged harm "will occur," Susan B. Anthony List v. Driehaus, 573 U.S. 149, 158 (2014) (quoting Clapper, 568 U.S. at 414 n.5), thus rendering it "sufficiently 'imminent' for standing purposes." Attias, 865 F.3d at 627 (quoting Food & Water Watch, 808 F.3d at 915).

ii. Causation and Redressability

Having addressed the common injuries-in-fact for four of Plaintiffs' claims, the Court now considers independently the other standing requirements — *viz.*, causation and redressability — for each of those counts.

(a) Elimination of 2016 Rule's Definition of Sex Discrimination

Plaintiffs first challenge HHS's repeal of the 2016 Rule's definition of discrimination "on the basis of sex," which explicitly prohibited discrimination based on sex stereotyping and gender identity. They must show that the injuries described above are "fairly . . . trace[able] to" such repeal. Lujan, 504 U.S. at 560–61 (alterations in original) (citation omitted). Where causation depends on the conduct of a third party not before the court, "standing is not precluded, but it is ordinarily substantially more difficult to establish." Id. at 562 (citation and internal quotation marks omitted). Plaintiffs must show that the third party will act "in such manner as to produce causation." Id. A permissible theory of standing "does not rest on mere speculation about the decisions of third parties; it relies instead on the predictable effect of Government action on the decisions of third parties." Dep't of Commerce v. New York, 139 S. Ct. 2551, 2566 (2019).

The health-provider Plaintiffs successfully clear the bar. Their proposed causal chain is relatively simple: the 2020 Rule's elimination of the prior explicit prohibitions on discrimination based on sex stereotyping and gender identity instilled in LGBTQ patients a fear of discrimination at the hands of external providers, thereby causing Plaintiff organizations to suffer the financial and operational consequences of higher demand. Of course, as this theory makes clear, it is the patients' decisions to seek services from the health-provider Plaintiffs that most immediately causes their harm. The law is clear, however, that Plaintiffs may establish standing

based on the actions of third parties, so long as there is "substantial evidence of a causal relationship between the government policy and the third-party conduct, leaving little doubt as to causation." Americans for Safe Access v. Drug Enforcement Admin., 706 F.3d 438, 446 (D.C. Cir. 2013) (citation omitted). Indeed, the D.C. Circuit has routinely found causation established in cases where the relevant "third-party conduct . . . is voluntary but reasonably predictable." Competitive Enter. Inst. v. FCC, No. 18-1281, 2020 WL 4745272, at *8 (D.C. Cir. Aug. 14, 2020); see also, e.g., Energy Future Coal. v. EPA, 793 F.3d 141, 144 (D.C. Cir. 2015); Tozzi v. HHS, 271 F.3d 301, 308–10 (D.C. Cir. 2001); Competitive Enter. Inst. v. NHTSA, 901 F.2d 107, 116–17 (D.C. Cir. 1990).

Plaintiffs have provided "substantial evidence," Americans for Safe Access, 706 F.3d at 446 (citation omitted), that the 2020 Rule's elimination of the explicit prohibition on discrimination based on sex stereotyping and gender identity has caused — and will continue to cause — patients to fear discrimination at the hands of third parties. See, e.g., Cummings Decl., ¶¶ 11–12 (explaining that elimination of these prohibitions "caused immediate panic" among LA LGBT patients and leads them to "fear discrimination"); Salcedo Decl., ¶ 23 (transgender woman stating that "[t]he [2020] Rule's elimination of the clear regulatory protections in the 2016 Final Rule . . . heightens my fears, as it communicates to health care providers that such discrimination is acceptable"); Pumphrey Decl., ¶ 9 (stating that repeal of prohibitions "will on its own invoke increased fear and trauma among LGBTQ patients"); Henn Decl., ¶ 7; Pl. Mot., Exh. 7 (Declaration of Ariana Inurritegui-Lint), ¶ 48; Exh. 13 (Declaration of Roy Harker), ¶ 14. It is that rational fear that will drive LGBTQ patients to rely increasingly on the services of the health-provider Plaintiffs. See *supra* at 21–23. The resulting harm that these organizations will likely suffer — principally, having to expend more resources to care for patients — is therefore

"attributable to" the 2020 Rule. Block v. Meese, 793 F.2d 1303, 1308 (D.C. Cir. 1986); see also Scenic Am., Inc. v. DOT, 983 F. Supp. 2d 170, 179–80 (D.D.C. 2013).

Defendants nonetheless argue that Simon v. Eastern Kentucky Welfare Rights Organization, 426 U.S. 26 (1976), precludes a finding of causation here. See Def. Opp. at 9–10; Def. Surreply at 4. But Simon does not stand for the proposition that Plaintiffs cannot establish causation when their injury stems most immediately from third-party conduct. See Block, 793 F.2d at 1309 ("It is impossible to maintain, of course, that there is no standing to sue regarding action of a defendant which harms the plaintiff only through the reaction of third persons."). The case, instead, turned on its particular facts. The plaintiffs there claimed that the Internal Revenue Service's favorable tax treatment of certain hospitals caused those hospitals to refrain from providing indigent patients free care. See 426 U.S. at 42–44. The Court only dismissed for lack of standing because the plaintiffs' allegations failed to show that the hospitals would have chosen to provide free care but for the challenged benefit. Id. This case, by contrast, involves "very different" evidence. Competitive Enter. Inst., 2020 WL 4745272, at *8. Plaintiffs have provided ample support for their allegation that they will likely suffer financial and operational injury as a result of the 2020 Rule. Id. (finding Simon inapplicable where plaintiff established a reasonable likelihood of harm from Government action, even when such harm turned on third-party conduct).

Although Defendants do not invoke it in the context of causation, Clapper likewise does not preclude a finding that Plaintiffs' injuries are fairly traceable to the 2020 Rule. There, the Supreme Court explained that plaintiffs do not have standing simply because they incur certain costs as a "reasonable reaction" to a risk of harm when that harm "is not certainly impending." Clapper, 568 U.S. at 416. The Court was concerned about the potential for plaintiffs to

"manufacture standing merely by inflicting harm on themselves based on their fears of hypothetical future harm that is not certainly impending." Id. No such hazard exists here. As the health-provider Plaintiffs explain, they will be forced to incur financial and operational costs because LGBTQ patients — independent third parties — will fear discrimination as a result of the 2020 Rule and respond accordingly. It is the substantial likelihood of increased demand caused by the patients' own independent decisions in response to the 2020 Rule that will generate Plaintiffs' injury, not the reactions of the organizations themselves to a risk of future discrimination as a result of the Rule. Because Plaintiffs' harm derives from the uncoordinated actions of non-plaintiffs, the organizations are not "inflicting harm on themselves," and Clapper thus does not control.

With causation satisfied, the Court now turns to redressability. As a reminder, "it must be 'likely,' as opposed to merely 'speculative,' that [Plaintiffs'] injury will be 'redressed by a favorable decision.'" Lujan, 504 U.S. at 561 (citation omitted); Int'l Ladies' Garment Workers' Union v. Donovan, 722 F.2d 795, 811 (D.C. Cir. 1983) (explaining that plaintiffs do not have "to prove that granting the requested relief is certain to alleviate' their injury"). "Causation and redressability typically 'overlap as two sides of a causation coin.'" Carpenters Indus. Council, 854 F.3d at 6 n.1 (quoting Dynalantic Corp. v. Dep't of Defense, 115 F.3d 1012, 1017 (D.C. Cir. 1997)). For "if a government action causes an injury, enjoining the action usually will redress that injury." Id.

Redressability here, however, involves an unexpected wrinkle, one involving the previously discussed decision from the Northern District of Texas. As a reminder, the 2016 Rule specifically defined Section 1557's prohibition on sex discrimination to include "discrimination on the basis of . . . sex stereotyping, and gender identity." 81 Fed. Reg. at 31,467 (formerly

codified at 45 C.F.R. § 92.4). Before the 2020 Rule was finalized, however, that Texas court vacated the "gender identity" portion of this definition. See Franciscan Alliance Order at ECF p. 3 ("[T]he Court VACATES the Rule insofar as the Rule defines 'On the basis of sex' to include gender identity . . . ."); see also Franciscan Alliance, 414 F. Supp. 3d at 945. That meant that the 2016 Rule's original prohibition on discrimination based on gender identity was no longer part of the regulation. As a result, even if this Court were to grant Plaintiffs their desired relief and enjoin HHS from enforcing its repeal of the 2016 definition, the resulting regulation would not contain any language barring gender-identity discrimination. Put differently, enjoining or vacating the 2020 Rule would not suddenly make gender-identity discrimination illegal under Section 1557 — or change how the regulatory text addresses gender-identity discrimination — because the relevant provision of the 2016 Rule was no longer in effect following Franciscan Alliance.

All Plaintiffs say in response is that the Supreme Court's recent decision in Bostock "abrogat[ed]" Franciscan Alliance, rendering its vacatur "a legal nullity." Pl. Reply at 3. Yet they identify no authority that would permit either this Court or HHS to disregard the final order of a district court vacating part of a regulation. Indeed, that vacatur remains final today, as the Government did not appeal the court's decision. When pressed at the hearing on this Motion, moreover, Plaintiffs insisted that they had also challenged other provisions that were not vacated. See Hrg. Tr. at 7. But Defendants' redressability argument is confined to this regulatory provision, see Def. Surreply at 3–4, vacatur of which renders the Court powerless to revive it. Cf. Charles H. Koch, Jr. & Richard Murphy, Admin. L. & Prac. § 10:29 (3d ed.) ("A court cannot, generally speaking, rewrite or 'fix' an agency's rule insofar as doing so would require the court to infringe on the agency's policymaking authority."). The Eastern District of New

York recently reached the same conclusion in a parallel case there. Walker, 2020 WL 4749859, at *7 (explaining that court "has no power to revive a rule vacated by another district court").

This result, however, does not completely doom Plaintiffs' challenge to this provision. That is because their claim is not confined to the "gender identity" language; they also contest HHS's elimination of the 2016 Rule's definition of sex discrimination as including discrimination based on sex stereotyping. See Pl. Reply at 5 (explaining that desired relief "would prohibit discrimination on the basis of gender identity and sex stereotypes") (emphasis added); Compl., ¶ 13. Franciscan Alliance, notably, did not vacate this latter definitional provision; the court's opinion never even mentioned it. See 414 F. Supp. 3d 928. Indeed, the court's final order explicitly stated that aside from the provision specifically vacated (and one other not relevant here), "[t]he remainder of 45 C.F.R. § 92 remains in effect." Franciscan Alliance Order at ECF p. 3.

Were this Court to enjoin the relevant provision of the 2020 Rule, therefore, Plaintiffs would be left with the 2016 Rule's prohibition on discrimination based on sex stereotyping. See Def. Opp. at 9 ("Enjoining the challenged 2020 Rule would leave plaintiffs with the non-vacated portions of the 2016 Rule."). That relief would clearly redress at least some of their injury. See Walker, 2020 WL 4749859, at *7 (finding redressability satisfied because "Franciscan Alliance did not address the concept of 'sex stereotyping' embodied in the 2016 Rule"); Defs. of Wildlife v. Gutierrez, 532 F.3d 913, 925 (D.C. Cir. 2008) (finding standing established when "order from the district court could redress appellants' injury, at least in part"). Just as eliminating the 2016 Rule's definition of "on the basis of sex" has and will increase fear of discrimination among LGBTQ patients, with the consequent harms for the health-provider Plaintiffs, reviving part of that prior provision will likely lessen those fears. It is far from "speculative," Lujan, 504 U.S. at

561 (citation omitted), to conclude that reinstating an explicit prohibition against discrimination based on sex stereotyping will affect the behavior of LGBTQ patients — especially when their alleged fear is directly attributable to the 2020 Rule, the arguable centerpiece of which eliminated language containing that prohibition. See, e.g., Shafi Decl., ¶ 34; Bolan Decl., ¶ 18; Henn Decl., ¶¶ 7, 19. Indeed, even HHS admits that the 2016 Rule "likely induced many covered entities to conform their policies and operations" to the regulation's definition of sex discrimination, and that elimination of that definition may cause some covered entities to "revert to the policies and practices they had in place before" the 2016 Rule. See 84 Fed. Reg. at 27,876.

In a brief attempt to escape this result, Defendants suggest that some providers could opt to avoid the strictures of Section 1557 by refusing to accept federal funds altogether. See Def. Opp. at 10; 42 U.S.C. § 18116(a) (applying restrictions to "any health program or activity, any part of which is receiving Federal financial assistance"). Defendants, however, fail to provide even a single instance in which an entity covered by Section 1557 has declined federal funding for the purpose of avoiding the provision's requirements. It defies belief that a "significant number" of covered entities would so surrender federal assistance, especially when there is no evidence of such behavior in the aftermath of the 2016 Rule. Action All. of Senior Citizens v. Heckler, 789 F.2d 931, 938–39 (D.C. Cir. 1986) (rejecting similar argument that redressability is not established because recipients of federal funding might surrender funding rather than comply with regulation).

Because a favorable ruling will likely redress at least some of Plaintiffs' injury, the Court finds that they have standing to attack the 2020 Rule's elimination of the 2016 Rule's prohibition on discrimination based on sex stereotyping.

(b) Incorporation of Title IX's Religious Exemption

Plaintiffs' challenge to the 2020 Rule's incorporation of Title IX's religious exemption similarly clears the causation and redressability bars. That exemption, to review, excuses certain religious organizations from Title IX's nondiscrimination mandate if application of such mandate would be inconsistent with the organization's "religious tenets." 20 U.S.C. § 1681(a)(3).

The analysis proceeds in similar fashion to that regarding Plaintiffs' challenge to the Rule's elimination of the sex-discrimination definition. Specifically, there is "substantial evidence" that HHS's newly and explicitly incorporated religious exemption will cause patients to fear discrimination at the hands of religiously affiliated providers, once again "leaving little doubt as to causation." Americans for Safe Access, 706 F.3d at 446 (citation omitted). As one declarant puts it, the 2020 Rule "will cause LGBTQ patients to attempt to hide their LGBTQ identities when seeking health care services, especially from religiously-affiliated health care organizations, in order to avoid discrimination." Harker Decl., ¶ 19; see also Bolan Decl., ¶ 17 (similar); Pl. Mot., Exh. 11 (Declaration of Adrian Shanker), ¶¶ 22–23 (stating that 2020 Rule's religious exemption will "exacerbate" number of LGBTQ patients who "remain closeted" while seeking health care out of fear of discrimination); Cummings Decl., ¶ 19 (explaining that "[t]ransgender and gender nonconforming clients are particularly likely to delay care as a result of the" 2020 Rule's religious exemption). Such apprehension, in turn, further contributes to increased demand for the services of the health-provider Plaintiffs and their accompanying financial and operational injuries.

Defendants yet again assail Plaintiffs' causation argument as unduly speculative, contending that it "assumes that a provider who would otherwise refuse to offer services as a

result of the dictates of his or her religion, would be willing to violate those same beliefs in order to comply with a hypothetical HHS regulation." Def. Surreply at 8. As already explained, however, Plaintiffs' argument for standing rests not on the possibility of third-party, religiously affiliated providers actually discriminating against LGBTQ patients, but rather on patients' genuine fear of encountering discrimination when seeking care from such institutions. It is that apprehension, immediately stimulated by the 2020 Rule's incorporation of Title IX's religious exemption, that contributes to the particular organizational injuries the health-provider Plaintiffs have asserted. Far from resting on "mere speculation about the decisions of third parties" — *viz.*, LGBTQ patients — therefore, Plaintiffs' theory "relies instead on the predictable effect of Government action" on such decisions. Dep't of Commerce, 139 S. Ct. at 2566.

"Having found that [Plaintiffs] satisf[y] the element of causation, the issue of redressability is straightforward." Ciox Health, LLC v. Azar, 435 F. Supp. 3d 30, 52 (D.D.C. 2020). Just as explicitly incorporating Title IX's religious exemption into Section 1557 spurred LGBTQ patients' fear of discrimination, enjoining such incorporation would likely palliate such fear and "redress [Plaintiffs'] injury, at least in part." Defs. of Wildlife, 532 F.3d at 925.

(c) Section 1554 and Establishment Clause

Plaintiffs claim that the 2020 Rule violates Section 1554's prohibition on, *inter alia*, regulations that "create[] any unreasonable barriers to the ability of individuals to obtain appropriate medical care" or "impede[] timely access to health care services." 42 U.S.C § 18114(1)–(2); Pl. Mot. at 26. They also contend that the 2020 Rule "facilitate[s] the religious beliefs of objecting providers, without exception," thereby running afoul of the Establishment Clause. See Pl. Mot. at 33. With the above discussion in mind, standing for each challenge is readily established.

While Plaintiffs' opening brief does not state the contours of their Section 1554 claim with much particularity, see Pl. Mot. at 26, their reply makes clear that the challenge is premised in part on the 2020 Rule's elimination of the explicit prohibition on discrimination based on sex stereotyping and gender identity, as well as its incorporation of religious exemptions. See Pl. Reply at 19–20. Their Establishment Clause claim, in turn, rests squarely on HHS's incorporation of Title IX's religious exemption. See Pl. Mot. at 33. Their standing to assert each claim thus follows directly from their standing to challenge the individual regulatory provisions as arbitrary and capricious. Defendants offer no reason why the analysis might differ.

b. Additional Organizational-Injury Claims

With standing thus established for the four "common-injury" claims, the Court now separately considers five additional counts that also rely on alleged organizational injury. It ultimately renders a split decision: Plaintiffs have successfully established standing for their challenges to HHS's elimination of: 1) the 2016 Rule's prohibition on categorical coverage exclusions for gender-affirming care; and 2) its notice requirements. They have not, however, demonstrated a substantial likelihood of standing for their claims that the 2020 Rule: 3) improperly restricted Section 1557's scope to Title I programs or activities; 4) improperly excluded health insurers from Section 1557's coverage; and 5) erroneously interpreted Section 1557's legal standard.

i. Elimination of Prohibition on Categorical Coverage Exclusions

In support of its challenge to HHS's elimination of the 2016 Rule's prohibition on categorical coverage exclusions for gender-affirming care, Plaintiff Whitman-Walker asserts a monetary injury — namely, that it will obtain reduced reimbursements from insurers that scale back their coverage of such treatment. See Shafi Decl., ¶ 35. Whitman-Walker hosts many

patients who require hormone therapy and affirming mental-health services. Id. As a result of the 2020 Rule's elimination of the 2016 Rule's prohibition on coverage exclusions for such care, Whitman-Walker asserts it will experience a monetary loss in the form of lower reimbursements. Id. That loss will further "undermin[e] the organization's ability to perform its fundamental programmatic services," Nat'l Veterans Legal Servs. Program, 2016 WL 4435175, at *6, and force it to rely more heavily on resources from other sources, including increasing charges to patients and drawing from its already depleted fundraising and grant revenue. See Shafi Decl., ¶ 35.

Defendants characterize this asserted injury as unduly speculative, pointing out that the 2016 Rule "prohibited only categorical exclusions — it did not speak to individual determinations." Def. Surreply at 5. They thus maintain that "a covered entity may choose to deny a claim" under either the 2016 or 2020 Rule. Id. The mere fact that insurers under the 2016 Rule could deny coverage based on individual determinations, however, does not vitiate the reality of a substantially increased risk of injury posed by a categorical exclusion. It is by no means speculative to conclude that, under the 2020 Rule, certain insurers will deny reimbursement for treatment they previously covered. See Shanker Decl., ¶ 28 (asserting that removing coverage requirements for insurance providers will cause patients to "most certainly experience increased denials of coverage for their medically necessary health care"); Carpenter Decl., ¶ 13 (mentioning patients' fear that "they will no longer have access to hormone therapy to treat gender dysphoria" as result of regulatory changes). Indeed, HHS itself admits that some insurers will not maintain coverage consistent with the 2016 Rule's requirements. See 85 Fed. Reg. at 37,181. Plaintiffs need only show a "substantial risk" of the alleged harm, not an

outright certainty; they have carried that burden. Susan B. Anthony, 573 U.S. at 158; Attias, 865 F.3d at 627.

They likewise successfully establish causation and redressability. The D.C. Circuit has repeatedly held that "injurious private conduct is fairly traceable to the administrative action contested in the suit if that action authorized the conduct or established its legality." Tel. & Data Sys., Inc. v. FCC, 19 F.3d 42, 47 (D.C. Cir. 1994); see also Nat'l Wrestling Coaches Ass'n v. Dep't of Educ., 366 F.3d 930, 940 (D.C. Cir. 2004), abrogation on other grounds recognized in Perry Capital LLC v. Mnuchin, 864 F.3d 591 (D.C. Cir. 2017) (collecting cases). Here, the injurious private conduct — insurers' eliminating prohibitions on categorical coverage exclusions of gender-affirming care — was illegal under the 2016 Rule but made permissible by the 2020 Rule. See Tel. & Data Sys., 19 F.3d at 47. The requisite causation, therefore, exists. See Cares Cmty. Health v. HHS, 346 F. Supp. 3d 121, 127 (D.D.C. 2018) (finding injury fairly traceable to government action even though monetary injury caused by insurance company's modifying contract because such modification "would be unlawful" in absence of government action). An order restoring the 2016 Rule's prohibition on categorical coverage exclusions, moreover, would redress Plaintiffs' injury. See Nat'l Wrestling Coaches, 366 F.3d at 940–41 ("Causation and redressability thus are satisfied in this category of cases, because the intervening choices of third parties are not truly independent of government policy.").

ii. Elimination of Notice Requirements

Plaintiffs next challenge HHS's repeal of the 2016 Rule's requirement that covered entities provide various notices and taglines informing the public of their nondiscrimination and accessibility rights under Section 1557. Their alleged injury stemming from that repeal once

again centers on harm to the organizations themselves, most urgently in the form of increased costs.

According to Plaintiff Whitman-Walker, the 2016 Rule's notice and tagline provisions "are critical to ensure meaningful access to care." Shafi Decl., ¶ 32. Those provisions required that covered entities issue notice to the public that they provide, among other things, language-assistance services, including translated documents and oral interpretation. See 81 Fed. Reg. at 31,469 (formerly codified at 45 C.F.R. § 92.8); see also id. at 31,470 (formerly codified at 45 C.F.R. § 92.201) (detailing covered entities' language-access obligations). Plaintiffs argue that notice of the availability of such services is "crucial to promoting positive patient health outcomes" by way of ensuring full communication between patient and provider. See Henn Decl., ¶¶ 16, 25. Indeed, even HHS acknowledged that at least some covered entities likely "experienced an increase in translation services after the 2016 Rule." 85 Fed. Reg. at 37,233. Removal of such notices, in turn, renders it increasingly difficult for patients with limited English proficiency (LEP) to understand their rights to language services and how they can utilize them, thereby hindering access to meaningful health care. See Shafi Decl., ¶ 32 (explaining that LEP patients "will not be aware of their rights or the programs or services available to them when they go to other health care facilities"); Pumphrey Decl., ¶ 13; Henn Decl., ¶ 25; see also 85 Fed. Reg. at 37,233 (acknowledging record evidence that "removing the notice and taglines requirements may cause [LEP] individuals to delay care or not receive care until their medical issues are more severe and costlier to treat").

The implication for Whitman-Walker is clear: provision of costlier and more difficult treatment. As previously described, see *supra* at 21–23, inadequate care elsewhere leads to increased patient demand, as well as a patient pool with conditions that are increasingly

advanced at diagnosis and less responsive to treatment. The elimination of notice and tagline provisions once again perpetuates these concrete harms. See Shafi Decl., ¶ 33 (explaining that Whitman-Walker will experience "increased costs because its patients will come to us sicker as a result of inadequate care elsewhere"); Henn Decl., ¶ 25 (asserting that elimination of notice requirements will "diminish[] . . . meaningful access to health care" and will, in turn, "cause more patients to seek out care at Whitman-Walker"); see also Shanker Decl., ¶ 27 (stating that elimination of notice and tagline requirements will "make it much more difficult for transgender and gender nonconforming patrons . . . to understand their rights and how to advocate for such rights"); Salcedo Decl., ¶ 41 (explaining that without the notices, patients "will avoid seeking care until they feel they are sufficiently proficient in speaking and reading English, which will worsen their underlying and untreated medical conditions").

In response, Defendants insist that Plaintiff organizations "remain free to voluntarily provide the notices required by the 2016 Rule." Def. Opp. at 12. True, but irrelevant. As explained, the harm Plaintiffs experience occurs when other providers do not post notices. Defendants also misunderstand the scope of the present Motion. Their surreply contends exclusively that Plaintiffs lack standing to challenge HHS's changes to language-access provisions, in part because they have not demonstrated imminent harm. See Def. Surreply at 6–7; see also Def. Opp. at 25–26. While Plaintiffs' opening brief is admittedly ambiguous as to whether they challenge regulatory action in addition to HHS's repeal of the notice and tagline requirements, their reply concentrates nearly exclusively on the repeal of those latter provisions. See Pl. Reply at 14–16; see also Hrg. Tr. at 22–23 (Plaintiffs stating that present Motion focuses on this repeal). In any event, Plaintiffs' asserted injury does not require the Court to assume "a highly attenuated chain of possibilities." Clapper, 568 U.S. at 410. Rather, "a substantial risk of

harm exists already," simply by virtue of the elimination of the notice and tagline requirements, which Plaintiffs have demonstrated will likely bear tangible implications for Whitman-Walker's provision of services. See Attias, 865 F.3d at 629.

Causation and redressability, once again, are easily established. The injurious private conduct — namely, providers' declining to deliver notices of patients' health-care rights under Section 1557 — was illegal under the 2016 Rule, but made permissible by the 2020 Rule. That reality renders such conduct "fairly traceable to the administrative action contested." Tel. & Data Sys., 19 F.3d at 47. And an order restoring the 2016 Rule's notice and tagline requirement would redress Plaintiffs' injury because covered entities would once again be required to provide them. See Nat'l Wrestling Coaches, 366 F.3d at 940–41.

iii. Narrowing Scope of Covered Entities

As previewed above, Plaintiffs' standing arguments are not all successful; indeed, they encounter significantly rockier terrain with respect to the claims that follow. The Court begins with their dual contentions that the 2020 Rule 1) improperly restricted Section 1557's coverage to programs or activities administered by HHS under Title I of the ACA, as opposed to all of the agency's health programs and activities; and 2) improperly excluded entities principally engaged in providing health insurance from Section 1557's coverage. Their fleeting attempt to invoke standing to challenge these regulatory actions is muddled at best and does not enable the Court, at this juncture, to conclude that they have stated a constitutionally cognizable injury.

Plaintiffs cite several declaration excerpts in support of their standing to challenge HHS's narrowing of entities covered under Section 1557. See Pl. Reply at 6; Hrg. Tr. at 15. All, however, share common defects. Two declarations simply allege that such narrowing "will result in discrimination against LGBTQ patients." Shafi Decl., ¶ 28; see also Cummings Decl.,

¶ 31 (similar). The health-professional-association Plaintiffs similarly assert that the 2020 Rule "invites harassment and discriminatory treatment of GLMA members with regard[] to terms and conditions of employment based on their LGBTQ status." Pl. Mot., Exh. 12 (Declaration of Hector Vargas), ¶ 18; see also Harker Decl., ¶¶ 16–17 (contending that members "could lose regulatory protections from discrimination regarding . . . employment benefits" and "may be subjected to discrimination"). In addition, a GLMA member who works for the Indian Health Service — which, as a non-Title I program, would no longer be covered by Section 1557 — states that she "will no longer . . . be protected from discrimination in health care pursuant to Section 1557." Pl. Mot., Exh. 14 (Declaration of Deborah Fabian), ¶¶ 2, 5, 21. Finally, TransLatin@ Coalition members who rely on public-health-insurance coverage through Medicaid — which also would no longer enjoy Section 1557's protections — allege that they will suffer discrimination. See Inurritegui-Lint Decl., ¶¶ 56–58; Salcedo Decl., ¶¶ 38–39.

The Court cannot credit these bids for standing. To satisfy Article III's strictures, the reader will well recall, Plaintiffs must demonstrate that the alleged future injury is "imminent." Bennett v. Spear, 520 U.S. 154, 167 (1997); see also Whitmore, 495 U.S. at 158 ("Allegations of possible future injury do not satisfy the requirements of [Article] III."). To "shift[] injury from 'conjectural' to 'imminent,'" Plaintiffs must show that there is a "substantial . . . probability" of injury. Sherley, 610 F.3d at 74. Simply asserting, without any elaboration, that individuals will experience discrimination at the hands of Title I programs and health insurers does not "suffice[] to demonstrate the 'substantial probability'" that discrimination will actually occur as required to establish standing. Chamber of Commerce v. EPA, 642 F.3d 192, 201 (D.C. Cir. 2011). Equally glaring is the absence of any explanation as to how Plaintiffs' alleged injury is caused by these regulatory actions. That is, they never attempt to demonstrate how narrowing the scope of

covered entities will give rise to injury, let alone provide "substantial evidence" in support of such a "causal relationship." Americans for Safe Access, 706 F.3d at 446 (citation omitted).

Separately, Plaintiff Bradbury-Sullivan Center suggests that it "no longer will be able to rely" on the 2016 Rule's "clear guidance" when advocating for patrons "when they encounter . . . insurance coverage exclusions." Pl. Reply at 8 (citing Shanker Decl., ¶¶ 8-9). Even assuming that the elimination of such guidance sufficiently "impair[s] [its] ability to provide services," nowhere does Bradbury-Sullivan explain how it has or will "use[] its resources to counteract that harm" — specifically, its alleged diminished ability to advocate on behalf of patients to insurers. See Food & Water Watch, 808 F.3d at 919 (citation omitted).

While Plaintiffs' inability to establish "a substantial likelihood of standing" requires denial of their present Motion with respect to these two claims regarding the scope of Section 1557's coverage, this is not necessarily the end of the line. The Court does not rule out the potential for Plaintiffs to better support their standing argument in the future with revamped allegations. See Food & Water Watch, 808 F.3d at 913. For instance, their briefs contain no mention of representational standing, which would provide them a chance to assert standing premised on future harm to their members and patients. See Chamber of Commerce, 642 F.3d at 199 (representational-standing criteria); Summers v. Earth Island Inst., 555 U.S. 488, 498 (2009) (requiring Plaintiffs to "make specific allegations establishing that at least one identified member had suffered or would suffer harm"). To be successful, of course, any such effort would need to address the various shortcomings identified in this Opinion.

iv. Section 1557 Legal Standard

The Court need not expend much effort in concluding that Plaintiffs similarly lack standing to assert their final Section 1557 claim. To spell out the precise dispute: Section 1557

states that "[t]he enforcement mechanisms provided for and available under such title VI, title IX, section [504 of the Rehabilitation Act], or such Age Discrimination Act shall apply for purposes of violations of this subsection." 42 U.S.C. § 18116(a). The 2020 Rule requires would-be plaintiffs to employ the particular enforcement mechanism and accompanying legal standard available under each statute, depending on the precise ground of discrimination asserted. See 85 Fed. Reg. at 37,202. In other words, a litigant bringing a claim based on race discrimination in violation of Title VI cannot employ the enforcement mechanism available for sex discrimination under Title IX. Plaintiffs, on the other hand, contend that Section 1557 created a new, health-specific, anti-discrimination cause of action subject to a singular standard. By their lights, Section 1557 allows a plaintiff to invoke the enforcement mechanism of any of the incorporated statutes for a health-discrimination claim, regardless of the particular type of discrimination alleged. See Pl. Mot. at 27.

Plaintiffs' theory of standing for this challenge is murky, to say the least. Nowhere do they suggest that HHS's interpretation of the standard for Section 1557 claims causes LGBTQ individuals to fear discrimination, or even that it exposes them to a heightened risk of discrimination. Nor do Plaintiffs contend that the regulatory action causes them organizational injury. Instead, they briefly reference excerpts from declarations emphasizing the challenges posed by the possibility of intersectional discrimination — that is, discrimination based on multiple protected grounds. According to one declarant, "Rather than being able to assert claims under a single legal standard, intersectional discrimination claims will be subject to different standards, enforcement mechanisms, and remedies based on which characteristics are at issue." Salcedo Decl., ¶ 37. That result, in turn, will "have a particularly harmful effect" on claimants "because discrimination based on sexual orientation, gender identity, transgender status, national

origin, disability, and LEP status does not occur in an identity vacuum." Inurritegui-Lint Decl., ¶ 52; see also ECF No. 37, Exh. 1 (AARP Amicus Brief) at 10–12 (describing intersectional discrimination experienced by LGBTQ older adults).

Much like before, however, Plaintiffs have not established that any future discrimination — especially discrimination causing an individual to actually sue under Section 1557 — would be sufficiently "imminent" to qualify as a valid injury-in-fact. Summers, 555 U.S. at 493. Even if it were, Plaintiffs could not plausibly allege that such discrimination would be "fairly traceable" to HHS's interpretation of Section 1557's legal standard in the 2020 Rule. Id.

The proper context for quarrels surrounding the legal standard for Section 1557 claims would be an actual lawsuit bringing such a claim. There, a plaintiff could argue that Section 1557 permits her to assert various discrimination counts under a single legal standard, and that HHS's interpretation to the contrary is inconsistent with the statutory text. Indeed, numerous courts entertaining claims of discrimination under Section 1557 have grappled with these precise arguments. See, e.g., Briscoe v. Health Care Serv. Corp., 281 F. Supp. 3d 725, 737–38 (N.D. Ill. 2017); York v. Wellmark, Inc., No. 16-627, 2017 WL 11261026, at *16–18 (S.D. Iowa 2017); Galuten *ex rel.* Galuten v. Williamson Med. Ctr., No. 18-519, 2019 WL 1546940, at *5 (M.D. Tenn. 2019). The posture of this case does not permit this Court to join them.

For these reasons, Plaintiffs cannot establish a "substantial likelihood of standing" to challenge HHS's interpretation of Section 1557's legal standard. Electronic Privacy Info. Ctr., 878 F.3d at 377.

B. Third-Party Standing

While it now emerges from the depths of its organizational-standing dive, having found standing on six of the nine claims analyzed, the Court's jurisdictional work is not complete. It

must now consider whether Plaintiffs can assert the rights of third-party LGBTQ patients to bring three remaining constitutional counts.

Plaintiffs contend that the 2020 Rule runs afoul of the Fifth Amendment's guarantees of equal protection and substantive due process, as well as the First Amendment's promise of free speech. Specifically, they claim that the regulation 1) "discriminates on the basis of sex, transgender status, and sexual orientation," in violation of equal protection; 2) impedes "the right to live openly and express oneself consistent with one's sexual orientation or gender identity," in violation of substantive due process; and 3) "impermissibly chills LGBTQ patients . . . from being open about their gender identity, transgender status, or sexual orientation," in violation of the First Amendment. See Pl. Mot. at 28, 31. These claims do not invoke organizational injuries, but rather are clearly premised on the rights of individuals — that is, LGBTQ people.

While the organizational Plaintiffs never specify the precise basis for their standing to assert these constitutional counts, several purport to bring claims on behalf of their patients or members. See, e.g., Compl., ¶ 32 (health-provider Plaintiffs assert claims "on behalf of their patients and recipients of services"); Pl. Reply at 7–8 (arguing that health-provider Plaintiffs satisfy criteria to bring claims on behalf of their patients). The Court, accordingly, will examine whether they may do so.

A litigant "generally must assert his own legal rights and interests, and cannot rest his claim to relief on the legal rights or interests of third parties." Warth v. Seldin, 422 U.S. 490, 499 (1975). That principle, however, is far from "absolute," as courts have recognized that there are circumstances in which it is "necessary to grant a third party standing to assert the rights of another." Kowalski v. Tesmer, 543 U.S. 125, 129–30 (2004). A plaintiff may bring suit on behalf of a third party upon satisfying three criteria: 1) the plaintiff "must have suffered an

'injury in fact,' thus giving him or her a 'sufficiently concrete interest' in the outcome of the issue in dispute"; 2) the plaintiff "must have a close relation to the third party"; and 3) "there must exist some hindrance to the third party's ability to protect his or her own interests." Powers v. Ohio, 499 U.S. 400, 411 (1991) (quoting Singleton v. Wulff, 428 U.S. 106, 112–16 (1976)). Because Plaintiffs satisfy these criteria with respect to the third parties in question — *i.e.*, their LGBTQ patients — they may assert equal-protection, substantive-due-process, and free-speech claims on their behalf.

The first prong is "easily satisfied." Lepelletier v. FDIC, 164 F.3d 37, 43 (D.C. Cir. 1999). As discussed above, the health-provider Plaintiffs have suffered an injury in fact — financial and operational harm — thus giving them a "'sufficiently concrete interest' in the outcome of the issue in dispute." Powers, 499 U.S. at 411 (quoting Singleton, 428 U.S. at 112).

The second criterion also goes Plaintiffs' way. The requirement that a plaintiff have a "close relation" to the relevant third party, Powers, 499 U.S. at 411, is "to ensure that the plaintiff will act as an effective advocate for the third party." Lepelletier, 164 F.3d at 43 (citation omitted). For the requirement to be fulfilled, "the relationship between the litigant and the third party may be such that the former is fully, or very nearly, as effective a proponent of the right as the latter." Singleton, 428 U.S. at 115; see also Lepelletier, 164 F.3d at 45 (remarking that third-party standing "does not require a perfect match" between interests).

Here, "there can be no doubt" that the health-provider Plaintiffs will be "motivated, effective advocate[s]" for their LGBTQ patients. Powers, 499 U.S. at 414. Whitman-Walker, for instance, "has a special mission to serve the LGBTQ community" and provides a range of community-based health and wellness services. See Compl., ¶ 37; Shafi Decl., ¶ 3. Nearly 45% of its patients identified as lesbian, gay, bisexual, or otherwise non-heterosexual, and more than

10% identified as transgender or gender nonconforming. See Compl., ¶ 37. Whitman-Walker even has an in-house legal-services department that exists to help LGBTQ patients combat discriminatory barriers to accessing quality health care. See Shafi Decl., ¶ 16. Just as the elimination of the 2016 Rule's explicit prohibition on discrimination based on sex stereotyping and gender identity and incorporation of Title IX's religious exemption will likely cause Whitman-Walker financial and operational injury, those same provisions instill in many LGBTQ patients a heightened fear of discrimination that will lead to worsened health outcomes. It seems clear that Whitman-Walker shares a "common interest" with LGBTQ patients, Powers, 499 U.S. at 413, such that the organization will serve as "an effective advocate" for them. Lepelletier, 164 F.3d at 43 (citation omitted).

Defendants do not contest any of the above. Instead, they briefly contend that Plaintiffs do not have a "close relation" with their potential future patients "who may experience alleged discrimination as a result of visiting other healthcare providers." Def. Surreply at 10. There are multiple problems with this argument. First, some of the individuals on whose behalf the health-provider Plaintiffs assert claims appear to be current patients. See Compl., ¶ 32; Pl. Reply at 7. For instance, those Plaintiffs maintain that the 2020 Rule undermines their ability to treat current patients by contributing to considerable financial and operational challenges. See Shafi Decl., ¶¶ 34–36; Carpenter Decl., ¶¶ 12, 16; Cummings Decl., ¶ 33. Defendants do not suggest the absence of a "close relation" in these circumstances.

In any event, Defendants are wrong to suggest that the health-provider Plaintiffs cannot assert the rights of LGBTQ patients they might treat in the future. The Supreme Court recently observed that "[w]e have long permitted abortion providers to invoke the rights of their actual or potential patients in challenges to abortion-related regulations." June Med. Servs. LLC v. Russo,

140 S. Ct. 2103, 2118 (2020) (plurality opinion) (emphasis added) (citing cases); see also id. at 2139 n.4 (Roberts, C.J., concurring in the judgment) (agreeing with plurality's third-party-standing analysis). There is no reason to think it should be any different in the case of LGBTQ health-care providers. To be sure, and as Defendants point out, Kowalski v. Tesmer declined to allow attorneys to assert the rights of future, "as yet unascertained" criminal defendants. See 543 U.S. at 130–31; Def. Surreply at 10. In that situation, however, the class of potential third parties could have been literally any person. By contrast, the health-provider Plaintiffs' present bid involves a far more limited universe of third parties — LGBTQ individuals seeking health care. And that universe bears notable resemblance to the similarly confined pool of women seeking abortions, where physicians can invoke the rights of unknown potential patients. Plaintiffs, accordingly, satisfy the second prong of the Powers test.

Finally, Plaintiffs make it a trifecta by successfully showing that there exists "some hindrance" to third-party patients' "ability to protect [their] own interests." Powers, 499 U.S. at 411. "There is no denying that transgender individuals face discrimination, harassment, and violence because of their gender identity." Whitaker v. Kenosha Unified Sch. Dist., 858 F.3d 1034, 1051 (7th Cir. 2017). Numerous courts have recognized that disclosure of transgender status may expose individuals to "a substantial risk of stigma, discrimination, intimidation, violence, and danger." Arroyo Gonzalez v. Rossello Nevares, 305 F. Supp. 3d 327, 333 (D.P.R. 2018); see also, e.g., F.V. v. Barron, 286 F. Supp. 3d 1131, 1137–38 (D. Id. 2018); Ray v. Director, No. 18-272, 2018 WL 8804858, at *1 (S.D. Ohio Apr. 5, 2018). Plaintiffs have alleged the same here. See Bolan Decl., ¶ 7 ("Many if not most of the individuals in our very diverse patient population face considerable stigma and discrimination."); Inurritegui-Lint Decl., ¶ 28; Salcedo Decl., ¶ 31; Shanker Decl., ¶ 21. Indeed, this situation closely resembles Singleton,

where the Supreme Court allowed physicians to assert the rights of women seeking abortions after noting that they "may be chilled from such assertion by a desire to protect the very privacy of [their] decision[s] from the publicity of a court suit." 428 U.S. at 117–18.

All Defendants say in response is that the fact that LGBTQ patients themselves sued as plaintiffs to challenge the 2020 Rule in another jurisdiction "undercuts plaintiffs' claim that their own patients are prevented from mounting challenges of their own." Def. Surreply at 10 (citing Walker v. Azar, No. 20-2834 (E.D.N.Y. 2020)). Yet the final Powers prong "does not require an absolute bar from suit." Pa. Psychiatric Soc. v. Green Spring Health Servs., Inc., 280 F.3d 278, 290 (3d Cir. 2002). It is enough that "patients' fear of stigmatization . . . operates as a powerful deterrent to bringing suit." Id.; see also id. at 290 n.14 (explaining that "cases do not demand an absolute impossibility of suit in order to fall within the [impediment] exception") (alteration in original) (quoting 15 James Wm. Moore et al., Moore's Federal Practice § 101.51 [3][c]); Singleton, 428 U.S. at 117–18 (acknowledging that suit could have been brought under pseudonym, but nevertheless finding third-party standing when woman's desire to protect privacy could discourage her from suing). Plaintiffs have made that showing here.

The health-provider Plaintiffs, accordingly, have standing to assert the equal-protection, substantive-due-process, and free-speech rights of third-party LGBTQ patients.

IV. Analysis

With its protracted jurisdictional prelude finally concluded, the Court may now finally turn to the four preliminary-injunction factors. It separately looks at likelihood of success on the merits and irreparable harm before jointly considering the balance of the equities and the public interest.

A. Likelihood of Success on the Merits

As to the first prong, the Court finds that Plaintiffs have shown their likelihood of success with respect to their claims that HHS: 1) improperly eliminated explicit prohibitions within the 2016 Rule's definition of sex discrimination; and 2) improperly incorporated Title IX's religious exemption into Section 1557. They do not fare as well on the remaining counts for which they have demonstrated standing — namely, their claims that HHS: 3) erroneously eliminated the 2016 Rule's prohibition on categorical coverage exclusions for gender-affirming care; 4) improperly repealed the 2016 Rule's notice requirements; and 5) violated Section 1554. In addition, as a result of the Court's disposition of these claims, Plaintiffs' four constitutional counts entitle them to no further relief. The Court separately analyzes all of these questions.

1. *Elimination of 2016 Rule's Definition of Sex Discrimination*

As previously recounted, the 2016 Rule defined discrimination "[o]n the basis of . . . sex" to include "discrimination on the basis of . . . sex stereotyping, and gender identity." 81 Fed. Reg. at 31,467 (formerly codified at 45 C.F.R. § 92.4). The 2020 Rule, however, repealed this definition entirely, and none of its provisions contains any reference whatsoever to "sex stereotyping" or "gender identity." Plaintiffs attack this policy change as arbitrary and capricious, largely in light of the Supreme Court's intervening decision in Bostock. The Court concurs.

When an agency changes or reverses a prior policy, it must first "display awareness that it is changing position." FCC v. Fox Television Stations, Inc., 556 U.S. 502, 515 (2009). It may not, for example, "depart from a prior policy *sub silentio*." Id. The agency also "must show that there are good reasons for the new policy," id., and must "supply a reasoned analysis for the change." Ark Initiative v. Tidwell, 816 F.3d 119, 127 (D.C. Cir. 2016) (quoting Motor Vehicle

Mfrs. Ass'n v. State Farm Mut. Auto Ins. Co., 463 U.S. 29, 42 (1983)); see also State Farm, 463 U.S. at 43 ("[T]he agency must examine the relevant data and articulate a satisfactory explanation for its action including a 'rational connection between the facts found and the choice made.'") (quoting Burlington Truck Lines v. United States, 371 U.S. 156, 168 (1962)). Agency action is arbitrary and capricious if the agency "entirely failed to consider an important aspect of the problem." Id.

This framework plainly applies to the present case. While the 2016 Rule made clear that sex discrimination includes discrimination based on sex stereotyping and gender identity, the 2020 Rule contains no such provision. As Defendants seem to concede, this regulatory reversal represents a change in prior policy under Fox. See Def. Opp. at 18 (acknowledging that HHS's "position had changed") (citing Fox, 556 U.S. at 514).

Turning, then, to the analysis under Fox, it is undisputed that HHS has discharged its initial obligation to "display awareness that it is changing position" when it issued the final rule. Fox, 556 U.S. at 515. The agency acknowledged that the 2016 Rule included sex stereotyping and gender identity within its prohibition on sex discrimination, see 85 Fed. Reg. 37,236, but nevertheless explained that the 2020 Rule "eliminates" that provision and omits any such definitional language. Id. at 37,161–62; see also id. at 37,178 (acknowledging that the 2020 Rule "repeals the 2016 Rule's definition of 'on the basis of sex'").

The agency, however, has not fulfilled its obligation to provide either "good reasons," Fox, 556 U.S. at 515, or a "reasoned analysis" supporting its policy change. State Farm, 463 U.S. at 42. Before the Court explains why, however, it must refer back to its earlier standing holding. Attentive readers will recall that the Court previously determined that Plaintiffs lack standing to challenge HHS's repeal of the 2016 Rule's prohibition on gender-identity

discrimination, given the Texas decision vacating that language. That conclusion, however, does not mean that the prohibition on gender-identity discrimination is entirely irrelevant to the present merits discussion. On the contrary, the Court's assessment of HHS's reasoning for its repeal of the 2016 Rule's sex-stereotyping provision necessarily includes some consideration of the gender-identity provision. That is so for a simple and intuitive reason: the two concepts share substantial overlap.

Discrimination based on transgender status — *i.e.*, gender identity — often cannot be meaningfully separated from discrimination based on sex stereotyping because the belief that an individual should identify with only their birth-assigned sex is such a sex-based stereotype. See, e.g., Adams *ex rel.* Kasper v. School Bd. of St. John's Cty., No. 18-13592, 2020 WL 4561817, at *9 (11th Cir. Aug. 7, 2020) ("Because [plaintiff] was assigned a female sex at birth but identifies consistently and persistently as a boy and presents as masculine, he defies the stereotype that one's gender identity and expression should align with one's birth sex."); Whitaker, 858 F.3d at 1048 ("By definition, a transgender individual does not conform to the sex-based stereotypes of the sex that he or she was assigned at birth."); Glenn v. Brumby, 663 F.3d 1312, 1316 (11th Cir. 2011) ("A person is defined as transgender precisely because of the perception that his or her behavior transgresses gender stereotypes."). Indeed, HHS itself admits the possibility that the 2016 Rule deployed the term "sex stereotyping . . . to encompass gender identity." 85 Fed. Reg. at 37,236. Nor do Defendants ever dispute Plaintiffs' contention that "the flaws that permeated the rulemaking process with respect to the elimination of 'gender identity' apply equally to the elimination of 'sex stereotyping.'" ECF No. 47 (Plaintiffs' Clarification Regarding Response) at 1; see also Hrg. Tr. at 21–22 (similar). For these reasons, even though the Court may only grant Plaintiffs relief with respect to HHS's elimination of the prohibition on discrimination based on

sex stereotyping, the agency's reasoning regarding the gender-identity provision necessarily informs its treatment of the sex-stereotyping provision.

HHS's shortcomings begin in the preamble to the 2020 Rule. "[T]he preamble to a regulation is evidence of an agency's contemporaneous understanding of its proposed rules." It may serve, accordingly, "as a source of evidence concerning contemporaneous agency intent." Wyo. Outdoor Council v. U.S. Forest Serv., 165 F.3d 43, 53 (D.C. Cir. 1999); see also Harman Min. Co. v. Director, 678 F.3d 305, 315–16 (4th Cir. 2012) (explaining that regulatory preamble may serve "as a source of explanation as to [agency's] rationale in amending . . . regulations"); CHW West Bay v. Thompson, 246 F.3d 1218, 1226–27, 1230 (9th Cir. 2001) (looking to regulation's preamble as evidence that agency action was arbitrary and capricious). It follows that the Court may consider HHS's statements in the preamble to the 2020 Rule as part of the agency's explanation underlying its action, which "will enable the court to evaluate the agency's rationale at the time of decision." Pension Ben. Guar. Corp. v. LTV Corp., 496 U.S. 633, 654 (1990). Indeed, Defendants themselves admit that "a Rule's preamble may help determine whether an Agency's decision to adopt a particular approach was supported by adequate reasoning." Def. Opp. at 16. Even if the preamble "lacks the force and effect of law," Saint Francis Med. Ctr. v. Azar, 894 F.3d 290, 297 (D.C. Cir. 2018), Defendants thus do not appear to dispute that the Court may consider HHS's statements therein when assessing whether the explanation for its action is satisfactory.

Here, the 2020 Rule's preamble brings into stark relief HHS's position that discrimination based on transgender status does not qualify as sex discrimination under Section 1557. The agency repeatedly explained that "the term 'on the basis of . . . sex' in Section 1557 does not encompass discrimination on the basis of gender identity." 85 Fed. Reg. at 37,191; see

also, e.g., id. at 37,183 (disagreeing with commenters "who contend that Section 1557 or Title IX encompass gender identity discrimination within their prohibition on sex discrimination"); id. at 37,168, 37,179–80, 37,194 (similar). It is evident that these legal conclusions drove the agency's decision to eliminate the 2016 Rule's inclusion of gender identity and sex stereotyping in its definition of sex discrimination. As HHS insisted in issuing the 2020 Rule, that prior definition "exceeded the scope of the authority delegated by Congress in Section 1557," id. at 37,161, imposing legal requirements "that cannot be justified by the text of Title IX, and in fact are in conflict with express exemptions in Title IX." Id. at 37,162; see also Walker, 2020 WL 4749859, at *9 ("It is clear from the preamble . . . that a central reason for HHS's action was a fundamental disagreement as to whether Title IX — and, by implication, § 1557 — prohibited discrimination based on gender identity and sex stereotyping."). By eliminating the explicit prohibitions, HHS explained, the 2020 Rule "bring[s] the provisions of the Code of Federal Regulations into compliance with the underlying statutes." 85 Fed. Reg. at 37,162.

Four days before HHS published the final rule, however, the Supreme Court issued a decision that — at the very least — called the validity of HHS's legal determinations into serious question. In Bostock, it held that under Title VII, discrimination based on transgender status or sexual orientation "necessarily entails discrimination based on sex." 140 S. Ct. at 1747. The Court reached that conclusion through a "straightforward application" of the statutory text, which prohibits employers from discriminating against any individual "because of . . . sex." Id. at 1743; 42 U.S.C. § 2000e–2(a)(1). As the Court ultimately found, "[I]t is impossible to discriminate against a person for being homosexual or transgender without discriminating against that individual based on sex." Bostock, 140 S. Ct. at 1741.

These principles plainly have implications for Title IX's prohibition on sex discrimination and, by extension, Section 1557. As previously recounted, Title IX bars discrimination "on the basis of sex." 20 U.S.C. § 1681(a). The reasoning of Bostock, at a minimum, suggests the possibility that this provision encompasses discrimination based on transgender status. There is no apparent reason why the Court's conclusion — that it is "impossible" to discriminate based on transgender status without discriminating based on sex, see 140 S. Ct. at 1741 — would remain cabined to Title VII and not extend to other statutes prohibiting sex discrimination. Put another way, just as "sex plays an unmistakable and impermissible role" in any decision to treat otherwise identical individuals differently simply because they possess different gender identities under Title VII, the same would appear to be true under Title IX. See id. at 1741–42. Indeed, two courts of appeals have already so held. See Adams, 2020 WL 4561817, at *11–12 (applying Bostock and concluding that "Title IX, like Title VII, prohibits discrimination against a person because he is transgender, because this constitutes discrimination based on sex"); Grimm v. Gloucester Cty. Sch. Bd., No. 19-1952, 2020 WL 5034430, at *21, 24 n.18 (4th Cir. Aug. 26, 2020) (similar). There exists a fairly strong case, therefore, that application of Bostock's textual analysis to Title IX (by way of Section 1557's incorporation of that statute) would yield the conclusion that the statute forbids discrimination based on gender identity and sex stereotyping, insofar as such stereotypes are based on the belief that an individual should identify with only their birth-assigned sex. Cf. Bostock, 140 S. Ct. at 1778–81 & n.57 (Alito, J., dissenting) (discussing potential "consequences" of Court's Title VII holding for statutes such as Title IX and Section 1557).

Notwithstanding Bostock's clear import for the meaning of discrimination based on sex under Title IX, HHS plowed ahead with the 2020 Rule implementing that precise statutory

phrase without even pausing to consider the Court's decision. The Department's 89-page final rule contains no discussion whatsoever of Bostock's reasoning or how the case might apply to Title IX. Indeed, HHS did not even acknowledge Bostock's holding. The agency instead clung to its position that "Title IX does not encompass discrimination on the basis of sexual orientation or gender identity," 85 Fed. Reg. at 37,168, and it repeatedly invoked that conclusion as justification for its elimination of the 2016 Rule's provision to the contrary. Id. at 37,161–62. HHS so acted despite itself admitting that "a holding by the U.S. Supreme Court on the meaning of 'on the basis of sex' under Title VII will likely have ramifications for the definition of 'on the basis of sex' under Title IX." Id. at 37,168 (emphasis added).

"The APA requires reasoning, deliberation, and process." California v. Bernhardt, No. 18-5712, 2020 WL 4001480, at *16 (N.D. Cal. July 15, 2020). HHS should have at least considered the import of Bostock for the reasons underlying its regulatory action — namely, the agency's belief that Title IX does not prohibit discrimination based on transgender status — before it eliminated regulatory language providing for precisely what Bostock seemed to guarantee. The agency's failure to take that obvious deliberative step prevents the Court from finding that its policy change was supported by "reasoned analysis" and compels the conclusion that its action was arbitrary and capricious. State Farm, 463 U.S. at 42. In so holding, the Court aligns itself with the Eastern District of New York's recent resolution of a similar challenge to the 2020 Rule. See Walker, 2020 WL 4749859, at *9–10 (finding repeal of 2016 Rule's definition of sex discrimination arbitrary and capricious in light of agency's failure to consider implications of Bostock).

Defendants offer several arguments in response, but none is persuasive. They begin by positing that the district court's decision in Franciscan Alliance "compelled" HHS to "not

includ[e] an expanded definition of 'on the basis of sex'" in the 2020 Rule because that case "vacated the language contained in the previous rule that plaintiffs now advocate for." Def. Opp. at 16. There are multiple problems with this argument. First, Defendants' premise is mistaken. As previously explained, Franciscan Alliance only vacated the 2016 Rule "insofar as the Rule defines 'On the basis of sex' to include gender identity" and one other provision not relevant here. Franciscan Alliance Order at ECF p. 3. The court made clear that the "remainder of 45 C.F.R. § 92 remains in effect." Id. Franciscan Alliance, accordingly, did not vacate the 2016 Rule's definitional provision relating to sex stereotyping; indeed, the decision never even mentioned it. See 414 F. Supp. 3d 928. Defendants thus cannot contend the decision was "reason enough for HHS to release the 2020 Rule in its current form." Def. Opp. at 17.

In addition, contrary to Defendants' assertion, nothing in Franciscan Alliance "compelled" HHS in any sense of the word with respect to the present rulemaking. See Def. Opp. at 16. Franciscan Alliance simply vacated a portion of the 2016 Rule's definition of discrimination on the basis of sex. It did not order the agency to do anything in particular when promulgating a future rule implementing Section 1557, or even to conduct another rulemaking at all. In fact, nothing in Franciscan Alliance prevented HHS from re-promulgating the very provisions that the court vacated. To be sure, any such regulation may have suffered the same fate as the 2016 Rule in subsequent litigation, but the point is that the order in Franciscan Alliance did not itself preclude HHS from following such a course. Defendants therefore cannot suggest that the decision effectively bound the agency's hands and "compelled" it to proceed as it did. See Def. Opp. at 16.

Even worse, HHS failed entirely to consider the implications of Bostock for the agency's reliance on Franciscan Alliance — to wit, the possibility that the Supreme Court thoroughly

undermined that earlier decision's reasoning. Franciscan Alliance's holding that Title IX's prohibition on sex discrimination did not include gender-identity discrimination was premised entirely on the court's belief that the statutory term "sex" "refer[red] to the biological differences between males and females." 227 F. Supp. 3d at 688. HHS, notably, drew from the Government's losing litigating position in Bostock to make this same argument. See 85 Fed. Reg. at 37,178–79. Bostock, however, expressly assumed that "sex" "refer[red] only to biological distinctions between male and female." 140 S. Ct. at 1739. Whether or not the term included some norms relating to gender identity was immaterial, the Court explained, because it is nevertheless "impossible" to discriminate based on transgender status without discriminating based on sex. Id. at 1741. To be sure, contrary to Plaintiffs' assertion, Bostock did not render Franciscan Alliance's vacatur "a legal nullity." Pl. Reply at 3. That disposition remains on the books. But HHS could not continue to invoke it as justification for an independent regulatory action without at least considering whether Bostock undermined the former decision's very basis.

Relatedly, Defendants contend that "HHS acted reasonably in finalizing its rule without waiting for [Bostock]" because that decision "concerned a separate statute" — *i.e.*, Title VII. See Def. Opp. at 17. As HHS itself admitted, however, "Title VII case law has often informed Title IX case law with respect to the meaning of discrimination 'on the basis of sex,'" and a decision in Bostock "will likely have ramifications" for Title IX. See 85 Fed. Reg. at 37,168. That much has already become clear, as evidenced by two courts of appeals' recent applications of Bostock to conclude that Title IX likewise prohibits discrimination based on transgender status. Adams, 2020 WL 4561817, at *11–12; Grimm, 2020 WL 5034430, at *21, 24 n.18. Indeed, even apart from Bostock, several courts have independently concluded that Title IX

prohibits discrimination based on sex stereotyping or gender identity. See, e.g., Whitaker, 858 F.3d at 1049; Dodds v. United States Dep't of Educ., 845 F.3d 217, 221 (6th Cir. 2016). HHS asserted vaguely that "the binary biological character of sex" may "take[] on special importance in the health context," leading to "implications" that a Title VII ruling "might not . . . fully address[]." 85 Fed. Reg. at 37,168; see also id. at 37,185. Even if one grants HHS's premise, the mere possibility that Bostock may apply slightly differently in the health-care context does not give the agency license to refuse to consider the decision entirely.

To be clear, the Court does not adopt Plaintiffs' contention that Bostock "conclusively rejects" HHS's position that Title IX (and Section 1557) do not prohibit discrimination based on transgender status. See Pl. Mot. at 14. It need not go so far, and it does not so hold today. It is sufficient for the Court to determine that Bostock, at the very least, has significant implications for the meaning of Title IX's prohibition on sex discrimination, and that it was arbitrary and capricious for HHS to eliminate the 2016 Rule's explication of that prohibition without even acknowledging — let alone considering — the Supreme Court's reasoning or holding. See Walker, 2020 WL 4749859, at *9 ("Whether or not it is dispositive of [the scope of sex discrimination] with respect to Title IX and § 1557, Bostock is at least 'an important aspect of the problem.'") (quoting State Farm, 463 U.S. at 43).

Finally, Defendants insist that the 2020 Rule cannot be arbitrary and capricious because it simply regurgitates the plain, unobjectionable text of Section 1557. Specifically, they argue that HHS "declin[ed] to include a definition of 'on the basis of sex' in the 2020 Rule," and "Plaintiffs cite no authority that would require a regulation to expand upon statutory text." Def. Opp. at 15; see also 85 Fed. Reg. at 37,244 (to be codified at 45 C.F.R. § 92.2). This misconstrues Plaintiffs' argument. HHS did not adopt the 2020 Rule in a vacuum devoid of context or history. As

previously explained, because the agency changed its position and opted to repeal a prior regulatory provision, it needed to provide a "reasoned analysis for the change" and a "satisfactory explanation for its action." State Farm, 463 U.S. at 42–43; see also Fox, 556 U.S. at 515; Encino Motorcars, LLC v. Navarro, 136 S. Ct. 2117, 2126 (2016). Regardless of the ultimate regulation the agency adopts, the Court must assess the reasonableness of the agency's explanation for why it made the change. And here, HHS's explanation is plainly insufficient, not least because it neglected to consider in any fashion an intervening Supreme Court decision that bore direct and undisputed consequences not only for the regulatory provision at issue, but also for the validity and coherence of the reasons HHS provided for its action. The agency cannot escape that conclusion by simply asserting that "the elimination of a regulatory definition of [a statutory] term would not preclude application of the [Supreme] Court's construction" of that term's meaning. See 85 Fed. Reg. at 37,168. When assessing the procedural validity of HHS's action, this Court remains obligated to "examin[e] the reasons" underlying HHS's action. Judulang v. Holder, 565 U.S. 42, 53 (2011).

The Court "do[es] not hold that the agency decision here was substantively invalid." Dep't of Commerce, 139 S. Ct. at 2576. It "address[es] only whether the agency complied with the procedural requirement that it provide a reasoned explanation for its action." Dep't of Homeland Security v. Regents of the Univ. of Cal., 140 S. Ct. 1891, 1916 (2020). Nothing prevents HHS from returning to the drawing board and attempting again to issue a regulation that parrots Section 1557's prohibition on sex discrimination. To be successful, however, any such effort must exhibit what was sorely lacking here — namely, compliance with the APA's procedural mandates.

2. *Incorporation of Title IX's Religious Exemption*

Next up is the 2020 Rule's incorporation of Title IX's religious exemption. Plaintiffs challenge that regulatory action as arbitrary and capricious, largely contending that HHS failed to sufficiently consider the implications of such incorporation for access to health care. They are correct.

As the reader well knows by this point, Section 1557 incorporates the particular grounds of discrimination contained in four other civil-rights statutes. Once again relevant here is Title IX. By referencing the "ground" of discrimination prohibited by Title IX, Section 1557 plainly barred discrimination on the basis of sex. See 20 U.S.C. § 1681(a); 42 U.S.C. § 18116(a). It did not, however, explicitly incorporate Title IX's exemption of certain educational operations of entities controlled by religious organizations from its nondiscrimination mandate. See 20 U.S.C. §§ 1681(a), 1687. The 2016 Rule, accordingly, "decline[d] to . . . import Title IX's blanket religious exemption into Section 1557." 81 Fed. Reg. at 31,380. HHS reached that conclusion both because "Section 1557 itself contains no religious exemption" and because it found that a categorical exemption would be inappropriate in the broader health-care context. Id.

The 2020 Rule, however, reversed course and explicitly incorporated Title IX's religious exemption into Section 1557's nondiscrimination scheme. See 45 C.F.R. § 92.6(b) (incorporating "exemptions" contained in various statutes, including Title IX). As imported into the current regulation, such exemption could be read so as to enable any educational operation of an entity controlled by a religious organization engaged in the provision of health care to evade the statute's prohibition on sex discrimination, if application of such prohibition would be inconsistent with the organization's religious tenets. See 20 U.S.C. §§ 1681(a), 1687; 85 Fed. Reg. at 37,207–08. It is this incorporation that Plaintiffs challenge as arbitrary and capricious.

The APA demands that an agency considering regulatory action "examine all relevant factors and record evidence." Am. Wild Horse Pres. Campaign v. Perdue, 873 F.3d 914, 923 (D.C. Cir. 2017). At a minimum, the agency "cannot entirely fail[] to consider an important aspect of the problem." State Farm, 463 U.S. at 43. Rather, it must "adequately analyze . . . the consequences" of its actions. Am. Wild Horse, 873 F.3d at 932. In doing so, "[s]tating that a factor was considered . . . is not a substitute for considering it." Getty v. Fed. Savs. & Loan Ins. Corp., 805 F.2d 1050, 1055 (D.C. Cir. 1986). The agency must instead provide more than "conclusory statements" to prove that it "consider[ed] the [relevant] priorities." Id. at 1057. For instance, the D.C. Circuit has held that concerns raised in public comments are sufficient to alert an agency to "an important aspect of the problem," which the agency must consider lest its action be deemed arbitrary and capricious. Gresham v. Azar, 950 F.3d 93, 103 (D.C. Cir. 2020).

Several of the 2016 Rule's primary justifications for declining to incorporate Title IX's religious exemption into Section 1557 focused on the potential negative implications of such an exemption for access to care and ultimate health outcomes. For instance, HHS referenced statements from the "overwhelming majority of individual commenters" and "[m]ost" commenting organizations that a religious exemption "would potentially allow for discrimination on the bases prohibited by Section 1557 or for the denial of health services to women." 81 Fed. Reg. at 31,379. Such concerns, HHS concluded, counseled against a "blanket religious exemption," which "could result in a denial or delay in the provision of health care" and could "discourag[e] individuals from seeking necessary care," thereby generating "life threatening results." Id. at 31,380. The agency also found that there were "significant differences between the educational and health care contexts that warrant different approaches." Id. While families selecting religious educational institutions "typically do so as a matter of choice," individuals in

the health-care context "may have limited or no choice of providers, particularly in rural areas or where hospitals have merged with or are run by religious institutions," or in "emergency circumstances." Id.

The 2020 Rule, however, "said almost nothing" about these important issues. Encino Motorcars, 136 S. Ct. at 2127. Nowhere did HHS grapple with the policy grounds against importing a religious exemption into Section 1557. More fundamentally, nowhere did it consider the "consequences" of such an exemption for access to care, Am. Wild Horse, 873 F.3d at 932, despite the fact that the "ACA's intended purpose [is] to broaden access to health care." Morris v. Cal. Physicians' Serv., 918 F.3d 1011, 1014 (9th Cir. 2019). To the extent the agency even gestured at these issues, its discussion was patently insufficient to discharge its duty to provide a "reasoned explanation" for its change in policy. Encino Motorcars, 136 S. Ct. at 2126.

For instance, at one point HHS asserted that the incorporation of Title IX's religious exemption will ensure patients receive "high-quality and conscientious care." 85 Fed. Reg. at 37,206. Yet that "conclusory statement[]" was delivered entirely without elaboration or support. Getty, 805 F.2d at 1057; see Gresham, 950 F.3d at 103 ("Nodding to concerns raised by commenters only to dismiss them in a conclusory manner is not a hallmark of reasoned decisionmaking."). Indeed, one would think that the more likely outcome would be patients' being denied care — a possibility HHS never acknowledged. Similarly, it did not even resist comments stating that, more generally, "religious exemptions would make it harder to find healthcare in low provider areas." 85 Fed. Reg. at 37,218.

Defendants briefly insist that HHS "concluded" that a "religious exemption[] is unlikely to lead to widespread diminishing of healthcare options for individuals." Def. Op. at 31. But the agency did no such thing. Indeed, it took no position whatsoever on the actual effects that a

religious exemption would have, a reality confirmed by the very preamble excerpt Defendants cite. There, HHS offered a vague summary of comments from select providers purportedly seeking exemptions from "providing certain treatments," not necessarily "from treating certain patients"; comments from "[s]ome" hospitals that prohibit discrimination on the basis of gender identity and sexual orientation; and comments from "[s]ome" religious providers that claim to "have never refused to care for a patient on the grounds of their identity as an LGBT individual." 85 Fed. Reg. at 37,206. The Court has no reason to dispute the truth of any of these comments. HHS, however, cited them not as evidence that a religious exemption will preserve health-care opportunities for individuals, but instead simply for the entirely unproductive proposition that "members of the public hold different opinions concerning conscience and religious freedom laws." Id. At no point did the agency even assert that a religious exemption would preserve meaningful access to health care for vulnerable populations — let alone provide evidence supporting any such conclusion.

Attempting to skirt this deficiency, Defendants contend that HHS was neither required to supply a more "detailed" justification for its policy reversal nor to "respond specifically" to the 2016 Rule's discussion of the serious risks posed by a categorical religious exemption for the prompt and nondiscriminatory provision of health care. See Def Opp. at 31 (quoting Nat'l Ass'n of Home Builders v. EPA, 682 F.3d 1032, 1038 (D.C. Cir. 2011)); Fox, 556 U.S. at 502 (requiring "a more detailed justification" for policy reversal when "new policy rests upon factual findings that contradict those which underlay [agency's] prior policy"). Even assuming Defendants are correct that the 2016 Rule's rejection of a religious exemption did not rest upon "factual findings" — a questionable premise, given HHS's reliance on the documented potential for denials and delays in health-care provision as a result of the exemption — their objection

misses the point. The Court does not here require HHS to provide a more "detailed justification than what would suffice for a new policy created on a blank slate." Fox, 556 U.S. at 515. It merely requires HHS to "consider an important aspect of the problem" — namely, the potential negative consequences that importing a blanket religious exemption into Section 1557 might have for access to health care. State Farm, 463 U.S. at 43. The agency's dereliction of that fundamental procedural obligation flunks the APA's standards for reasoned decisionmaking. See Gresham, 950 F.3d at 103 (holding agency action arbitrary and capricious for failing to adequately consider potential for loss in health-care coverage as result of action); Am. Wild Horse, 873 F.3d at 932 (faulting agency for "brush[ing] aside critical facts" and not "adequately analyz[ing]" consequences of decision).

To be sure, Defendants identify other factors that HHS considered in deciding to import Title IX's religious exemption into Section 1557. In particular, they point to the agency's consideration of 1) the fact that Title IX has been interpreted to apply outside of core educational institutions; 2) the Religious Freedom Restoration Act; 3) Franciscan Alliance's invalidation of the 2016 Rule's definition of sex discrimination in part because of HHS's not incorporating Title IX's religious exemption; and 4) the need to "protect . . . providers' medical judgment and their consciences." Def. Opp. at 29–31; 85 Fed. Reg. at 37,206–08. The Court need not address the legitimacy of these considerations today. For even if HHS could properly consider such factors, its "wholesale failure" to adequately address a "salient factor" — namely, access to care — renders its decision arbitrary and capricious. Humane Soc'y v. Zinke, 865 F.3d 585, 607 (D.C. Cir. 2017). That is not to say, of course, that HHS could never promulgate a rule under Section 1557 incorporating Title IX's religious exemption. "Rather, [the Court] holds today only that [HHS] must adequately consider the effect of" a blanket religious exemption on the ability for

individuals to access care on a prompt and nondiscriminatory basis. See Stewart v. Azar, 313 F. Supp. 3d 237, 272 (D.D.C. 2018). It never did so here.

In closing this particular area of discussion, the Court notes that nothing in this decision renders religiously affiliated providers devoid of protection. Far from it. To name a few safeguards: the ACA instructs that no provision "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). The 2020 Rule, moreover, explicitly acknowledges that Section 1557 is subject to RFRA's protections of religious conscience from government-imposed burdens, see 45 C.F.R. § 92.6(b) — protections the Supreme Court has confirmed are "very broad." Burwell v. Hobby Lobby Stores, Inc., 573 U.S. 682, 693 (2014). Nothing in the Court's decision today implicates in any fashion the applicability of these independent statutory safeguards.

3. *Elimination of Prohibition on Categorical Coverage Exclusions*

Plaintiffs encounter less success in their challenge to HHS's elimination of the 2016 Rule's prohibition on "categorical coverage exclusion[s] or limitation[s] for all health services related to gender transition." 81 Fed. Reg. at 31,471–72 (formerly codified at 45 C.F.R. § 92.207(b)(4)). Although they no doubt have ardent policy objections to the agency's removal of such prohibitions on insurers' having or implementing categorical coverage exclusions, the sole question before the Court is whether HHS "examine[d] the relevant data and articulate[d] a satisfactory explanation for its action including a 'rational connection between the facts found and the choice made.'" State Farm, 463 U.S. at 43 (quoting Burlington Truck Lines, 371 U.S. at 168). At least at the present juncture, Plaintiffs have not shown otherwise. Mindful of the

"narrow" scope of arbitrary-and-capricious review — a standard that bars courts from "substitut[ing] [their] judgment for that of the agency" — the Court finds that Plaintiffs have not demonstrated a likelihood of success on this aspect of their case. Id.

As an initial matter, Defendants contend that HHS exceeded its authority under the 2016 Rule when it prohibited categorical coverage exclusions of gender-affirming care, including sex-reassignment procedures. See Def. Opp. at 19. As the agency asserted in the 2020 Rule, "There is no statutory authority to require the provision or coverage of such procedures under Title IX protections from discrimination on the basis of sex." 85 Fed. Reg. at 37,198; see also id. at 37,199. Plaintiffs, somewhat puzzlingly, never argue to the contrary; nor do they maintain that Section 1557 compels the inclusion of a prohibition on coverage exclusions. Instead, Plaintiffs simply contend that HHS "did not offer a reasonable explanation" for its policy change, which ran "counter to the evidence" and "was not the product of reasoned decision-making." Pl. Reply at 13. In light of this more limited argument, the Court need not resolve the precise limits of HHS's authority to implement Section 1557's prohibition on sex discrimination. Even assuming that the 2016 Rule's prohibition on categorical coverage exclusions of gender-affirming care was lawful, the Court cannot presently conclude that the agency's decision to remove that prohibition was arbitrary and capricious.

When an agency changes a policy position, "it need not demonstrate to a court's satisfaction that the reasons for the new policy are better than the reasons for the old one." Fox, 556 U.S. at 515. Instead, "it suffices that the new policy is permissible under the statute," and "that there are good reasons for it." Id. Here, HHS expressly confronted its prior policy regarding prohibitions on categorical coverage exclusions and delivered a sufficiently reasoned explanation for its new position. In promulgating the 2020 Rule, the agency consulted scientific

studies, government reviews, and comments from a host of medical professionals regarding treatment for gender dysphoria. See 85 Fed. Reg. 37,187, 37,196–98. The upshot, according to HHS, was that "the medical community is divided on many issues related to gender identity, including the value of various 'gender-affirming' treatments for gender dysphoria (especially for minors)." Id. at 37,187. That division counseled against a blanket prohibition on categorical coverage exclusions of gender-affirming care. According to the agency, eliminating the prohibition would enable providers and insurers "to use their best medical judgment" when delivering and covering care, as informed by "ongoing medical debate and study" regarding gender-affirming treatment. Id. at 37,187.

In the 2020 Rule, HHS acknowledged the 2016 Rule's assumption that entities offering categorical coverage exclusions for gender-affirming care were relying on medical judgments that were "outdated and not based on current standards of care." Id. at 37,187 (quoting 81 Fed. Reg. at 31,429). The agency, however, concluded that this earlier assertion was "erroneous" and that there was "a lack of scientific and medical consensus to support" it. Id. Plaintiffs take issue with three pieces of evidence HHS cited in support of that conclusion. Without entering the merits of the debate, the Court is satisfied that each was valid for HHS to consider, and that each reinforced the agency's ultimate determination.

First, HHS pointed to a 2016 CMS decision declining to issue a National Coverage Determination that would have mandated coverage for sex-reassignment surgery for Medicare beneficiaries with gender dysphoria. See 85 Fed. Reg. at 37,187. There, CMS determined, "[b]ased on an extensive assessment of the clinical evidence," that "there is not enough high quality evidence to determine whether gender reassignment surgery improves health outcomes for Medicare beneficiaries with gender dysphoria and whether patients most likely to benefit

from these types of surgical intervention can be identified prospectively." CMS, Decision Memo for Gender Dysphoria and Gender Reassignment Surgery (CAG-00446N) (Aug. 30, 2016), https://perma.cc/9S73-4WQB. Plaintiffs emphasize that CMS's decision did not mean there would be national non-coverage for gender-affirming care, but only that coverage determinations would occur on a case-by-case basis. See Pl. Mot. at 17. That point, however, is non-responsive, as HHS invokes the CMS decision only as evidence for the "lack of scientific and medical consensus" regarding such treatment. See 85 Fed. Reg. at 37,187.

Second, HHS referenced a 2018 Department of Defense report, which found that there is "considerable scientific uncertainty and overall lack of high quality scientific evidence demonstrating the extent to which transition-related treatments . . . remedy the multifaceted mental health problems associated with gender dysphoria." Id. (quoting Department of Defense, Report and Recommendations on Military Service by Transgender Persons at 5 (Feb. 22, 2018), https://perma.cc/7369-K2VC). Plaintiffs attempt to blunt the force of this report by pointing out that it summarized recommendations "based on each Panel member's independent military judgment." DOD Report at 4 (emphasis added). As HHS noted, however, the report also included input from civilian medical professionals with experience treating gender dysphoria. See 85 Fed. Reg. at 37,187; DOD Report at 18. In any event, even assuming that the military context in which the report was issued counsels against unguarded acceptance of all of its conclusions in the context of civilian health care, the report's factual finding regarding the "scientific uncertainty and overall lack of high quality scientific evidence" surrounding gender-affirming treatment ultimately echoes CMS's similar finding two years earlier — which Plaintiffs do not and cannot dispute was tailored to civilians.

Finally, HHS characterized a scientific study as concluding "that children who socially transition in childhood faced dramatically increased likelihood of persistence of gender dysphoria into adolescence and adulthood." 85 Fed. Reg. at 37,187 (citing Thomas D. Steensma et al., "Factors Associated with Desistance and Persistence of Childhood Gender Dysphoria: A Quantitative Follow-Up Study," 52(6) J. Am. Acad. of Child & Adolescent Psych. 582–90 (2013)). Plaintiffs dispute that representation, emphasizing that the study concluded only that the intensity of early gender dysphoria appears to be an important predictor of the persistence of gender dysphoria in later years of life. See Pl. Mot. at 18 (citing Steensma et al. at 582). Defendants, however, correctly point out that the study found that boys who transitioned during childhood experienced "significantly" greater gender dysphoria in later years, a finding consistent with HHS's characterization. See Steensma at 586–87; see also id. at 588 (explaining that "[c]hildhood social transitions were important predictors of persistence" and that "[s]ocial transitions were associated with more intense [gender dysphoria] in childhood").

Beyond criticizing HHS's reliance on these sources, Plaintiffs point to standards issued by the World Professional Association for Transgender Health — and adopted by additional organizations — that endorse various forms of treatment for gender dysphoria. See Pl. Mot. at 16–17. But HHS explicitly considered these standards in promulgating the 2020 Rule, referencing submissions from various commenters who agreed with the group's approach. See 85 Fed. Reg. at 37,196 & nn.220–25. After summarizing such evidence, the agency turned to comments from clinicians who criticized the WPATH standards for reaching "policy conclusions without adequate clinical evidence." Id. at 37,197 & n.232 (citing studies). HHS also indicated its agreement with certain commenters "that the 2016 Rule relied excessively on the conclusions of an advocacy group (WPATH) rather than on independent scientific fact-finding" such as the

aforementioned CMS decision that conducted an "extensive assessment of the clinical evidence" only to find an absence of evidence sufficient "to determine whether gender reassignment surgery improves health outcomes" for individuals with gender dysphoria. Id. at 37,187, 37,198.

Once again, it is not this Court's place to resolve this scientific debate. Nor may it pass judgment on the wisdom of the agency's decision. The Court is limited, rather, to considering whether "the agency has examined relevant data and has articulated a rational explanation for its action." Eagle-Picher Indus., Inc. v. EPA, 759 F.2d 905, 921 (D.C. Cir. 1985). The above discussion makes clear that HHS thoroughly considered the evidence Plaintiffs raise, but nevertheless concluded that "there is no medical consensus to support one or another form of treatment for gender dysphoria." 85 Fed. Reg. at 37,198. Plaintiffs cannot show that determination to be arbitrary and capricious simply by pointing to evidence that the agency plainly took into account. See Pl. Mot. at 16–17.

Plaintiffs also briefly contend that HHS failed to consider the "reliance" interests of various stakeholders, including transgender patients, on the 2016 Rule's prohibition on categorical coverage exclusions. Id. at 18. Even assuming Plaintiffs have identified "serious reliance interests" with the requisite particularity, Encino Motorcars, 136 S. Ct. at 2126 (quoting Fox, 556 U.S. at 515), nowhere do they acknowledge HHS's express statement that nothing in the 2020 Rule "prohibits a healthcare provider from offering or performing sex-reassignment treatments and surgeries, or an insurer from covering such treatments and procedures, either as a general matter or on a case-by-case basis." 85 Fed. Reg. at 37,188. Indeed, HHS went on, "The large number of comments received from healthcare providers who perform such treatments and procedures suggests that there is no shortage of providers willing to do so." Id.; see also id. at 37,196 (acknowledging comments claiming that 2020 Rule's insurance coverage provisions

jeopardize access to gender transition services). If Plaintiffs deem that discussion insufficient to discharge HHS's duty to consider "legitimate reliance on prior interpretation," they will need to address it head on. Smiley v. Citibank (S.D.), N.A., 517 U.S. 735, 742 (1996).

Plaintiffs, consequently, have not demonstrated a likelihood of success on the merits of their challenge to HHS's repeal of the 2016 Rule's prohibition on categorical coverage exclusions for gender-transition-related health services.

4. *Elimination of Notice Requirements*

Plaintiffs next take aim at HHS's elimination of the 2016 Rule's notice and tagline requirements. Here, too, the Court finds that they have not demonstrated a likelihood of success on their claim that such repeal was procedurally invalid.

As previously discussed, although their briefing at times references unspecified revisions to the 2016 Rule's language-access requirements, Plaintiffs confine their present challenge to HHS's repeal of the prior Rule's notice and tagline provisions. See Hrg. Tr. at 22–23; Pl. Mot. at 24. Those provisions required covered entities to post certain notices and taglines in their "significant publications and significant communications" with members of the public, as well as in "conspicuous physical locations." 81 Fed. Reg. at 31,469 (formerly codified at 45 C.F.R. § 92.8(f)–(g)). The notices were intended to inform the public that, *inter alia*, the covered entity does not discriminate on the grounds incorporated into Section 1557, and that it provides various language-assistance services and auxiliary aids. See id. (formerly codified at 45 C.F.R. § 92.8(a)). Covered entities also had to include short "taglines" in certain significant communications and locations, in either fifteen languages (for larger-sized communications and physical locations) or in two languages (for smaller communications), indicating the availability of these language-assistance services. Id. (formerly codified at 45 C.F.R. §§ 92.4, 92.8).

The 2020 Rule eliminated these notice and tagline requirements entirely. In reviewing that action, the Court is once more tasked with determining whether the repeal was arbitrary and capricious — in other words, whether HHS neglected to provide a sufficiently "reasoned analysis" for its change in policy. State Farm, 463 U.S. at 42. Finding that the agency's explanation was more than adequate, the Court declines Plaintiffs' invitation to set aside the repeal.

By this point in the journey, the reader knows all too well that in order to justify a change in policy, an agency must "display awareness that it is changing position" and "must show that there are good reasons for the new policy." Fox, 556 U.S. at 515. Here, HHS did both. It plainly acknowledged its shift in course from the 2016 Rule, stating explicitly that it sought to "repeal in toto the Section 1557 provisions on taglines . . . and notices of non-discrimination." 84 Fed. Reg. at 27,868; see also 85 Fed. Reg. at 37,204. The agency likewise provided an array of reasons for its change in position. For instance, HHS determined that the costs and burdens imposed by the notice and tagline requirements were "substantially larger than originally anticipated." 84 Fed. Reg. at 27,857. The 2016 Rule had estimated that the total cost of complying with these provisions would be $7.2 million, with expenditures declining to zero after the first year of implementation notwithstanding covered entities' continuing obligation to provide the notices on all "significant publications and significant communications." 81 Fed. Reg. at 31,453, 31,458 (Table 5); 84 Fed. Reg. at 27,875. HHS ultimately concluded that these projections were a "gross underestimation" of costs, and that eliminating the requirements would save approximately $2.9 billion over a five-year period. See 85 Fed. Reg. at 37,163, 37,224.

In addition, the agency cited reports from covered entities of implementation difficulties, largely resulting from the many different and overlapping notice and language-access

requirements imposed by federal and state governments. See id. at 37,211 & n.281 (citing statutes). Even when implemented correctly, stakeholders feared that the "repetitive nature" of the notices "dilute[d] the messages contained in significant communications to the point that some recipients may be disregarding the information entirely." Id. at 37,211. HHS also noted that high costs often yielded minimal benefit, both because the "vast majority of recipients of taglines do not require translation services" and because providers were often required to print taglines in languages that very few individuals spoke. Id. at 37,233. In Wyoming, for instance, health-insurance issuers needed to provide translation notices in Gujarati and Navajo in every significant communication sent to beneficiaries to account for a combined 79 speakers of those languages. Id. HHS could validly consider these concerns in determining that a new approach was warranted. The agency, after all, need not establish that its stated justifications are "better than the reasons for the old" policy; it suffices that the agency "believes [the new policy] to be better." Fox, 556 U.S. at 515.

Plaintiffs do not address any of these justifications for HHS's change in position, much less contest their legitimacy. Instead, they contend that the agency neglected to explain or sufficiently consider how individuals will become apprised of their health-care rights under Section 1557, along with the availability of various language-assistance services, without the notices or taglines. See Pl. Mot. at 19, 24–25. As will presently become clear, however, HHS grappled with the precise considerations that Plaintiffs insist it ignored. Indeed, it found that limited evidence of notice and taglines' leading to increased access was a principal reason that their significant costs and burdens outweighed their far more limited benefits.

An agency discharges its obligation to "consider an important aspect of the problem" when it "g[ives] the specific reasons for which it disagree[s]" with the basis for the alleged

problem. Am. Petroleum Inst. v. EPA, 684 F.3d 1342, 1350 (D.C. Cir. 2012) (citation omitted). Here, in the 2020 Rule, HHS squarely considered the possibility that "[r]epealing the notice and taglines requirement may impose costs, such as decreasing access to, and utilization of, healthcare for non-English speakers." 85 Fed. Reg. at 37,232. The agency acknowledged a report from one commenting hospital that had experienced an uptick in requests for translation services after the 2016 Rule, and it remarked that other entities had documented a similar trend. Id. at 37,233. But the agency also cited ample evidence that pointed in the other direction. Several commenters, including at least one health plan, reported no increase in the number of callers requesting translation services since the 2016 Rule's promulgation. Id. at 37,232–33; 84 Fed. Reg. at 27,859. Another health plan reported lower numbers of requests for translation services over the same three-month period in 2017 compared to 2016. See 84 Fed. Reg. at 27,859.

Ultimately, even as it acknowledged the "difference in reports" among commenters, HHS determined that the evidence, viewed in its entirety, was consistent with the conclusion that the 2016 Rule's notice and tagline requirements "did not appreciably increase the use of translation services." 85 Fed. Reg. at 37,233. The agency likewise found that the significant burdens imposed by the requirements — including their dramatically underestimated cost — were "disproportionate" to such limited evidence of their potential benefit. Id. Notably, the 2020 Rule specifically required covered entities to take "reasonable steps to ensure meaningful access to [language-access] programs or activities by limited English proficient individuals." 45 C.F.R. § 92.101; see also 85 Fed. Reg. at 37,209–10. HHS simply eliminated the requirement that "all significant communications contain taglines," which the agency determined, in light of the evidence, was "unduly broad, sometimes confusing, and inefficient." 85 Fed. Reg. at 37,176

(emphasis added). "Such cost-benefit analyses epitomize the types of decisions that are most appropriately entrusted to the expertise of an agency." Office of Communication of United Church of Christ v. FCC, 707 F.2d 1413, 1440 (D.C. Cir. 1983).

In sum, therefore, HHS plainly "acknowledge[d]" the possibility of a reduction in access to health care, Am. Petroleum Inst., 684 F.3d at 1350, and "articulate[d] a satisfactory explanation for its action including a 'rational connection between the facts found and the choice made.'" State Farm, 463 U.S. at 43 (quoting Burlington Truck Lines, 371 U.S. at 168). The APA requires nothing more.

Plaintiffs also briefly dispute HHS's reasoning on a narrower ground. Specifically, they home in on the agency's apparent determination that the notice requirements under Section 1557's incorporated statutes would adequately inform individuals of their nondiscrimination rights in the event the additional notices and taglines under Section 1557 were eliminated. See Pl. Mot. at 19. As the agency explained, each of the four statutes incorporated into Section 1557 independently requires covered entities to distribute various forms of notice regarding individuals' right to be free from discrimination on the relevant protected ground. See 85 Fed. Reg. at 37,175–76 & n.61 (citing 45 C.F.R. § 80.6(d) (Title VI); 45 C.F.R. § 84.8 (Section 504); 45 C.F.R. § 86.9 (Title IX); 45 C.F.R. § 91.32 (Age Discrimination Act)). Those provisions would be unaffected by the repeal of Section 1557's supplementary notice requirements, and, according to HHS, would continue to provide broad notification of patients' nondiscrimination rights. See id. at 37,204 ("[HHS] is unaware of data suggesting that those regulations have been or are inadequate to their purpose of making individuals aware of their civil rights.").

In response, Plaintiffs claim that HHS never explained how some individuals would learn of such rights in the absence of Section 1557's notices and taglines because "the underlying

[incorporated] statutes . . . may not apply to every health care entity." Pl. Mot. at 25; see also id. at 19 (asserting vaguely that "not all the underlying statutes apply to every health care provider"). But Plaintiffs make no effort whatsoever to elaborate on that posited coverage cap, either as to its extent or the type of health-care entity that would fall within it. They simply make tentative declarations that unidentified patients at an unspecified number of facilities "may" not receive affirmative notice of particular protected grounds of nondiscrimination. On this record, and especially in light of HHS's analysis of the limited benefits of the notice and tagline requirements in relation to their significant burdens, the Court cannot conclude that Plaintiffs have established that HHS "failed to consider an important aspect of the problem" or "offered an explanation for its decision that runs counter to the evidence before the agency." State Farm, 463 U.S. at 43.

Finally, in their reply brief, Plaintiffs argue for the first time that HHS "failed to adequately consider regulatory alternatives" to a repeal of the notice and tagline provisions, such as the possibility of issuing guidance clarifying the communications the agency considered to be "significant." Pl. Reply at 15. As an initial matter, "district courts . . . generally deem arguments made only in reply briefs to be forfeited." Pardo-Kronemann v. Donovan, 601 F.3d 599, 610 (D.C. Cir. 2010). In any event, Plaintiffs appear to be squarely mistaken that HHS "did not consider" such an alternative, see Pl. Reply at 15, as the agency specifically "decline[d] to retain [the notice and tagline] requirements while merely issuing more guidance on what constitute significant communications." 85 Fed. Reg. at 37,176. Plaintiffs never acknowledge that discussion.

As Plaintiffs have not demonstrated any procedural deficiency in HHS's elimination of the 2016 Rule's notice and tagline requirements, the Court rejects their proposal to enjoin such repeal.

5. *Section 1554*

Across their two briefs, the sum total of Plaintiffs' argument that the 2020 Rule violates Section 1554 of the ACA amounts to approximately a single page. See Pl. Mot. at 26; Pl. Reply at 19–20. The Court likewise need not spend much time here.

Section 1554 prohibits HHS from promulgating any regulation that, *inter alia*, "creates any unreasonable barriers to the ability of individuals to obtain appropriate medical care," "impedes timely access to health care services," or "interferes with communications regarding a full range of treatment options between the patient and the provider." 42 U.S.C. § 18114(1)–(3). Plaintiffs contend that the 2020 Rule runs afoul of these prohibitions.

Although caselaw construing Section 1554 is extremely sparse, the Court draws guidance from the sole court of appeals decision interpreting the provision. There, the *en banc* Ninth Circuit explained that "[t]he most natural reading of § 1554 is that Congress intended to ensure that HHS, in implementing the broad authority provided by the ACA, does not improperly impose regulatory burdens on doctors and patients." California *ex rel.* Becerra v. Azar, 950 F.3d 1067, 1094 (9th Cir. 2020) (*en banc*). The court rejected the plaintiffs' argument that an HHS regulation implementing various measures designed to ensure that certain funds would not be used to promote abortion services violated Section 1554. Id. at 1092. According to the court, because the rule at issue "places no substantive barrier on individuals' ability to obtain appropriate medical care or on doctors' ability to communicate with clients," it "does not

implicate § 1554," which prevents only "direct government interference with health care." Id. at 1094–95.

Plaintiffs provide no reason to depart from this interpretation. Indeed, they do not address California at all, despite the fact that Defendants highlighted the case in their brief. See Def. Opp. at 32. Nor do Plaintiffs cite a single case construing Section 1554 or otherwise offer anything resembling an interpretation of the provision. Instead, they reference broad assertions in their declarations that various provisions of the 2020 Rule "invite[] discrimination against LGBTQ people," "discourage[] them from seeking care in the first instance," and "burden [their] access to health care." Pl. Reply at 19–20; see also id. (alleging that 2020 Rule will cause a "reduction of coverage" and hinder receipt of "health care information"). Plaintiffs, however, cannot show that the Rule places a "substantive barrier on individuals' ability to obtain appropriate medical care." California, 950 F.3d at 1095. A regulation that does so would itself affirmatively "impede[]" access to health care and itself "interfere[]" with communications regarding treatment options; by contrast, the challenged provisions principally reduce regulatory burdens affecting patients and covered entities. See 42 U.S.C. § 18114(2)–(3); see also Planned Parenthood of Md., Inc. v. Azar, No. 20-361, 2020 WL 3893241, at *9–10 (D. Md. July 10, 2020) (holding that regulation violated Section 1554 by requiring insurers to provide two separate bills for particular services, as opposed to one combined bill, thereby "mak[ing] it harder for consumers to pay for insurance," and distinguishing California given that direct imposition of regulatory burden).

To be clear, the Court today need not, and does not, fully embrace California's interpretation of Section 1554. It preserves the possibility that a regulation generating sufficiently severe and demonstrated negative consequences for the "ability of individuals to

obtain appropriate medical care" or "timely access to health care services" might violate Section 1554, see 42 U.S.C. § 18114(1)–(2), even if the rule itself does not amount to "direct government interference with health care" by requiring providers or patients to perform or abstain from certain conduct. California, 950 F.3d at 1094. Plaintiffs however, must offer a greater showing of those negative implications than simply broad statements in declarations attesting to alleged future harm at the hands of unnamed providers and insurers, and they must sufficiently tie such harm to the challenged regulation itself. Their inability to do so here prevents their success on the merits.

6. *Constitutional Claims*

The Court's last merits destination is Plaintiffs' four constitutional claims. As a reminder, they contend that the 2020 Rule runs afoul of the Fifth Amendment's guarantees of equal protection and substantive due process, infringes their right to free speech, and violates the Establishment Clause. The reader need not gather her wits again, for very little discussion is warranted. In light of its prior disposition of Plaintiffs' various arbitrary-and-capricious challenges, the Court finds that it need not presently rule on any of these tag-along constitutional claims. This is so, essentially, because resolution of Plaintiffs' APA claims provides them all the relief they seek with respect to the relevant challenged provisions.

a. Equal Protection

Start with the equal-protection claim. As Plaintiffs' briefing makes clear, this challenge is premised in whole on HHS's elimination of the 2016 Rule's definition of sex discrimination. According to Plaintiffs, the "[2020] Rule constitutes government action that purports to permit discrimination on the basis of gender identity under Section 1557." Pl. Reply at 21. They focus exclusively on how the Rule "does not simply repeat the text of the statute — it excludes gender

identity and sex stereotyping from Section 1557's protections." Id.; see also Pl. Mot. at 28 (arguing 2020 Rule "carv[es] . . . out" LGBTQ people "from regulatory nondiscrimination protections under Section 1557"). Separately, they contend that HHS violated the Equal Protection Clause because it harbored impermissible discriminatory animus against LGBTQ people. See Pl. Mot. at 29–31. But that assertion, once more, rests entirely on the elimination of the 2016 Rule's explicit prohibitions. See Pl. Reply at 21 (claiming there is "discriminatory animus behind the [2020] Rule's exclusion of LGBTQ people from Section 1557"); Pl. Mot. at 29 ("[T]he exclusion of LGBTQ people from the nondiscrimination protections under Section 1557 is motivated by the Trump administration's and HHS officials' clear animus against LGBTQ people.").

The Court, however, has already found that HHS's repeal of the 2016 Rule's prohibition on discrimination based on sex stereotyping was arbitrary and capricious, and that Plaintiffs lack standing to challenge the elimination of the gender-identity provision. See *supra* at 31, 57. The former disposition will, for the reasons given below, yield an injunction barring enforcement of that repeal. As a result, the Court need not presently consider an independent constitutional challenge to the same provision that would generate for Plaintiffs no additional relief. See Damus v. Nielson, 313 F. Supp. 3d 317, 335 (D.D.C. 2018) (declining to address plaintiffs' additional constitutional argument when resolution of APA claim yielded desired injunctive relief); Aracely, R. v. Nielsen, 319 F. Supp. 3d 110, 154 n.29 (D.D.C. 2018) (same). Indeed, forbearance is all the more warranted in light of the Supreme Court's longstanding instruction that courts "ought not to pass on questions of constitutionality . . . unless such adjudication is unavoidable." Spector Motor Serv. v. McLaughlin, 323 U.S. 101, 105 (1944).

b. Substantive Due Process

Plaintiffs' substantive-due-process claim yields the same outcome, as it is once again premised on the "[2020] Rule's elimination of the definition of 'on the basis of sex.'" Pl. Reply at 22; see also id. (arguing that 2020 Rule "interfere[s] with LGBTQ people's ability to express their identity . . . by inviting discrimination against LGBTQ people," thereby violating substantive due process). By finding for Plaintiffs on their arbitrary-and-capricious challenge to that repeal, the Court rendered unnecessary any consideration of an alternative ground for enjoining the same agency action.

It bears noting that, although their reply brief appears to limit any substantive-due-process argument to the elimination of the 2016 Rule's sex-discrimination definition, Plaintiffs at times cast their due-process claim as challenging the 2020 Rule as a whole. See Pl. Mot. at 31 ("The [2020] Rule must be set aside."). Their exceedingly brief discussion, however, identifies no specifically challenged regulatory action other than the repeal of the 2016 Rule's definition. In any event, the Court's standing and merits dispositions leave only two provisions for potential discussion: the elimination of the 2016 Rule's prohibition on categorical coverage exclusions and notice requirements. At no point do Plaintiffs suggest that these repeals amount to a substantive-due-process violation.

c. Free Speech

Plaintiffs next posit that the 2020 Rule "impermissibly chills LGBTQ patients . . . from being open about their gender identity, transgender status, or sexual orientation and from expressing themselves in a manner consistent with each's gender identity or sexual orientation," in violation of the First Amendment. See Pl. Mot. at 31. Although Plaintiffs never point to the specific regulatory provision that causes this alleged "chill[ing]" of expression, their discussion

appears to attribute it to the 2020 Rule's repeal of the prior definition of sex discrimination and incorporation of Title IX's religious exemption. See Pl. Reply at 22 (contending that 2020 Rule "discourages and constrains" expression by "inviting health care discrimination against LGBTQ people"); Pl. Mot. at 32 (similar). Nowhere do Plaintiffs identify any other components of the 2020 Rule that might underlie their free-speech claim. Once again, therefore, because this constitutional challenge is apparently confined to regulatory actions already deemed arbitrary and capricious, the Court need not presently resolve it.

d. Establishment Clause

Finally, Plaintiffs insist that the 2020 Rule violates the Establishment Clause "because it imposes costs, burdens, and harms on plaintiffs, their members, and patients to facilitate the religious beliefs of objecting providers." Pl. Mot. at 33. Perhaps predictably, this challenge is based entirely on the Rule's incorporation of religious exemptions from Section 1557's nondiscrimination mandate. See id.; Pl. Reply at 22–23. The Court has already found HHS's adoption of Title IX's religious exemption to be arbitrary and capricious, so it need not presently resolve any Establishment Clause challenge regarding that particular regulatory action, for the same reasons previously discussed.

Plaintiffs also appear to take issue with the 2020 Rule's incorporation of "'definitions, exemptions, affirmative rights, or protections' from unrelated statutes." Pl. Mot. at 33 (quoting 45 C.F.R. § 92.6(b)). This vague invocation, however, does not come anywhere close to informing the Court of the precise basis for their constitutional challenge. The cited regulatory provision incorporates protections from more than ten distinct statutes, as well as "any related, successor, or similar Federal laws or regulations." 45 C.F.R. § 92.6(b). Aside from Title IX, Plaintiffs mention none of these laws, let alone explain why incorporation of their various rights

or protections violates the Establishment Clause. The Court declines to analyze the merits of a claim Plaintiffs have not coherently pressed.

B. Irreparable Harm

Although the first prong of the preliminary-injunction test consumed no small amount of ink, the next one is not nearly as prolix. It asks whether Plaintiffs are "likely to suffer irreparable harm in the absence of preliminary relief." Winter, 555 U.S. at 20. Since the Court has determined that they are likely to succeed on their challenges to HHS's repeal of the 2016 Rule's definition of sex discrimination and incorporation of Title IX's religious exemption, it need only consider irreparable harm with respect to those two claims. The Court finds that the health-provider Plaintiffs have made the requisite showing as to each.

"To demonstrate irreparable injury, a plaintiff must show that it will suffer harm that is 'more than simply irretrievable; it must also be serious in terms of its effect on the plaintiff.'" Hi-Tech Pharmacal Co. v. FDA, 587 F. Supp. 2d 1, 11 (D.D.C. 2008) (quoting Gulf Oil Corp. v. Dep't of Energy, 514 F. Supp. 1019, 1026 (D.D.C. 1981)). In other words, the harm must be "both certain and great; it must be actual and not theoretical," and of a nature "of such imminence that there is a clear and present need for equitable relief to prevent irreparable harm." Wis. Gas Co. v. FERC, 758 F.2d 669, 674 (D.C. Cir. 1985) (quotation marks and emphasis omitted). In addition, the harm "must be beyond remediation." Chaplaincy of Full Gospel Churches, 454 F.3d at 297.

Here, there is little question that the health-provider Plaintiffs have shown they will suffer some harm. As the D.C. Circuit has confirmed, "[O]bstacles" that "unquestionably make it more difficult for [an organization] to accomplish [its] primary mission . . . provide injury for purposes both of standing and irreparable harm." League of Women Voters, 838 F.3d at 9 (emphasis

added); see also Open Communities All. v. Carson, 286 F. Supp. 3d 148, 177 (D.D.C. 2017) (same). As the Court has already determined, see *supra* at 28–29, 34, elimination of the 2016 Rule's sex-discrimination definition and incorporation of Title IX's religious exemption will likely "perceptibly impair[]" the health-provider Plaintiffs' "ability to provide services." Food & Water Watch, 808 F.3d at 919.

With harm having been established, the Court may move to the principal issues in assessing the irreparability of Plaintiffs' injuries — namely, the harm's extent and remediability. The health-provider Plaintiffs have demonstrated that they will likely experience an array of financial and operational burdens as a result of the two regulatory actions at issue. As a reminder, they have shown that the 2020 Rule will lead to a significant increase in demand for their health-care services from LGBTQ patients who fear discrimination at the hands of external providers. See Bolan Decl., ¶¶ 11, 13, 18; Shafi Decl., ¶ 34; Henn Decl., ¶¶ 19, 29. It "will demand organizational resources" to service this increased patient population, as care does not pay for itself. Dist. of Columbia, 444 F. Supp. 3d at 41. In addition, the health-provider Plaintiffs will be forced to provide increasingly difficult treatment for LGBTQ patients who arrive with more acute conditions, either because they refrain from being fully transparent with their external providers given their heightened fears of discrimination, or because such apprehension causes them to delay seeking necessary care entirely. See Bolan Decl., ¶¶ 11, 17; Shafi Decl., ¶ 21; Salcedo Decl., ¶ 33; Cummings Decl., ¶ 16; Carpenter Decl., ¶ 20.

Whitman-Walker, for instance, explains that many of its health-care services currently lose money, and the "pressure" on those services will be "exacerbate[d]" by an influx of new clients. See Shafi Decl., ¶¶ 34–35; see also id., ¶ 34 (questioning Whitman-Walker's ability to "sustain the additional financial burdens resulting from an increased load of patients"). The

delayed provision of care — from either increased demand or patients' deferring such care and arriving with worsened conditions — will "strain Whitman-Walker's resources," "increase costs," and "make it harder for [its] health care providers to treat the patients." Henn Decl., ¶¶ 21, 29. For its own part, LA LGBT asserts that the 2020 Rule "makes it difficult, if not impossible, for the Center to continue providing the same level of social, mental, and physical health care to its patients." Cummings Decl., ¶ 33; see also Carpenter Decl., ¶ 16 (describing how "increase in demand . . . will limit my ability to provide adequate care and time to my patients" and may worsen outcomes); Cummings Decl., ¶ 20 (explaining how "increased demand" will cause "financial strains on the Center"). As the Court has already shown, see *supra* at 26, these harms are far from "speculative." Def. Opp. at 42. And they will "be serious in terms of [their] effect[s] on [Plaintiffs],'" jeopardizing their ability to treat all patients who turn to their organizations for urgent health-care needs. See Hi-Tech Pharmacal Co., 587 F. Supp. 2d at 11 (quoting Gulf Oil Corp., 514 F. Supp. at 1026).

Beyond these injuries, the health-provider Plaintiffs have also pointed to other ways in which they will "expend[] resources 'in response to, and to counteract, the effects of the [2020 Rule].'" PETA II, 797 F.3d at 1097 (quoting Equal Rights Ctr., 633 F.3d at 1140). It is well established that even resources "expend[ed] . . . to educate [an organization's] members and others" qualifies as injury where "doing so subjects the organization to 'operational costs beyond those normally expended.'" Food & Water Watch, 808 F.3d at 920 (quoting Nat'l Taxpayers Union, 68 F.3d at 1434); see also Nat'l Ass'n of Home Builders v. EPA, 667 F.3d 6, 12 (D.C. Cir. 2011).

That is exactly what will occur here, as the health-provider Plaintiffs will "need to devote more resources to working with outside providers and organizations to remind them of the

importance of providing health care to all patients on nondiscriminatory terms." Shafi Decl., ¶ 37 (emphasis added); see also id. (citing plans to "increase [Whitman-Walker's] education programs and community outreach" to deal with effects of 2020 Rule). LA LGBT has cited "confusion and panic created by the [2020] Rule" as leading it to "already . . . expend additional resources educating its clients and staff about their rights," and it intends to continue doing so. See Cummings Decl., ¶¶ 9, 14 (emphasis added); Dist. of Columbia, 444 F. Supp. 3d at 41 (crediting similar allegations of need to expend resources on "outreach" and "education" regarding agency action). It likewise intends to host informational sessions about how the Rule will affect patients and LA LGBT's services, which will force the organization "to divert resources away from other programming." Cummings Decl., ¶ 26. These expenditures will further burden budgets that are already severely strained, subjecting the health-provider Plaintiffs to additional operational expenses. See Shafi Decl., ¶ 36–37; Cummings Decl., ¶ 8.

Courts routinely find irreparable harm based on similar allegations of future injury. See Open Communities All., 286 F. Supp. 3d at 178 (irreparable harm where agency action threatened to "frustrate[]" organization's mission, and where organization stated intention to counteract action by spending resources on outreach, public education, and advocacy); Dist. of Columbia, 444 F. Supp. 3d at 40–42 (irreparable harm where organization alleged that agency action would cause individuals to "turn to [its] food assistance program, increasing demand and forcing [organization] to divert resources"); E. Bay Sanctuary Covenant v. Trump, 354 F. Supp. 3d 1094, 1109, 1116 (N.D. Cal. 2018) (irreparable harm when organization "experienced difficulty implementing its programs" and expended resources to counteract agency action); see also League of Women Voters, 838 F.3d at 9 (irreparable harm when challenged action "ma[de] it more difficult for [organizations] to accomplish their primary mission of registering voters").

The plentiful evidence indicating that Plaintiffs will suffer their alleged harms renders this case far afield from John Doe Company v. CFPB, 849 F.3d 1129 (D.C. Cir. 2017), cited by Defendants, where the plaintiff simply asserted it would suffer economic harm in conclusory fashion "unaccompanied by any relevant declarations." Id. at 1134 (emphasis added); see Def. Opp. at 42. Because of the significant financial and operational harms the health-provider Plaintiffs will suffer on account of the 2020 Rule — and the consequent, well-established threat to their ability to deliver timely and effective care to their patients — the Court finds that their asserted injuries clear the irreparable-harm threshold.

In response, Defendants primarily insist that the health-provider Plaintiffs cannot demonstrate irreparable injury through economic harm unless such harm "threaten[s]" the "'very existence' of [their] business." Def. Surreply at 13 (quoting Soundboard Assn. v. U.S. Fed. Trade Comm'n, 254 F. Supp. 3d 7, 13 (D.D.C. 2017)); Def. Opp. at 42. Defendants are correct that while "economic loss does not, in and of itself, constitute irreparable harm," such loss may be sufficient where it "threatens the very existence of the movant's business." Wis. Gas. Co., 758 F.2d at 674. But that is not the entire story. As particularly relevant here, courts in this district have suggested that a lesser showing is permissible when the economic injury at issue is unrecoverable. Specifically, "where economic loss will be unrecoverable, such as in a case against a Government defendant where sovereign immunity will bar recovery, economic loss can be irreparable" even if it would not wipe the business out. Everglades Harvesting & Hauling, Inc. v. Scalia, 427 F. Supp. 3d 101, 115 (D.D.C. 2019); see also Dist. of Columbia, 444 F. Supp. 3d at 37 n.25 (deeming "existential harm requirement" inapplicable to unrecoverable economic harm) (citing Open Communities All., 286 F. Supp. 3d at 178); Texas Children's Hospital v. Burwell, 76 F. Supp. 3d 224, 242–44 (D.D.C. 2014). Other jurisdictions have adopted similar

approaches. See Chamber of Commerce v. Edmondson, 594 F.3d 742, 770–71 (10th Cir. 2010) ("Imposition of monetary damages that cannot later be recovered for reasons such as sovereign immunity constitutes irreparable injury."); Iowa Utilities Bd. v. FCC, 109 F.3d 418, 426 (8th Cir. 1996) ("The threat of unrecoverable economic loss, however, does qualify as irreparable harm.").

Overlooking this line of authority, Defendants rely on but a single case — National Mining Association v. Jackson, 768 F. Supp. 2d 34 (D.D.C. 2011) — for the proposition that unrecoverable monetary damages are irreparable only if they threaten a business's existence. See Def. Opp. at 42. Yet they never quote from the decision, and it is clear why: nothing contained within it stands for their asserted principle. On the contrary, National Mining Association states that "if a movant seeking a preliminary injunction 'will be unable to sue to recover any monetary damages against' a government agency in the future because of, among other things, sovereign immunity, financial loss can constitute irreparable injury." 768 F. Supp. 2d at 52 (quoting Brendsel v. Office of Fed. Hous. Enter. Oversight, 339 F. Supp. 2d 52, 66–67 (D.D.C. 2004)); see also Texas Children's Hospital, 76 F. Supp. 3d at 242–44 (citing National Mining Association before concluding that unrecoverable economic harm was irreparable even though it "would not drive plaintiffs out of business") (emphasis added); Everglades Harvesting & Hauling, 427 F. Supp. 3d at 116 (finding irreparable harm from "unrecoverable" projected losses, even if they "do not sink these small businesses"). The court went on to suggest that other factors may prevent non-existential economic losses from rising to the level of irreparable harm, but nonetheless concluded that "[i]f a plaintiff has shown that financial losses are certain, imminent, and unrecoverable, then the imposition of a preliminary injunction is appropriate and necessary." Nat'l Mining Ass'n, 768 F. Supp. 2d at 52–53; see also Texas Children's Hospital, 76 F. Supp. 3d at 242 (similar). Here, the health-provider Plaintiffs check all three boxes.

As an initial matter, their injuries are unrecoverable because the present suit arises under the APA, which does not allow for recovery of monetary damages. See 5 U.S.C. § 702 (providing for relief "other than money damages"); E. Bay Sanctuary Covenant v. Barr, 964 F.3d 832, 854 (9th Cir. 2020) ("In the APA context, economic harms may be irreparable because plaintiffs are otherwise unable to recover monetary damages."); Open Communities All., 286 F. Supp. 3d at 178 (concluding that plaintiff need not show existential threat to business because its "monetary losses . . . are not recoverable, as the APA provides no damages remedy"). Defendants, moreover, have at no point suggested any waiver of sovereign immunity that might enable recovery of monetary damages from HHS. See Dist. of Columbia, 444 F. Supp. 3d at 34 (explaining that "economic injury caused by federal agency action is unrecoverable because the APA's waiver of sovereign immunity does not extend to damages claims"); Everglades Harvesting & Hauling, 427 F. Supp. 3d at 115 (similar). In addition, as previously discussed, Plaintiffs' financial losses are "certain" and "imminent." Nat'l Mining Ass'n, 768 F. Supp. 2d at 53. The Court also does not turn a blind eye to the reality that here, "economic loss" is not simply "loss of profit"; rather, it means "reducing [health-care] services" to patients, many of whom are indigent. See Texas Children's Hospital, 76 F. Supp. 3d at 243–44.

Concluding that Plaintiffs need not show a threat to their very existence in order to establish irreparable harm, of course, does not excuse them from their obligation to show that future economic injury will be "certain," "great," and "actual." Wis. Gas Co., 758 F.2d at 674. The Court readily acknowledges that "[a] prospective injury that is sufficient to establish standing . . . does not necessarily satisfy the more demanding burden of demonstrating irreparable injury." Cal. Ass'n of Private Postsecondary Schs. v. DeVos, 344 F. Supp. 3d 158, 170 (D.D.C. 2018). Here, however, for the reasons explained above, the health-provider

Plaintiffs' unrecoverable future harm is of such a degree, severity, and "imminence that there is a clear and present need for equitable relief to prevent" it. Wis. Gas Co., 758 F.2d at 674.

As a final coda, the Court briefly notes that the preliminary injunction recently issued by the Eastern District of New York does not alter this result. See Walker, 2020 WL 4749859, at *10. That injunction barred HHS from carrying out its repeal of the relevant provisions of the 2016 Rule's sex-discrimination definition. Id. This state of affairs thus raises potential questions as to whether Plaintiffs can still demonstrate irreparable harm regarding sex stereotyping in the absence of a similar order here. In other words, if that provision of the Rule is already enjoined, where is the pressing injury? While it is true that HHS cannot eliminate the Rule's explicit prohibition on sex stereotyping today, circumstances may well be different tomorrow. This Court, after all, has no "power over or knowledge of whether and, if so, when" Walker's preliminary injunction "will be lifted or modified." Cook Cty. v. McAleenan, 417 F. Supp. 3d 1008, 1030 (N.D. Ill. 2019). Indeed, "[e]ven a temporary lag between the lifting" of that injunction (or restriction of its geographic scope) and entry of an injunction by this Court would likely "entail some irreparable harm" to Plaintiffs. Id.

For these reasons, courts routinely grant follow-on injunctions against the Government, even in instances when an earlier nationwide injunction has already provided plaintiffs in the later action with their desired relief. See, e.g., California v. HHS, 390 F. Supp. 3d 1061, 1065–66 (N.D. Cal. 2019) (issuing nationwide injunction, even though another court had already ordered same relief, because "the existence of another injunction — particularly one in a different circuit that could be overturned or limited at any time — does not negate [plaintiff's] claimed irreparable harm"); Mayor & City Council of Baltimore v. Azar, 392 F. Supp. 3d 602, 618–19 (D. Md. 2019) (ordering "overlapping" injunction even though nationwide injunction

had been issued in earlier case, and rejecting argument that there was no irreparable harm); Batalla Vidal v. Nielsen, 279 F. Supp. 3d 401, 435 (E.D.N.Y. 2018), vacated in part and rev'd in part on other grounds, Regents of the Univ. of California, 140 S. Ct. 1891 (granting injunction notwithstanding prior nationwide injunction because prior injunction could be lifted, and noting that Government "cite[s] no authority for the proposition that Plaintiffs cannot establish irreparable harm simply because another court has already enjoined the same challenged action").

The Court acknowledges that other courts have taken different approaches. Some, for instance, have entered discretionary stays or otherwise denied preliminary-injunction motions upon the issuance of a nationwide injunction granting relief similar to what plaintiffs in the later suit sought. See Pars Equality Ctr. v. Trump, No. 17-255, slip op. at 6–7 (D.D.C. Mar. 2, 2018); Washington v. Trump, No. 17-0141, 2017 WL 4857088, at *6 (W.D. Wash. Oct. 27, 2017). Recognizing that "overlapping injunctions appear to be a common outcome of parallel litigation," however, the Court finds that Plaintiffs have established irreparable harm on their sex-discrimination-definition claim notwithstanding the injunction in Walker. See California, 390 F. Supp. 3d at 1065. The Court declines to forbear when neither party has asked it to do so, and when the relevant out-of-circuit injunction could be stayed, modified, or otherwise vacated at any time.

C. Balance of Equities and Public Interest

Having established a likelihood of success on the merits and irreparable harm, Plaintiffs must finally demonstrate "that the balance of equities tips in [their] favor," and that "an injunction is in the public interest." Sherley, 644 F.3d at 392 (quoting Winter, 555 U.S. at 20). These last two prongs — which "merge when the Government is the opposing party," FBME

Bank Ltd. v. Lew, 125 F. Supp. 3d 109, 127 (D.D.C. 2015) (quoting Nken v. Holder, 556 U.S. 418, 435 (2009)) — pose no serious obstacle to Plaintiffs' request for a preliminary injunction.

The health-provider Plaintiffs have shown that they will suffer significant financial and programmatic harm as a result of HHS's repeal of the 2016 Rule's sex-discrimination definition and its incorporation of Title IX's religious exemption. These irreparable injuries, which the Court need not belabor again here, will impair Plaintiffs' public-health programs and cause them to divert already scarce resources to counteract the 2020 Rule's effects. In addition, denying an injunction would impede the public interest by threatening the health of LGBTQ individuals at large, some of whom will likely develop increasingly acute conditions on account of their delaying necessary care or refraining from transparent communication with providers out of fear of discrimination. There is clearly a robust public interest in safeguarding prompt access to health care. See New York v. DHS, Nos. 19-3591, 19-3595, 2020 WL 4457951, at *31 (2d Cir. Aug. 4, 2020) (finding that public interest favored preliminary injunction where agency action would likely result in worse health outcomes); California v. Azar, 911 F.3d 558, 582 (9th Cir. 2018) (similar). The COVID-19 pandemic only reinforces the importance of that public interest and the concomitant need to ensure the availability and provision of care on a nondiscriminatory basis.

On the other side of the ledger, Defendants emphasize the harm to an agency if a court enjoins it "from effectuating statutes enacted" by Congress. See Def. Opp. at 43 (quoting Maryland v. King, 567 U.S. 1301 (2012) (Roberts, C.J., in chambers)). But "[t]here is generally no public interest in the perpetuation of unlawful agency action." League of Women Voters, 838 F.3d at 12. "To the contrary, there is a substantial public interest 'in having governmental agencies abide by the federal laws that govern their existence and operations.'" Id. (quoting

Washington v. Reno, 35 F.3d 1093, 1103 (6th Cir. 1994)); see also N. Mariana Islands v. United States, 686 F. Supp. 2d 7, 21 (D.D.C. 2009) ("The public interest is served when administrative agencies comply with their obligations under the APA."). HHS cannot invoke the public interest as being in favor of its actions when it promulgated the two relevant provisions in disregard of the APA's procedural mandates.

In addition, although Defendants cite the 2016 Rule's "substantial costs," Def. Opp. at 43, they fail to trace any to the two regulatory actions at issue here, as opposed to more likely subjects such as the prior Rule's notice and tagline provisions. Defendants separately claim that the 2016 Rule "failed to protect religious interests" and "interfered with . . . medical and ethical judgment." Id. Yet nothing in this Court's Order affects the application of RFRA — which the 2020 Rule made clear applies in full to Section 1557, see 45 C.F.R. § 92.6(b) — or any of the additional religious protections previously discussed. As these asserted harms do not outweigh those of Plaintiffs, the Court finds that the balance of equities tips in Plaintiffs' favor, and that an injunction is in the public interest.

V. Remedy

Having found that Plaintiffs are entitled to an injunction — at least as to the sex-stereotyping and religious-exemption issues — the Court now turns to its scope. Both Circuit precedent and the need to provide Plaintiffs complete relief confirm that a nationwide injunction is the appropriate remedy here.

"Once invoked, the scope of a district court's equitable powers . . . is broad, for breadth and flexibility are inherent in equitable remedies." Brown v. Plata, 563 U.S. 493, 538 (2011) (citation and internal quotation marks omitted). The D.C. Circuit has confirmed that the "broad discretion" district courts enjoy when awarding equitable relief includes the authority to issue

nationwide injunctions. Nat'l Mining Ass'n v. U.S. Army Corps of Eng'rs, 145 F.3d 1399, 1408–09 (D.C. Cir. 1998). In National Mining Association, the court of appeals explained that "[w]hen a reviewing court determines that agency regulations are unlawful, the ordinary result is that the rules are vacated — not that their application to the individual petitioners is proscribed." Id. at 1409 (alteration in original) (quoting Harmon v. Thornburgh, 878 F.2d 484, 495 n.21 (D.C. Cir. 1989)). That is, upon demonstrating the illegality of an agency action of general applicability, "a single plaintiff, so long as he is injured by the rule, may obtain 'programmatic' relief that affects the rights of parties not before the court." Id. (quoting Lujan v. Nat'l Wildlife Fed'n, 497 U.S. 871, 913 (1990) (Blackmun, J., dissenting)). With these principles in mind, the D.C. Circuit affirmed the district court's nationwide injunction and rejected the agencies' argument that the injunctive relief should have extended only to the named plaintiffs. Id. at 1408–09.

The APA itself points in the same direction, providing clear instruction for what courts must do if they find that agency action is "arbitrary" or "capricious" — namely, "hold unlawful and set aside" the defective action. See 5 U.S.C. § 706(2); see also United Steel v. Mine Safety & Health Admin., 925 F.3d 1279, 1287 (D.C. Cir. 2019) ("The ordinary practice is to vacate unlawful agency action.") (citing 5 U.S.C. § 706(2)); Innovation Law Lab v. Wolf, 951 F.3d 1073, 1094 (9th Cir. 2020) (describing "presumption . . . in APA cases that the offending agency action should be set aside in its entirety rather than only in limited geographical areas").

This binding authority confirms the propriety of nationwide injunctions in APA cases where the challenged policy is found to be arbitrary and capricious or otherwise facially unlawful. Other courts in this district have recognized the same, leveraging the above reasoning and enjoining improper agency action on a nationwide basis. See, e.g., Dist. of Columbia, 444 F.

Supp. 3d at 47–49; Make the Road New York v. McAleenan, 405 F. Supp. 3d 1, 67–72 (D.D.C. 2019), rev'd on other grounds sub nom. Make the Road New York v. Wolf, 962 F.3d 612 (D.C. Cir. 2020); Doe v. Rumsfeld, 341 F. Supp. 2d 1, 17–19 (D.D.C. 2004); Am. Lands All. v. Norton, No. 00-2339, 2004 WL 3246687, at *3 (D.D.C. June 2, 2004); see also Planned Parenthood Fed'n of Am., Inc. v. Heckler, 712 F.2d 650, 651 (D.C. Cir. 1983) (affirming injunction prohibiting enforcement of federal regulations).

Ignoring this line of precedent entirely, Defendants briefly suggest that nationwide injunctions are historically dubious and are at odds with "traditional equitable practice." Def. Opp. at 43 (quoting DHS v. New York, 140 S. Ct. 599, 600 (2020) (Gorsuch, J., concurring in the grant of stay)). Whether or not this history is right, see Mila Sohoni, The Lost History of the "Universal" Injunction, 133 Harv. L. Rev. 920 (2020), Defendants do not cite a single binding precedent applying any such "established principles" to overturn or otherwise "narrow injunctive relief under the APA." Dist. of Columbia, 444 F. Supp. 3d at 48. On the contrary, as just explained, the D.C. Circuit has expressly endorsed nationwide injunctions in this context.

Defendants also contend that any relief ordered by this Court "should extend only to the named plaintiffs," Def. Opp. at 43, and that "injunctive relief should be no more burdensome to the defendant than necessary to provide complete relief to the plaintiffs." Id. at 43 (quoting Madsen v. Women's Health Ctr., Inc., 512 U.S. 753, 765 (1994)). But the "scope of injunctive relief is dictated by the extent of the violation established." Califano v. Yamasaki, 442 U.S. 682, 702 (1979). In fact, Defendants completely overlook the reality that their proposed remedy — an injunction that "extend[s] only to the named plaintiffs," Def. Opp. at 43 — would not provide Plaintiffs with any meaningful relief, let alone "complete relief." Califano, 442 U.S. at 702. That is because their asserted harms, as discussed at length above, derive largely from the effects

of the 2020 Rule on third-party LGBTQ patients. The reader well knows by now the relevant chain of events: the 2020 Rule's elimination of explicit sex-discrimination prohibitions and incorporation of Title IX's religious exemption instill in LGBTQ patients a fear of discrimination at the hands of external providers, thereby causing the health-provider Plaintiffs to suffer the significant financial and operational consequences of heightened demand and patients' arriving with increasingly acute conditions. Because these Plaintiffs' harms stem most immediately from the foreseeable responses of third parties to the 2020 Rule — rather than from any direct imposition of regulatory burden — an order barring enforcement of the Rule solely as to themselves would not remedy their injuries. Complete relief will only obtain upon an injunction with a broader sweep — one that reinstates the relevant provisions of the 2016 Rule as applied to all covered entities, a remedy that will mitigate the fears of LGBTQ patients and in turn alleviate the health-provider Plaintiffs' consequent harms.

In addition, although Defendants never specifically request an injunction limited in geographic scope, the Court notes that any such restriction on the applicability of its order would impair the provision of complete relief to Plaintiffs. Although Whitman-Walker is based in Washington, D.C., it delivers health-care services not only to locals, but also to people from Maryland, Virginia, Pennsylvania, West Virginia, and Delaware. See Shafi Decl., ¶ 4. LA LGBT, meanwhile, reports that many of its patients come from various parts of California, other states, and even other countries. See Cummings Decl., ¶ 4; Bolan Decl., ¶ 5. Many of the out-of-state individuals who seek the Center's services do so specifically out of fear of discrimination from local providers, and the organization reasonably expects these numbers only to increase. See Cummings Decl., ¶ 5. Just as an injunction limited to the health-provider

Plaintiffs would be futile to remediate their injuries, neither will one restricted in scope to their immediate locales provide them full relief.

Indeed, to the extent similarly situated LGBTQ-affirming health-care providers across the country experience comparable harms as a result of the 2020 Rule, nationwide relief becomes all the more appropriate. See Dist. of Columbia, 444 F. Supp. 3d at 51 (ordering nationwide injunction in part "because the burdens that would fall on the plaintiffs upon the Final Rule's implementation would also fall on those similarly situated"). There is no reason to believe — and nowhere do Defendants suggest — that the financial, programmatic, and operational injuries claimed by the health-provider Plaintiffs will be unique to them. Rather, the consequences of increased demand and patients' arriving with more acute conditions threaten the activities of all organizations that subscribe to a similar LGBTQ-affirming mission.

In rendering such a decision, the Court does not discount Defendants' general concern that nationwide relief may truncate the process by which legal challenges percolate through various jurisdictions in the federal court system. See Def. Opp. at 44. These concerns are significantly tempered here, though, by the fact that two district courts in other jurisdictions have already issued opinions on preliminary-injunction motions raising similar challenges to the 2020 Rule. See Walker, No. 20-2834 (E.D.N.Y. 2020); Washington, No. 20-1105 (W.D. Wash. 2020). Nothing in this Court's Order, moreover, prevents other courts from tackling these same issues — much like the injunction in Walker did not bar this Court from considering Plaintiffs' challenge to the repeal of the 2016 Rule's sex-discrimination definition. See also *supra* at 92–93 (citing instances of courts' issuing follow-on injunctions when other courts had previously ordered nationwide relief). In addition, Defendants' reservations ignore the D.C. Circuit's explicit instruction that unlawful agency regulations are ordinarily vacated universally, not

simply enjoined in application solely to the individual plaintiffs. Nat'l Mining Ass'n, 145 F.3d at 1409.

While the Court rejects Defendants' arguments against nationwide relief, so, too, does it decline Plaintiffs' sweeping invitation to enjoin the 2020 Rule "in its entirety." Pl. Mot. at 44 (capitalization altered). Plaintiffs believe that the rule is "so infected" that "there is no point in enjoining it on a piecemeal basis," and that HHS's failure to consider the Supreme Court's decision in Bostock "is indicative of the lack of reasoned decision-making that permeates the entire Revised Rule." Id. Such a holding would, of course, undo much of the analysis the Court has performed in this doorstop of an Opinion. As explained at length above, aside from the two provisions the Court enjoins, Plaintiffs have not demonstrated that any other component of the 2020 Rule was insufficiently reasoned (or that they have standing to assail it). Nowhere, moreover, do they explain how the agency's non-consideration of Bostock infects any of the Rule's numerous provisions — the majority of which Plaintiffs do not even mention, let alone challenge — other than the repeal of the 2016 Rule's sex-discrimination definition. See 85 Fed. Reg. at 37,243–48 (reproducing 2020 Rule's amendments in full). In addition, and unacknowledged by Plaintiffs, the 2020 Rule retains a severability clause. See 45 C.F.R. § 92.3(d). They never suggest that the extensive remainder of the 2020 Rule cannot "function sensibly" without the two discrete provisions the Court enjoins. MD/DC/DE Broads. Ass'n v. FCC, 236 F.3d 13, 23 (D.C. Cir. 2001).

At the end of the day, the Court finds an injunction of nationwide scope to be the appropriate remedy here. Such injunction will be limited to the two challenges for which Plaintiffs have demonstrated a likelihood of success on the merits — the 2020 Rule's repeal of the prior Rule's explicit prohibition on discrimination based on sex stereotyping, and the 2020

Rule's incorporation of Title IX's religious exemption. This ruling as to the former tracks in part the order of the Eastern District of New York in Walker, which enjoined HHS from enforcing the repeal "of the 2016 definition of discrimination on the basis of sex." Walker, 2020 WL 4749859, at *10. The injunction here, as discussed above, applies only to the repeal of the 2016 Rule's definition insofar as it included "sex stereotyping," as Plaintiffs lack standing to challenge the repeal of the previously vacated prohibition on "gender identity" discrimination. As to Title IX's religious exemption, however, this injunction is the first to issue.

VI. Conclusion

The Court, accordingly, will grant in part and deny in part Plaintiffs' Motion for a Preliminary Injunction or, in the Alternative, a Stay Pending Judicial Review. HHS will be preliminarily enjoined from enforcing the repeal of the 2016 Rule's definition of discrimination "[o]n the basis of sex" insofar as it includes "discrimination on the basis of . . . sex stereotyping." 81 Fed. Reg. at 31,467. In addition, the agency will be preliminarily enjoined from enforcing its incorporation of the religious exemption contained in Title IX. See 45 C.F.R. § 92.6(b). Plaintiffs' Motion will be denied in all other respects. A separate Order so stating will issue this day.

/s/ James E. Boasberg
JAMES E. BOASBERG
United States District Judge

Date: September 2, 2020

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

WHITMAN-WALKER CLINIC, INC., *et al.*, Plaintiffs,	)	
v.	)	Case No. 1:20-cv-01630-JEB
U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, *et al.*, Defendants.	)	

NOTICE OF APPEAL

Notice is hereby given that Defendants U.S. Department of Health and Human Services ("HHS"); Alex M. Azar II, in his official capacity as Secretary of HHS; Roger Severino, in his official capacity as Director, Office for Civil Rights, HHS; and Seema Verma, in her official capacity as Administrator for Centers for Medicare and Medicaid Services, HHS; hereby appeal to the United States Court of Appeals for the District of Columbia Circuit from the Order (ECF No. 55) and memorandum opinion (ECF No. 56) entered in this action on September 2, 2020.

Dated: October 31, 2020

Respectfully submitted,

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U.S. District Court
District of Columbia (Washington, DC)
CIVIL DOCKET FOR CASE #: 1:20-cv-01630-JEB

WHITMAN-WALKER CLINIC, INC. et al v. U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES et al
Assigned to: Judge James E. Boasberg
Case in other court: USCA, 20-05331
Cause: 05:551 Administrative Procedure Act

Date Filed: 06/22/2020
Jury Demand: None
Nature of Suit: 899 Administrative Procedure Act/Review or Appeal of Agency Decision
Jurisdiction: U.S. Government Defendant

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PRO HAC VICE
ATTORNEY TO BE NOTICED

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Plaintiff

TRANSLATIN@ COALITION represented by **Omar Francisco Gonzalez-Pagan**
(See above for address)
LEAD ATTORNEY
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Carl Solomon Charles
(See above for address)
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Jamie Avra Gliksberg
(See above for address)
TERMINATED: 10/27/2020
PRO HAC VICE

Karen Loewy
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Khristoph Becker
(See above for address)
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Laura Joy Edelstein
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Michael A. Vatis
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ATTORNEY TO BE NOTICED

Johanna Dennehy
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Plaintiff

LOS ANGELES LGBT CENTER represented by **Omar Francisco Gonzalez-Pagan**
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Johanna Dennehy
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ATTORNEY TO BE NOTICED

Plaintiff

BRADBURY-SULLIVAN LGBT COMMUNITY CENTER represented by **Omar Francisco Gonzalez-Pagan**
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Carl Solomon Charles
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TERMINATED: 10/27/2020
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Michael A. Vatis
(See above for address)
ATTORNEY TO BE NOTICED

Johanna Dennehy
(See above for address)
ATTORNEY TO BE NOTICED

Plaintiff

AMERICAN ASSOCIATION OF PHYSICIANS FOR HUMAN RIGHTS, INC.
doing business as
GLMA: HEALTH PROFESSIONALS ADVANCING LGBT EQUALITY

represented by **Omar Francisco Gonzalez-Pagan**
(See above for address)
LEAD ATTORNEY
PRO HAC VICE
ATTORNEY TO BE NOTICED

Carl Solomon Charles
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ATTORNEY TO BE NOTICED

Jamie Avra Gliksberg
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TERMINATED: 10/27/2020
PRO HAC VICE

Karen Loewy
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Khristoph Becker
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ATTORNEY TO BE NOTICED

Johanna Dennehy
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ATTORNEY TO BE NOTICED

Plaintiff

AGLP: THE ASSOCIATION OF LGBTQ PSYCHIATRISTS represented by **Omar Francisco Gonzalez-Pagan**
(See above for address)
LEAD ATTORNEY
PRO HAC VICE
ATTORNEY TO BE NOTICED

Carl Solomon Charles
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PRO HAC VICE
ATTORNEY TO BE NOTICED

Jamie Avra Gliksberg
(See above for address)
TERMINATED: 10/27/2020
PRO HAC VICE

Karen Loewy
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Khristoph Becker
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ATTORNEY TO BE NOTICED

Laura Joy Edelstein
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PRO HAC VICE
ATTORNEY TO BE NOTICED

Michael A. Vatis
(See above for address)

ATTORNEY TO BE NOTICED

Johanna Dennehy
(See above for address)
ATTORNEY TO BE NOTICED

Plaintiff

SARAH HENN
MD, MPH

represented by **Omar Francisco Gonzalez-Pagan**
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PRO HAC VICE
ATTORNEY TO BE NOTICED

Carl Solomon Charles
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PRO HAC VICE
ATTORNEY TO BE NOTICED

Jamie Avra Gliksberg
(See above for address)
TERMINATED: 10/27/2020
PRO HAC VICE

Karen Loewy
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PRO HAC VICE
ATTORNEY TO BE NOTICED

Khristoph Becker
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ATTORNEY TO BE NOTICED

Laura Joy Edelstein
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ATTORNEY TO BE NOTICED

Michael A. Vatis
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ATTORNEY TO BE NOTICED

Johanna Dennehy
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ATTORNEY TO BE NOTICED

Plaintiff

RANDY PUMPHREY
D.MIN, LCC, BCC

represented by **Omar Francisco Gonzalez-Pagan**
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LEAD ATTORNEY
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Carl Solomon Charles

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PRO HAC VICE
ATTORNEY TO BE NOTICED

Jamie Avra Gliksberg
(See above for address)
TERMINATED: 10/27/2020
PRO HAC VICE

Karen Loewy
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Khristoph Becker
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Laura Joy Edelstein
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ATTORNEY TO BE NOTICED

Michael A. Vatis
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ATTORNEY TO BE NOTICED

Johanna Dennehy
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ATTORNEY TO BE NOTICED

Plaintiff

ROBERT BOLAN
MD

represented by **Omar Francisco Gonzalez-Pagan**
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Carl Solomon Charles
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Jamie Avra Gliksberg
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TERMINATED: 10/27/2020
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Karen Loewy
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ATTORNEY TO BE NOTICED

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Khristoph Becker
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PRO HAC VICE
ATTORNEY TO BE NOTICED

Laura Joy Edelstein
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ATTORNEY TO BE NOTICED

Michael A. Vatis
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ATTORNEY TO BE NOTICED

Johanna Dennehy
(See above for address)
ATTORNEY TO BE NOTICED

Plaintiff

WARD CARPENTER
MD

represented by **Omar Francisco Gonzalez-Pagan**
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Carl Solomon Charles
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Jamie Avra Gliksberg
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TERMINATED: 10/27/2020
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ATTORNEY TO BE NOTICED

Michael A. Vatis
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ATTORNEY TO BE NOTICED

Johanna Dennehy
(See above for address)
ATTORNEY TO BE NOTICED

V.

Defendant

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES

represented by **Liam Holland**
U.S. DEPARTMENT OF JUSTICE
Civil Division, Federal Programs Branch
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ATTORNEY TO BE NOTICED

Defendant

ALEX M. AZAR, II
in his official capacity as Secretary of U.S. Department of Health and Human Services,

represented by **Liam Holland**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

William Kerwin Lane , III
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Jordan Landrum von Bokern
(See above for address)
ATTORNEY TO BE NOTICED

Defendant

ROGER SEVERINO *in his official capacity as Director, Office for Civil Rights, U.S. Department of Health and Human Services*	represented by **Liam Holland** (See above for address) *LEAD ATTORNEY* *ATTORNEY TO BE NOTICED* **William Kerwin Lane , III** (See above for address) *LEAD ATTORNEY* *ATTORNEY TO BE NOTICED* **Jordan Landrum von Bokern** (See above for address) *ATTORNEY TO BE NOTICED*

Defendant

SEEMA VERMA *in her official capacity as Administrator for the Centers for Medicare and Medicaid Services, U.S. Department of Health and Human Services*	represented by **Liam Holland** (See above for address) *LEAD ATTORNEY* *ATTORNEY TO BE NOTICED* **William Kerwin Lane , III** (See above for address) *LEAD ATTORNEY* *ATTORNEY TO BE NOTICED* **Jordan Landrum von Bokern** (See above for address) *ATTORNEY TO BE NOTICED*

Date Filed	#	Docket Text
06/22/2020	1	COMPLAINT against ALEX M. AZAR, II, ROGER SEVERINO, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, SEEMA VERMA (Filing fee $ 400 receipt number ADCDC-7253108) filed by SARAH HENN, MD, MPH, BRADBURY-SULLIVAN LGBT COMMUNITY CENTER, RANDY PUMPHREY, D.MIN, LCC, BCC, WARD CARPENTER, MD, LOS ANGELES LGBT CENTER, ROBERT BOLAN, MD, AMERICAN ASSOCIATION OF PHYSICIANS FOR HUMAN RIGHTS, INC. d/b/a GLMA: HEALTH PROFESSIONALS ADVANCING LGBTQ EQUALITY, THE TRANSLATIN@ COALITION, WHITMAN-WALKER CLINIC, Inc. d/b/a WHITMAN-WALKER HEALTH, AGLP: THE ASSOCIATION OF LGBTQ PSYCHIATRISTS. (Attachments: # 1 Exhibit 1, # 2 Exhibit 2, # 3 Civil Cover Sheet, # 4 Summons U.S. Department of Health and Human Services, # 5 Summons Alex M. Azar II, # 6 Summons Roger Severino, # 7 Summons Seema Verma, # 8 Summons U.S. Attorney General, # 9 Summons U.S. Attorney for the District of Columbia)(Dennehy, Johanna) (Entered: 06/22/2020)
06/22/2020	2	LCvR 26.1 CERTIFICATE OF DISCLOSURE of Corporate Affiliations and Financial Interests by AMERICAN ASSOCIATION OF PHYSICIANS FOR HUMAN RIGHTS, INC. d/b/a GLMA: HEALTH PROFESSIONALS ADVANCING LGBTQ EQUALITY (Dennehy, Johanna) (Entered: 06/22/2020)
06/22/2020	3	LCvR 26.1 CERTIFICATE OF DISCLOSURE of Corporate Affiliations and Financial

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		Interests by BRADBURY-SULLIVAN LGBT COMMUNITY CENTER (Dennehy, Johanna) (Entered: 06/22/2020)
06/22/2020	4	LCvR 26.1 CERTIFICATE OF DISCLOSURE of Corporate Affiliations and Financial Interests by LOS ANGELES LGBT CENTER (Dennehy, Johanna) (Entered: 06/22/2020)
06/22/2020	5	LCvR 26.1 CERTIFICATE OF DISCLOSURE of Corporate Affiliations and Financial Interests by THE TRANSLATIN@ COALITION (Dennehy, Johanna) (Entered: 06/22/2020)
06/22/2020	6	LCvR 26.1 CERTIFICATE OF DISCLOSURE of Corporate Affiliations and Financial Interests by WHITMAN-WALKER CLINIC, Inc. d/b/a WHITMAN-WALKER HEALTH (Dennehy, Johanna) (Entered: 06/22/2020)
06/22/2020	7	NOTICE *of Fed. R. Civ. P. 7.1 Disclosure Statement* by THE TRANSLATIN@ COALITION (Dennehy, Johanna) (Entered: 06/22/2020)
06/22/2020	8	NOTICE *of Fed. R. Civ. P. 7.1 Disclosure Statement* by BRADBURY-SULLIVAN LGBT COMMUNITY CENTER (Dennehy, Johanna) (Entered: 06/22/2020)
06/22/2020	9	NOTICE *of Fed. R. Civ. P. 7.1 Disclosure Statement* by AMERICAN ASSOCIATION OF PHYSICIANS FOR HUMAN RIGHTS, INC. d/b/a GLMA: HEALTH PROFESSIONALS ADVANCING LGBTQ EQUALITY (Dennehy, Johanna) (Entered: 06/22/2020)
06/22/2020	10	NOTICE *of Fed. R. Civ. P. 7.1 Disclosure Statement* by LOS ANGELES LGBT CENTER (Dennehy, Johanna) (Entered: 06/22/2020)
06/22/2020	11	NOTICE *of Fed. R. Civ. P. 7.1 Disclosure Statement* by WHITMAN-WALKER CLINIC, Inc. d/b/a WHITMAN-WALKER HEALTH (Dennehy, Johanna) (Entered: 06/22/2020)
06/22/2020	12	MOTION for Leave to Appear Pro Hac Vice :Attorney Name- Laura J. Edelstein, Filing fee $ 100, receipt number ADCDC-7254978. Fee Status: Fee Paid. by AGLP: THE ASSOCIATION OF LGBTQ PSYCHIATRISTS, AMERICAN ASSOCIATION OF PHYSICIANS FOR HUMAN RIGHTS, INC. d/b/a GLMA: HEALTH PROFESSIONALS ADVANCING LGBTQ EQUALITY, ROBERT BOLAN, MD, BRADBURY-SULLIVAN LGBT COMMUNITY CENTER, WARD CARPENTER, MD, SARAH HENN, MD, MPH, LOS ANGELES LGBT CENTER, RANDY PUMPHREY, D.MIN, LCC, BCC, THE TRANSLATIN@ COALITION, WHITMAN-WALKER CLINIC, Inc. d/b/a WHITMAN-WALKER HEALTH (Attachments: # 1 Declaration of Laura J. Edelstein, # 2 Text of Proposed Order)(Dennehy, Johanna) (Entered: 06/22/2020)
06/22/2020	13	MOTION for Leave to Appear Pro Hac Vice :Attorney Name- Khristoph A. Becker, Filing fee $ 100, receipt number ADCDC-7255109. Fee Status: Fee Paid. by AGLP: THE ASSOCIATION OF LGBTQ PSYCHIATRISTS, AMERICAN ASSOCIATION OF PHYSICIANS FOR HUMAN RIGHTS, INC. d/b/a GLMA: HEALTH PROFESSIONALS ADVANCING LGBTQ EQUALITY, ROBERT BOLAN, MD, BRADBURY-SULLIVAN LGBT COMMUNITY CENTER, WARD CARPENTER, MD, SARAH HENN, MD, MPH, LOS ANGELES LGBT CENTER, RANDY PUMPHREY, D.MIN, LCC, BCC, THE TRANSLATIN@ COALITION, WHITMAN-WALKER CLINIC, Inc. d/b/a WHITMAN-WALKER HEALTH (Attachments: # 1 Declaration of Khristoph A. Becker, # 2 Text of Proposed Order)(Dennehy, Johanna) (Entered: 06/22/2020)
06/22/2020	14	MOTION for Leave to Appear Pro Hac Vice :Attorney Name- Omar Gonzalez-Pagan, Filing fee $ 100, receipt number ADCDC-7255804. Fee Status: Fee Paid. by AGLP: THE ASSOCIATION OF LGBTQ PSYCHIATRISTS, AMERICAN ASSOCIATION OF PHYSICIANS FOR HUMAN RIGHTS, INC. d/b/a GLMA: HEALTH PROFESSIONALS ADVANCING LGBTQ EQUALITY, ROBERT BOLAN, MD, BRADBURY-SULLIVAN LGBT COMMUNITY CENTER, WARD CARPENTER, MD, SARAH HENN, MD,

		MPH, LOS ANGELES LGBT CENTER, RANDY PUMPHREY, D.MIN, LCC, BCC, THE TRANSLATIN@ COALITION, WHITMAN-WALKER CLINIC, Inc. d/b/a WHITMAN-WALKER HEALTH (Attachments: # 1 Declaration of Omar Gonzalez-Pagan, # 2 Text of Proposed Order)(Dennehy, Johanna) (Entered: 06/22/2020)
06/22/2020	15	MOTION for Leave to Appear Pro Hac Vice :Attorney Name- Karen L. Loewy, Filing fee $ 100, receipt number ADCDC-7255839. Fee Status: Fee Paid. by AGLP: THE ASSOCIATION OF LGBTQ PSYCHIATRISTS, AMERICAN ASSOCIATION OF PHYSICIANS FOR HUMAN RIGHTS, INC. d/b/a GLMA: HEALTH PROFESSIONALS ADVANCING LGBTQ EQUALITY, ROBERT BOLAN, MD, BRADBURY-SULLIVAN LGBT COMMUNITY CENTER, WARD CARPENTER, MD, SARAH HENN, MD, MPH, LOS ANGELES LGBT CENTER, RANDY PUMPHREY, D.MIN, LCC, BCC, THE TRANSLATIN@ COALITION, WHITMAN-WALKER CLINIC, Inc. d/b/a WHITMAN-WALKER HEALTH (Attachments: # 1 Declaration of Karen L. Loewy, # 2 Text of Proposed Order)(Dennehy, Johanna) (Entered: 06/22/2020)
06/22/2020	16	MOTION for Leave to Appear Pro Hac Vice :Attorney Name- Carl S. Charles, Filing fee $ 100, receipt number ADCDC-7255870. Fee Status: Fee Paid. by AGLP: THE ASSOCIATION OF LGBTQ PSYCHIATRISTS, AMERICAN ASSOCIATION OF PHYSICIANS FOR HUMAN RIGHTS, INC. d/b/a GLMA: HEALTH PROFESSIONALS ADVANCING LGBTQ EQUALITY, ROBERT BOLAN, MD, BRADBURY-SULLIVAN LGBT COMMUNITY CENTER, WARD CARPENTER, MD, SARAH HENN, MD, MPH, LOS ANGELES LGBT CENTER, RANDY PUMPHREY, D.MIN, LCC, BCC, THE TRANSLATIN@ COALITION, WHITMAN-WALKER CLINIC, Inc. d/b/a WHITMAN-WALKER HEALTH (Attachments: # 1 Declaration of Carl S. Charles, # 2 Text of Proposed Order)(Dennehy, Johanna) (Entered: 06/22/2020)
06/23/2020	17	MOTION for Leave to Appear Pro Hac Vice :Attorney Name- Jamie Gliksberg, Filing fee $ 100, receipt number ADCDC-7260338. Fee Status: Fee Paid. by AGLP: THE ASSOCIATION OF LGBTQ PSYCHIATRISTS, AMERICAN ASSOCIATION OF PHYSICIANS FOR HUMAN RIGHTS, INC. d/b/a GLMA: HEALTH PROFESSIONALS ADVANCING LGBTQ EQUALITY, ROBERT BOLAN, MD, BRADBURY-SULLIVAN LGBT COMMUNITY CENTER, WARD CARPENTER, MD, SARAH HENN, MD, MPH, LOS ANGELES LGBT CENTER, RANDY PUMPHREY, D.MIN, LCC, BCC, THE TRANSLATIN@ COALITION, WHITMAN-WALKER CLINIC, Inc. d/b/a WHITMAN-WALKER HEALTH (Attachments: # 1 Declaration of Jamie Gliksberg, # 2 Text of Proposed Order)(Dennehy, Johanna) (Entered: 06/23/2020)
06/24/2020		Case assigned to Judge James E. Boasberg. (zmc) (Entered: 06/24/2020)
06/24/2020	18	SUMMONS (6) Issued Electronically as to ALEX M. AZAR, II, ROGER SEVERINO, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, SEEMA VERMA, U.S. Attorney and U.S. Attorney General (Attachment: # 1 Notice and Consent) (zmc) (Entered: 06/24/2020)
06/26/2020	19	NOTICE of Appearance by Michael A. Vatis on behalf of All Plaintiffs (Vatis, Michael) (Entered: 06/26/2020)
06/29/2020		MINUTE ORDER GRANTING 12 Motion for Admission *Pro Hac Vice* of LAURA J. EDELSTEIN. **Counsel should register for e-filing via PACER and file a notice of appearance pursuant to LCvR 83.6(a). Click for instructions**. So ORDERED by Judge James E. Boasberg on 6/29/2020. (lcjeb2) (Entered: 06/29/2020)
06/29/2020		MINUTE ORDER GRANTING 13 Motion for Admission *Pro Hac Vice* of KRISTOPH A. BECKER. **Counsel should register for e-filing via PACER and file a notice of appearance pursuant to LCvR 83.6(a). Click for instructions**. So ORDERED by Judge James E. Boasberg on 6/29/2020. (lcjeb2) (Entered: 06/29/2020)

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06/29/2020		MINUTE ORDER GRANTING 14 Motion for Admission *Pro Hac Vice* of OMAR GONZALEZ-PAGAN. **Counsel should register for e-filing via PACER and file a notice of appearance pursuant to LCvR 83.6(a).** **Click for instructions**. So ORDERED by Judge James E. Boasberg on 6/29/2020. (lcjeb2) (Entered: 06/29/2020)
06/29/2020		MINUTE ORDER GRANTING 15 Motion for Admission *Pro Hac Vice* of KAREN L. LOEWY. **Counsel should register for e-filing via PACER and file a notice of appearance pursuant to LCvR 83.6(a).** **Click for instructions**. So ORDERED by Judge James E. Boasberg on 6/29/2020. (lcjeb2) (lcmg) (Entered: 06/29/2020)
06/29/2020		MINUTE ORDER GRANTING 16 Motion for Admission *Pro Hac Vice* of CARL S. CHARLES. **Counsel should register for e-filing via PACER and file a notice of appearance pursuant to LCvR 83.6(a).** **Click for instructions**. So ORDERED by Judge James E. Boasberg on 6/29/2020. (lcjeb2) (lcmg) (Entered: 06/29/2020)
06/29/2020		MINUTE ORDER GRANTING 17 Motion for Admission *Pro Hac Vice* of JAMIE AVRA GLIKSBERG. **Counsel should register for e-filing via PACER and file a notice of appearance pursuant to LCvR 83.6(a).** **Click for instructions**. So ORDERED by Judge James E. Boasberg on 6/29/2020. (lcjeb2) (Entered: 06/29/2020)
06/30/2020	20	NOTICE of Appearance by Omar Francisco Gonzalez-Pagan on behalf of All Plaintiffs (Gonzalez-Pagan, Omar) (Entered: 06/30/2020)
06/30/2020	21	NOTICE of Appearance by Laura Joy Edelstein on behalf of All Plaintiffs (Edelstein, Laura) (Entered: 06/30/2020)
06/30/2020	22	NOTICE of Appearance by Khristoph Becker on behalf of All Plaintiffs (Becker, Khristoph) (Entered: 06/30/2020)
07/02/2020	23	NOTICE of Appearance by Karen Loewy on behalf of All Plaintiffs (Loewy, Karen) (Entered: 07/02/2020)
07/02/2020	24	NOTICE of Appearance by Carl Solomon Charles on behalf of All Plaintiffs (Charles, Carl) (Entered: 07/02/2020)
07/03/2020	25	NOTICE of Appearance by Jamie Avra Gliksberg on behalf of All Plaintiffs (Gliksberg, Jamie) (Entered: 07/03/2020)
07/07/2020	26	RETURN OF SERVICE/AFFIDAVIT of Summons and Complaint Executed. ALEX M. AZAR, II served on 6/25/2020 (Dennehy, Johanna) (Entered: 07/07/2020)
07/07/2020	27	RETURN OF SERVICE/AFFIDAVIT of Summons and Complaint Executed on United States Attorney General. Date of Service Upon United States Attorney General 6/26/2020. (Dennehy, Johanna) (Entered: 07/07/2020)
07/07/2020	28	RETURN OF SERVICE/AFFIDAVIT of Summons and Complaint Executed as to the United States Attorney. Date of Service Upon United States Attorney on 6/26/2020. Answer due for ALL FEDERAL DEFENDANTS by 8/25/2020. (Dennehy, Johanna); Modified event and text on 7/21/2020 (ztth). (Entered: 07/07/2020)
07/08/2020		NOTICE OF ERROR re 26 Summons Returned Executed as to Federal Defendant; emailed to jdennehy@steptoe.com, cc'd 16 associated attorneys -- The PDF file you docketed contained errors: 1. FYI for future filings of this sort. Do not use the Affidavit of mailing forms. Use the form attached to the summons, Proof of Service. (ztd,) (Entered: 07/08/2020)
07/09/2020	29	MOTION for Preliminary Injunction *or, in the Alternative*, MOTION to Stay *Pending Judicial Review Pursuant to 5 U.S.C. 705* by AGLP: THE ASSOCIATION OF LGBTQ PSYCHIATRISTS, AMERICAN ASSOCIATION OF PHYSICIANS FOR HUMAN

		RIGHTS, INC., ROBERT BOLAN, BRADBURY-SULLIVAN LGBT COMMUNITY CENTER, WARD CARPENTER, SARAH HENN, LOS ANGELES LGBT CENTER, RANDY PUMPHREY, TRANSLATIN@ COALITION, WHITMAN-WALKER CLINIC, INC. (Attachments: # 1 Memorandum in Support, # 2 Index of Declarations, # 3 Declaration of Naseema Shafi, CEO, Whitman-Walker Health, # 4 Declaration of Dr. Sarah Henn, MD, MPH, Chief Medical Officer, Whitman-Walker Health, # 5 Declaration of Dr. Randy Pumphrey, D. Min, LPC, BCC, Senior Director of Behavioral Health, Whitman-Walker Health, # 6 Declaration of Bamby Salcedo, President & CEO, The Translatin@ Coalition, # 7 Declaration of Arianna Inurritegui-Lint, Executive Director of Arianna's Center, # 8 Declaration of Darrel Cummings, Chief of Staff, Los Angeles LGBT Center, # 9 Declaration of Dr. Robert Bolan, MD, Chief Medical Officer, Los Angeles LGBT Center, # 10 Declaration of Dr. Ward Carpenter, MD, Co-Director of Health Services, Los Angeles LGBT Center, # 11 Declaration of Adrian Shanker, Executive Director, Bradbury-Sullivan LGBT Community Center, # 12 Declaration of Hector Vargas, Executive Director, GLMA, # 13 Declaration of Roy Harker, Executive Director, AGLP: The Association of LGBTQ+ Psychiatrists, # 14 Declaration of Dr. Deborah Fabian, MD, # 15 Declaration of Dr. Randi C. Ettner, PhD, # 16 Declaration of Elena Rose Vera, Executive Director, Trans Lifeline, # 17 Declaration of Carrie Davis, Chief Community Officer, The Trevor Project, # 18 Text of Proposed Order, # 19 Certificate of Service) (Dennehy, Johanna) (Entered: 07/09/2020)
07/10/2020		MINUTE ORDER: The Court ORDERS that a conference call is hereby set for Friday, July 10, at 3:30 p.m. to discuss a briefing schedule regarding Plaintiffs' 29 Motion for Preliminary Injunction. The Court ORDERS that the parties shall dial into Chambers toll-free conference-call number, (877) 402-9753, at this time. Chambers have contacted the parties via email with the dial-in code. So ORDERED by Judge James E. Boasberg on 07/10/2020. (lcjeb2) (Entered: 07/10/2020)
07/10/2020		MINUTE ORDER: As discussed in todays telephonic hearing, the Court ORDERS that: 1) Defendants PI Opposition shall be due by July 24, 2020, with Plaintiffs Reply due by July 29, 2020; and 2) The parties shall appear for a hearing on the PI Motion on August 3, 2020 at 2:00 PM Eastern. So ORDERED by Judge James E. Boasberg on 07/10/2020. (lcjeb2) (Entered: 07/10/2020)
07/10/2020		Set/Reset Deadlines/Hearings: Responses due by 7/24/2020. Replies due by 7/29/2020. Preliminary Injunction Hearing set for 8/3/2020 at 02:00 PM in Telephonic/VTC before Judge James E. Boasberg. (znbn) (Entered: 07/13/2020)
07/10/2020		Minute Entry for proceedings held before Judge James E. Boasberg: Status Conference held on 7/10/2020. (Court Reporter Lisa Griffith) (nbn) (Entered: 07/13/2020)
07/14/2020	30	MOTION for Leave to File Amicus Brief by ALLIANCE OF BLACK AND WHITE EX-GAY AND EX-TRANS, CENTER FOR GARDEN STATE FAMILIES, COALITION OF DOCTORS DEFENDING REPARATIVE THERAPY, COALITION OF MULTI-RACIAL PASTORS, DE FACTO ATTORNEY GENERAL, SPECIAL FORCES OF LIBERTY, WARRIORS FOR CHRIST. (Attachments: # 1 Exhibit Amicus Brief, # 2 Declaration, # 3 Declaration, # 4 Declaration, # 5 Declaration, # 6 Declaration, # 7 Declaration, # 8 Declaration, # 9 Declaration, # 10 Declaration, # 11 Declaration, # 12 Declaration)(ztth) (Entered: 07/14/2020)
07/15/2020		MINUTE ORDER: The Court ORDERS that the 30 Motion for Leave to File Amicus Brief is DENIED WITHOUT PREJUDICE for failure to comply with LCvR 7(o). So ORDERED by Judge James E. Boasberg on 07/15/2020. (lcjeb2) (Entered: 07/15/2020)
07/15/2020	31	NOTICE of Appearance by Jordan Landrum von Bokern on behalf of All Defendants (von Bokern, Jordan) (Entered: 07/15/2020)

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07/15/2020	32	Consent MOTION for Leave to File *Amicus Brief* by AARP, AARP FOUNDATION, SAGE (Attachments: # 1 Amicus Brief, # 2 Text of Proposed Order Proposed Order)(Bagby, Kelly) (Entered: 07/15/2020)
07/15/2020	33	NOTICE of Appearance by Kelly Riseden Bagby on behalf of AARP, AARP FOUNDATION, SAGE (Bagby, Kelly) (Entered: 07/15/2020)
07/15/2020		MINUTE ORDER: The Court ORDERS that Amici's 32 Motion is GRANTED. As their proposed attached brief [32-1] violates the Local Rules' prohibition on excessive footnotes, however, it will not be deemed filed. Amici may file a brief with no more than 10 footnotes containing no more than 50 aggregate lines of text. So ORDERED by Judge James E. Boasberg on 07/15/2020. (lcjeb2) (Entered: 07/15/2020)
07/15/2020	34	Consent MOTION for Leave to File *Brief Amicus Curiae* by HOUSE OF REPRESENTATIVES (Attachments: # 1 Exhibit Proposed Brief, # 2 Text of Proposed Order)(Letter, Douglas) (Entered: 07/15/2020)
07/15/2020		MINUTE ORDER: The Court ORDERS that Amicus's 34 Motion is GRANTED and its brief deemed FILED. So ORDERED by Judge James E. Boasberg on 07/15/2020. (lcjeb2) (Entered: 07/15/2020)
07/15/2020	35	AMICUS BRIEF by AARP, AARP FOUNDATION, SAGE. (Bagby, Kelly) (Entered: 07/15/2020)
07/15/2020	36	AMICUS BRIEF by HOUSE OF REPRESENTATIVES. (ztth) (Entered: 07/16/2020)
07/20/2020	37	ERRATA *Notice* by AARP, AARP FOUNDATION, SAGE 35 Amicus Brief filed by SAGE, AARP FOUNDATION, AARP. (Attachments: # 1 Exhibit Amici Curiae Brief of AARP, AARP Foundation and Sage)(Bagby, Kelly) (Entered: 07/20/2020)
07/21/2020		Set/Reset Deadlines: Answer due by 8/25/2020. Correction made to docket entry 28 at the request of counsel. (ztth) (Entered: 07/21/2020)
07/24/2020	38	NOTICE of Appearance by William Kerwin Lane, III on behalf of All Defendants (Lane, William) Modified on 7/24/2020 to correct docket text (rj). (Entered: 07/24/2020)
07/24/2020	39	RETURN OF SERVICE/AFFIDAVIT of Summons and Complaint Executed. UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES served on 6/25/2020 (Dennehy, Johanna) (Entered: 07/24/2020)
07/24/2020	40	RETURN OF SERVICE/AFFIDAVIT of Summons and Complaint Executed. SEEMA VERMA served on 6/25/2020 (Dennehy, Johanna) (Entered: 07/24/2020)
07/24/2020	41	RETURN OF SERVICE/AFFIDAVIT of Summons and Complaint Executed. ROGER SEVERINO served on 6/25/2020 (Dennehy, Johanna) (Entered: 07/24/2020)
07/24/2020	42	Memorandum in opposition to re 29 MOTION for Preliminary Injunction *or, in the Alternative* MOTION to Stay *Pending Judicial Review Pursuant to 5 U.S.C. 705* filed by ALEX M. AZAR, II, ROGER SEVERINO, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, SEEMA VERMA. (Attachments: # 1 Text of Proposed Order)(Lane, William) (Entered: 07/24/2020)
07/29/2020	43	REPLY to opposition to motion re 29 MOTION for Preliminary Injunction *or, in the Alternative* MOTION to Stay *Pending Judicial Review Pursuant to 5 U.S.C. 705* filed by AGLP: THE ASSOCIATION OF LGBTQ PSYCHIATRISTS, AMERICAN ASSOCIATION OF PHYSICIANS FOR HUMAN RIGHTS, INC., ROBERT BOLAN, BRADBURY-SULLIVAN LGBT COMMUNITY CENTER, WARD CARPENTER, SARAH HENN, LOS ANGELES LGBT CENTER, RANDY PUMPHREY, TRANSLATIN@ COALITION, WHITMAN-WALKER CLINIC, INC.. (Attachments: # 1

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		Declaration of Omar Gonzalez-Pagan, # 2 Exhibit 1 - Defendants' Motion to Remand or Stay (Franciscan Alliance), # 3 Exhibit 2 - Plaintiffs' Motion for Summary Judgment (Franciscan Alliance), # 4 Exhibit 3 - Defendants' Motion to Modify Final Judgment (Franciscan Alliance), # 5 Exhibit 4 - Court Order dated Nov. 21, 2019 (Franciscan Alliance), # 6 Exhibit 5 - Lambda Legal Defense and Education Fund's Comments on Proposed Rule, # 7 Exhibit 6 - GLMA's Comments on Proposed Rule, # 8 Exhibit 7 - American Psychiatric Association's Comments on Proposed Rule, # 9 Exhibit 8 - American College of Obstetricians and Gynecologists' Comments on Proposed Rule, # 10 Exhibit 9 - State Insurance Commissioners of California et al. Comments on Proposed Rule, # 11 Exhibit 10 - Cities of New York et al. Comments on Proposed Rule, # 12 Exhibit 11 - National Center for Transgender Equality's Comments on Proposed Rule, # 13 Exhibit 12 - The California Endowment's Comments on Proposed Rule, # 14 Exhibit 13 - American Psychological Association's Response to Request for Information, # 15 Exhibit 14 - 9/1/17 Letter from James L. Madara, MD to Roger Severino, # 16 Exhibit 15 - New York Legal Assistance Group's Comments on Proposed Rule)(Dennehy, Johanna) (Entered: 07/29/2020)
08/03/2020		Minute Entry for proceedings held before Judge James E. Boasberg: Motion Hearing held on 8/3/2020 re 29 MOTION for Preliminary Injunction *or, in the Alternative* MOTION to Stay *Pending Judicial Review Pursuant to 5 U.S.C. 705* filed by BRADBURY-SULLIVAN LGBT COMMUNITY CENTER, WARD CARPENTER, RANDY PUMPHREY, AGLP: THE ASSOCIATION OF LGBTQ PSYCHIATRISTS, ROBERT BOLAN, TRANSLATIN@ COALITION, AMERICAN ASSOCIATION OF PHYSICIANS FOR HUMAN RIGHTS, INC., SARAH HENN, WHITMAN-WALKER CLINIC, INC., LOS ANGELES LGBT CENTER. Oral arguments heard. Government Response due by 8/10/2020. (Court Reporter Lisa Griffith) (znbn) (Entered: 08/03/2020)
08/04/2020	44	NOTICE of Appearance by Josephine T. Morse on behalf of HOUSE OF REPRESENTATIVES (Morse, Josephine) (Entered: 08/04/2020)
08/06/2020	45	ENTERED IN ERROR.....NOTICE *(Clarification of Statement at Oral Argument)* by AGLP: THE ASSOCIATION OF LGBTQ PSYCHIATRISTS, AMERICAN ASSOCIATION OF PHYSICIANS FOR HUMAN RIGHTS, INC., ROBERT BOLAN, BRADBURY-SULLIVAN LGBT COMMUNITY CENTER, WARD CARPENTER, SARAH HENN, LOS ANGELES LGBT CENTER, RANDY PUMPHREY, TRANSLATIN@ COALITION, WHITMAN-WALKER CLINIC, INC. re 29 MOTION for Preliminary Injunction *or, in the Alternative* MOTION to Stay *Pending Judicial Review Pursuant to 5 U.S.C. 705* (Dennehy, Johanna); Modified on 8/7/2020 (ztth). (Entered: 08/06/2020)
08/07/2020	46	TRANSCRIPT OF PROCEEDINGS before Judge James E. Boasberg held on 8-3-2020; Page Numbers: 1-50. Date of Issuance:8-7-2020. Court Reporter/Transcriber Lisa W Griffith, Telephone number (202) 354-3247, Transcripts may be ordered by submitting the Transcript Order Form For the first 90 days after this filing date, the transcript may be viewed at the courthouse at a public terminal or purchased from the court reporter referenced abo ve. After 90 days, the transcript may be accessed via PACER. Other transcript formats, (multi-page, condensed, CD or ASCII) may be purchased from the court reporter. **NOTICE RE REDACTION OF TRANSCRIPTS:** The parties have twenty-one days to file with the court and the court reporter any request to redact personal identifiers from this transcript. If no such requests are filed, the transcript will be made available to the public via PACER without redaction after 90 days. The policy, which includes the five personal identifiers specifically covered, is located on our website at www.dcd.uscourts.gov.

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		Redaction Request due 8/28/2020. Redacted Transcript Deadline set for 9/7/2020. Release of Transcript Restriction set for 11/5/2020.(Griffith, Lisa) (Entered: 08/07/2020)
08/07/2020		NOTICE OF ERROR re 45 Notice (Other); emailed to jdennehy@steptoe.com, cc'd 34 associated attorneys -- The PDF file you docketed contained errors: 1. Please refile document, 2. Docket Entry 45 was entered in error. The pleading should be filed in pleading format. See LCvR 5.1 (a). (ztth,) (Entered: 08/07/2020)
08/07/2020	47	NOTICE *(Clarification of Statement at Oral Argument)* by AGLP: THE ASSOCIATION OF LGBTQ PSYCHIATRISTS, AMERICAN ASSOCIATION OF PHYSICIANS FOR HUMAN RIGHTS, INC., ROBERT BOLAN, BRADBURY-SULLIVAN LGBT COMMUNITY CENTER, WARD CARPENTER, SARAH HENN, LOS ANGELES LGBT CENTER, RANDY PUMPHREY, TRANSLATIN@ COALITION, WHITMAN-WALKER CLINIC, INC. re 29 MOTION for Preliminary Injunction *or, in the Alternative* MOTION to Stay *Pending Judicial Review Pursuant to 5 U.S.C. 705* (Dennehy, Johanna) (Entered: 08/07/2020)
08/10/2020	48	SURREPLY to re 29 MOTION for Preliminary Injunction *or, in the Alternative* MOTION to Stay *Pending Judicial Review Pursuant to 5 U.S.C. 705* filed by ALEX M. AZAR, II, ROGER SEVERINO, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, SEEMA VERMA. (Lane, William) (Entered: 08/10/2020)
08/12/2020	49	NOTICE *of Additional Developments in Franciscan Alliance Litigation* by AGLP: THE ASSOCIATION OF LGBTQ PSYCHIATRISTS, AMERICAN ASSOCIATION OF PHYSICIANS FOR HUMAN RIGHTS, INC., ROBERT BOLAN, BRADBURY-SULLIVAN LGBT COMMUNITY CENTER, WARD CARPENTER, SARAH HENN, LOS ANGELES LGBT CENTER, RANDY PUMPHREY, TRANSLATIN@ COALITION, WHITMAN-WALKER CLINIC, INC. (Dennehy, Johanna) (Entered: 08/12/2020)
08/17/2020	50	NOTICE OF SUPPLEMENTAL AUTHORITY by AGLP: THE ASSOCIATION OF LGBTQ PSYCHIATRISTS, AMERICAN ASSOCIATION OF PHYSICIANS FOR HUMAN RIGHTS, INC., ROBERT BOLAN, BRADBURY-SULLIVAN LGBT COMMUNITY CENTER, WARD CARPENTER, SARAH HENN, LOS ANGELES LGBT CENTER, RANDY PUMPHREY, TRANSLATIN@ COALITION, WHITMAN-WALKER CLINIC, INC. (Attachments: # 1 Exhibit 1 - Memorandum and Order, Walker v. Azar, No. 20-cv-02834 (E.D.N.Y. Aug. 17, 2020))(Dennehy, Johanna) (Entered: 08/17/2020)
08/21/2020	51	MOTION for Extension of Time to File Answer re 1 Complaint,,, by ALEX M. AZAR, II, ROGER SEVERINO, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, SEEMA VERMA (Attachments: # 1 Text of Proposed Order)(Lane, William) (Entered: 08/21/2020)
08/24/2020		MINUTE ORDER: If Plaintiffs oppose Defendants' 51 Motion for Extension, the Court ORDERS that they shall file such opposition by August 26, 2020. So ORDERED by Judge James E. Boasberg on 08/24/2020. (lcjeb2) (Entered: 08/24/2020)
08/24/2020		Set/Reset Deadlines: Opposition due by 8/26/2020. (znbn) (Entered: 08/24/2020)
08/25/2020	52	RESPONSE re 51 MOTION for Extension of Time to File Answer re 1 Complaint,,, filed by AGLP: THE ASSOCIATION OF LGBTQ PSYCHIATRISTS, AMERICAN ASSOCIATION OF PHYSICIANS FOR HUMAN RIGHTS, INC., ROBERT BOLAN, BRADBURY-SULLIVAN LGBT COMMUNITY CENTER, WARD CARPENTER, SARAH HENN, LOS ANGELES LGBT CENTER, RANDY PUMPHREY, TRANSLATIN@ COALITION, WHITMAN-WALKER CLINIC, INC.. (Dennehy, Johanna) (Entered: 08/25/2020)

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08/31/2020	53	NOTICE of Appearance by Liam Holland on behalf of All Defendants (Holland, Liam) (Entered: 08/31/2020)
08/31/2020	54	NOTICE OF SUPPLEMENTAL AUTHORITY by ALEX M. AZAR, II, ROGER SEVERINO, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, SEEMA VERMA (Attachments: # 1 Exhibit)(Holland, Liam) (Entered: 08/31/2020)
09/02/2020	55	ORDER: For the reasons set forth in the accompanying Memorandum Opinion, the Court ORDERS that Plaintiffs' 29 Motion for a Preliminary Injunction or, in the Alternative, a Stay Pending Judicial Review is GRANTED IN PART and DENIED IN PART. Signed by Judge James E. Boasberg on 9/2/2020. (lcjeb1) (Entered: 09/02/2020)
09/02/2020	56	MEMORANDUM OPINION re 55 Order on Motion for a Preliminary Injunction or, in the Alternative, a Stay Pending Judicial Review. Signed by Judge James E. Boasberg on 9/2/2020. (lcjeb1) (Entered: 09/02/2020)
09/08/2020		MINUTE ORDER: The Court ORDERS that Defendants' 51 Motion for Extension is GRANTED, and they may file their Answer by September 29, 2020. So ORDERED by Judge James E. Boasberg on 09/08/2020. (lcjeb2) (Entered: 09/08/2020)
09/08/2020		Set/Reset Deadlines: Answer due by 9/29/2020. (znbn) (Entered: 09/08/2020)
09/29/2020	57	MOTION to Dismiss by ALEX M. AZAR, II, ROGER SEVERINO, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, SEEMA VERMA (Attachments: # 1 Memorandum in Support, # 2 Text of Proposed Order)(Holland, Liam) (Entered: 09/29/2020)
10/06/2020	58	MOTION to Compel *Defendants to Produce the Administrative Record*, MOTION to Hold in Abeyance re 57 MOTION to Dismiss , MOTION for Scheduling Order *for Filing and Briefing Motions to Dismiss and/or Motions for Summary Judgment* by AGLP: THE ASSOCIATION OF LGBTQ PSYCHIATRISTS, AMERICAN ASSOCIATION OF PHYSICIANS FOR HUMAN RIGHTS, INC., ROBERT BOLAN, BRADBURY-SULLIVAN LGBT COMMUNITY CENTER, WARD CARPENTER, SARAH HENN, LOS ANGELES LGBT CENTER, RANDY PUMPHREY, TRANSLATIN@ COALITION, WHITMAN-WALKER CLINIC, INC. (Attachments: # 1 Declaration of Omar Gonzalez-Pagan, # 2 Exhibit 1, # 3 Exhibit 2, # 4 Exhibit 3, # 5 Exhibit 4, # 6 Exhibit 5, # 7 Exhibit 6)(Dennehy, Johanna) (Entered: 10/06/2020)
10/07/2020		MINUTE ORDER: The Court ORDERS that Plaintiffs need not respond to Defendants' 57 Motion to Dismiss until the Court resolves Plaintiffs' 58 Motion to Compel. So ORDERED by Judge James E. Boasberg on 10/07/2020. (lcjeb2) (Entered: 10/07/2020)
10/07/2020	59	NOTICE of Change of Address by Karen Loewy (Loewy, Karen) (Entered: 10/07/2020)
10/20/2020	60	Memorandum in opposition to re 58 MOTION to Compel *Defendants to Produce the Administrative Record* MOTION to Hold in Abeyance re 57 MOTION to Dismiss MOTION for Scheduling Order *for Filing and Briefing Motions to Dismiss and/or Motions for Summary Judgment* filed by ALEX M. AZAR, II, ROGER SEVERINO, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, SEEMA VERMA. (Holland, Liam) (Entered: 10/20/2020)
10/27/2020	61	NOTICE OF WITHDRAWAL OF APPEARANCE as to AGLP: THE ASSOCIATION OF LGBTQ PSYCHIATRISTS, AMERICAN ASSOCIATION OF PHYSICIANS FOR HUMAN RIGHTS, INC., ROBERT BOLAN, BRADBURY-SULLIVAN LGBT COMMUNITY CENTER, WARD CARPENTER, SARAH HENN, LOS ANGELES LGBT CENTER, RANDY PUMPHREY, TRANSLATIN@ COALITION, WHITMAN-

		WALKER CLINIC, INC.. Attorney Jamie Avra Gliksberg terminated. (Gliksberg, Jamie) (Entered: 10/27/2020)
10/27/2020	62	REPLY to opposition to motion re 58 MOTION to Compel *Defendants to Produce the Administrative Record* MOTION to Hold in Abeyance re 57 MOTION to Dismiss MOTION for Scheduling Order *for Filing and Briefing Motions to Dismiss and/or Motions for Summary Judgment* filed by AGLP: THE ASSOCIATION OF LGBTQ PSYCHIATRISTS, AMERICAN ASSOCIATION OF PHYSICIANS FOR HUMAN RIGHTS, INC., ROBERT BOLAN, BRADBURY-SULLIVAN LGBT COMMUNITY CENTER, WARD CARPENTER, SARAH HENN, LOS ANGELES LGBT CENTER, RANDY PUMPHREY, TRANSLATIN@ COALITION, WHITMAN-WALKER CLINIC, INC.. (Dennehy, Johanna) (Entered: 10/27/2020)
10/31/2020	63	NOTICE OF APPEAL TO DC CIRCUIT COURT re 55 ORDER & 56 MEMORANDUM OPINION by ROGER SEVERINO, SEEMA VERMA, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, ALEX M. AZAR, II. Fee Status: No Fee Paid. Parties have been notified. (Holland, Liam) Modified to add linkage on 11/2/2020 (zrdj). (Entered: 10/31/2020)
11/02/2020	64	Transmission of the Notice of Appeal, Order Appealed (Memorandum Opinion), and Docket Sheet to US Court of Appeals. The Court of Appeals docketing fee was not paid because the appeal was filed by the government re 63 Notice of Appeal to DC Circuit Court. (zrdj) (Entered: 11/02/2020)
11/03/2020	65	ORDER re 58 Motion to Compel. The Court ORDERS that: 1) Plaintiffs' 58 Motion to Compel is GRANTED IN PART and DENIED IN PART; 2) Defendants need not produce the administrative record at this point; 3) Plaintiffs shall have until December 18, 2020, to oppose Defendants' Motion; 4) Defendants shall have until January 19, 2021, to reply; and 5) The Court will not grant any portion of Defendants' Motion that Plaintiffs establish relies on the administrative record or that requires access to such record for Plaintiffs to respond. Signed by Judge James E. Boasberg on 11/3/2020. (lcjeb1) (Entered: 11/03/2020)
11/03/2020		Set/Reset Deadlines: Responses due by 12/18/2020. Replies due by 1/19/2021. (znbn) (Entered: 11/03/2020)
11/09/2020		USCA Case Number 20-5331 for 63 Notice of Appeal to DC Circuit Court, filed by SEEMA VERMA, ROGER SEVERINO, ALEX M. AZAR, II, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES. (zrdj) (Entered: 11/10/2020)
12/18/2020	66	Memorandum in opposition to re 57 MOTION to Dismiss filed by AGLP: THE ASSOCIATION OF LGBTQ PSYCHIATRISTS, AMERICAN ASSOCIATION OF PHYSICIANS FOR HUMAN RIGHTS, INC., ROBERT BOLAN, BRADBURY-SULLIVAN LGBT COMMUNITY CENTER, WARD CARPENTER, SARAH HENN, LOS ANGELES LGBT CENTER, RANDY PUMPHREY, TRANSLATIN@ COALITION, WHITMAN-WALKER CLINIC, INC.. (Attachments: # 1 Text of Proposed Order, # 2 Declaration of Amy Nelson, # 3 Declaration of Kellan Valentin Pedroza) (Edelstein, Laura) (Entered: 12/18/2020)

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CERTIFICATE OF SERVICE

I hereby certify that on January 19, 2021, I electronically filed the foregoing brief with the Clerk of the Court for the United States Court of Appeals for the District of Columbia Circuit by using the appellate CM/ECF system. Participants in the case are registered CM/ECF users, and service will be accomplished by the appellate CM/ECF system.

/s/ Joshua Dos Santos
JOSHUA DOS SANTOS