October 4, 2022

RAOUL JOINS COALITION SUPPORTING RESTORATION OF ANTI-DISCRIMINATION PROTECTIONS UNDER AFFORDABLE CARE ACT

Raoul Applauds Federal Government's Efforts to Restore Comprehensive Anti-Discrimination Protections Eliminated in 2020

Chicago — Attorney General Kwame Raoul today joined a coalition of 22 attorneys general in a comment letter supporting the U.S. Department of Health and Human Services' (HHS) proposed rule strengthening anti-discrimination protections under the Affordable Care Act (ACA). The proposed rule would implement Section 1557 of the ACA, which prohibits health care programs, benefits and services from discriminating on the basis of race, color, national origin, age, disability or sex (including pregnancy, sexual orientation, gender identity and sex characteristics).

"At a time when some states are rolling back rights to reproductive and sexual health care, it is more important than ever that people can access needed health care services without the fear of discrimination," Raoul said. "I appreciate the Biden administration's commitment to prohibiting discrimination in health care, and I will continue to fight any attempts to weaken the Affordable Care Act's promise of quality health care services for millions of Illinoisans."

Raoul and the coalition argue the new rule is critical to safeguarding the health and well-being of communities of color, people with pregnancy-related conditions, LGBTQ+ individuals, people with limited English proficiency and those with disabilities. Creating an equitable, accessible and affordable health care system is a continuing priority for states across the country, and the proposed rule is an important step in that direction.

When Congress enacted the ACA in 2010, it contained a landmark civil rights provision, Section 1557. Implemented in 2016, the provision prohibits discrimination in federal health care programs, benefits and services. Specifically, Section 1557 prohibits discrimination on the basis of race, color, national origin, sex, age or disability.

But this provision was undermined significantly in 2020, when HHS finalized a rule rolling back those protections, effectively sanctioning discrimination in our health care system. Now, HHS has invited comments on a proposed revision that would restore comprehensive anti-discrimination protections to the ACA.

In their letter responding to HHS' notice, Raoul and the coalition assert their support for the proposed rule because, among other reasons, preventing a broader group of entities from discrimination in the health care system will reduce adverse health outcomes, the costs of which would otherwise be borne by the states' public health systems. In addition, limiting the scope of Section 1557, as the 2020 rule sought to do, increases the burden on the states to monitor and enforce nondiscrimination laws.

Raoul and the coalition applaud the rule for preserving and broadening the following protections:

- Prohibiting sex discrimination based on gender identity, including against transgender people.
- Establishing language access requirements to ensure people of all national origins, including those with limited English proficiency, have meaningful access to health programs and activities.

- Prohibiting discrimination on the basis of pregnancy-related medical conditions, such as past pregnancy and the termination of pregnancy.
- Recognizing that the prohibition on discrimination in healthcare encompasses algorithms and other automated clinical decision-making tools.
- Clarifying, for the first time, that Section 1557 prohibits discrimination in telehealth services.

Earlier this year, Raoul led a coalition of 20 attorneys general defending key provisions of the ACA that provide preventive services, most notably contraceptive care and prophylactic anti-HIV care. In 2020, as part of a coalition of 20 states and the District of Columbia, Raoul filed a brief in the U.S. Supreme Court defending the ACA against efforts to repeal the entire law, which would have gutted health care coverage protections for 133 million Americans.

Joining Raoul in filing the comment letter are the attorneys general of California, Connecticut, Delaware, the District of Columbia, Hawaii, Iowa, Maine, Maryland, Massachusetts, Michigan, Minnesota, Nevada, New Jersey, New Mexico, New York, North Carolina, Oregon, Pennsylvania, Rhode Island, Vermont and Washington.

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October 3, 2022

Via Federal eRulemaking Portal
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RE: 1557 NPRM (RIN 0945-AA17)

Dear Secretary Becerra, Administrator Brooks-LaSure, and Director Fontes Rainer:

The undersigned State Attorneys General of California, Massachusetts, New York and Connecticut, Delaware, Hawai'i, Illinois, Iowa, Maine, Maryland, Michigan, Minnesota, Nevada, New Jersey, New Mexico, North Carolina, Oregon, Pennsylvania, Rhode Island, Vermont, Washington, and the District of Columbia (the States) write in response to the Notice of Proposed Rulemaking issued by the U.S. Department of Health and Human Services's (HHS's) Centers for Medicare and Medicaid Services (CMS) and Office for Civil Rights entitled

"Nondiscrimination in Health Programs and Activities," which proposes to revise regulations implementing Section 1557 of the Patient Protection and Affordable Care Act (ACA), (codified at 42 U.S.C. § 18116). 87 Fed. Reg. 47,824 (proposed Aug. 4, 2022), (to be codified at 42 CFR pts. 438, 440, 457, and 460 and 45 CFR pts. 80, 84, 92, 147, 155, and 15) (the Proposed Rule).

As many of the States explained in litigation challenging the prior federal administration's rulemaking, the 2020 Rule, Nondiscrimination in Health and Health Education Programs or Activities, Delegation of Authority, 85 Fed. Reg. 37,160 (June 19, 2020) (to amend and be codified at 42 CFR pts. 438, 440, and 460 and 45 CFR parts 86, 92, 147, 155, and 156).) (2020 Rule), was contrary to law and an unreasonable and arbitrary interpretation of Section 1557.[1] Section 1557 broadly prohibits health programs and activities receiving federal financial assistance from discriminating against individuals on the basis of race, color, national origin, sex, age, or disability. By undermining legal protections to healthcare, the 2020 Rule licensed discrimination and inflicted harm on the States and their residents, particularly underserved populations including women and others seeking reproductive healthcare or with pregnancy-related conditions, individuals with limited English proficiency (LEP), people with disabilities and lesbian, gay, bisexual, transgender, and queer or questioning (LGBTQ) individuals. The States commend HHS for proposing to restore comprehensive antidiscrimination protections and to ensure consistency with federal law, including the Supreme Court's decision in *Bostock v. Clayton County*, 140 S. Ct. 1731 (2020) (recognizing that the prohibition on sex discrimination under Title VII of the Civil Rights Act of 1964, 42 U.S.C. § 2000e *et seq*. prohibits discrimination based on sexual orientation or transgender status). We urge the federal government to move expeditiously to finalize the Proposed Rule.

As described below, the States retain a strong interest in ensuring that the federal government's interpretation of the ACA and Section 1557 promotes equitable access to healthcare for all the States' residents. We request that HHS consider our prior comments opposing the 2020 Rule,[2] as well as the legal analysis and evidence submitted in support of the States' motions against implementation of the 2020 Rule, in finalizing the current regulation.[3]

I. BACKGROUND

Congress enacted the ACA to expand access to healthcare, ensure that health services are broadly available in the United States, and address significant barriers to healthcare access caused by inadequate and discriminatory health insurance coverage.[4] To reduce these barriers,

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[1] Complaint for Declaratory and Injunctive Relief, *New York v. U.S. Dep't of Health & Human Servs.*, No. 1:20-cv-5583-AKH, Dk. 1 (S.D.N.Y. July 20, 2020).

[2] Comment on FR Doc # 2019-11512, Regulations.gov, (September 5, 2019), https://www.regulations.gov/comment/HHS-OCR-2019-0007-142194.

[3] *See, e.g.*, Pls. Mot. for Summ. J., *New York v. U.S. Dep't of Health & Human Servs.*, No. 1:20-cv-5583-AKH Dk. 62 (S.D.N.Y. Dec. 2, 2020).

[4] Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119 (2010) (codified at 42 U.S.C. §§ 18001-18122).

the ACA included Section 1557, which broadly prohibits all health programs and activities receiving federal financial assistance, including medical providers, health systems, and health insurers, from discriminating against individuals on the basis of race, color, national origin, sex, age, or disability.[5]

In 2016, when HHS first issued a final rule implementing Section 1557, it recognized that discrimination within the healthcare system contributes to poor coverage and inadequate health outcomes, exacerbates existing health disparities in underserved communities, and leads to ineffective distribution of healthcare resources. Nondiscrimination in Health Programs and Activities, 81 Fed. Reg. 31,376, 31,444 (May 18, 2016) (codified at 45 C.F.R. pt. 92) (the "2016 Rule"). To prevent statutorily prohibited discriminatory treatment and coverage in healthcare and its specific impact on historically marginalized populations—in particular, transgender people, women and others seeking reproductive healthcare or with pregnancy-related conditions, individuals with LEP, and people with disabilities—the 2016 Rule adopted several key provisions, including: (a) clarifying that Section 1557 broadly applies to all health providers and insurers that receive federal financial assistance, *id.* at 31,467 (codified at 45 C.F.R. § 92.4); (b) clarifying that Section 1557's prohibition on discrimination on the basis of sex included discrimination based on gender identity, sex stereotypes, and pregnancy-related conditions, *id*.; (c) specifying covered entities' obligations to transgender individuals, *id*. at 31,471-72 (codified at 45 C.F.R. §§ 92.206, 92.207); (d) establishing detailed language access requirements to ensure nondiscriminatory access to health services for people of all national origins, including those with LEP, *id*. at 31,410-11 (codified at 45 C.F.R. § 92.201); and (e) establishing a uniform enforcement scheme for all forms of discrimination prohibited by the statute, *id*. at 31,439-40.

Although the 2016 Rule unquestionably improved access to healthcare services and programs by vulnerable groups, HHS reversed course just three years later and adopted a new rule that, contrary to the text of the ACA, attempted to undermine many of Section 1557's core protections. In particular, the 2020 Rule arbitrarily and unlawfully stripped healthcare rights statutorily guaranteed by Section 1557 from transgender people, women and other individuals seeking reproductive healthcare or with pregnancy-related conditions, LEP individuals, individuals with disabilities, and other individuals experiencing discrimination. Remarkably, HHS published the 2020 Rule in the midst of the COVID-19 pandemic and just days after the Supreme Court confirmed in *Bostock* that the prohibition on sex discrimination under Title VII of the Civil Rights Act of 1964, 42 U.S.C. § 2000e *et seq*., prohibits discrimination based on sexual orientation or transgender status. The 2020 Rule ignored *Bostock*, redefined discrimination "on the basis of sex" to exclude express regulatory protections against gender identity discrimination, removed the specific protections for transgender people contained in the 2016 Rule, and struck the express prohibitions on sexual orientation and gender identity discrimination from other HHS regulations.

[5] Specifically, Section 1557 prohibits discrimination on the basis of any protected classification covered under Title VI of the Civil Rights Act (race, color, and national origin), Section 504 of the Rehabilitation Act of 1973 (disability), Title IX of the Education Amendments (sex), and the Age Discrimination Act of 1975 (age).

Furthermore, the 2020 Rule, without sufficient justification, redefined covered "health program or activity" to newly exclude many health insurers not "principally engaged in the business of providing healthcare." 85 Fed. Reg. at 37,244. This redefinition conflicted with the statute by arbitrarily and narrowly defining "healthcare" to exclude health insurance, thus removing many private employer-based plans, Medicare Part B providers, and the Federal Employee Health Benefits program from the Rule's scope. The 2020 Rule also gutted the 2016 Rule's language access provisions, and sowed unnecessary confusion by deleting the uniform Section 1557 enforcement standards contained in the 2016 Rule. Finally, the 2020 Rule created a broad religious exemption that had no statutory basis in Section 1557 and gave religiously affiliated providers and insurers license to deny care and coverage for discriminatory reasons.

Myriad lawsuits were quickly filed to enjoin the 2020 Rule based on its arbitrary and unlawful revisions to the 2016 Rule. Several States challenged the 2020 Rule in *New York v U.S. Department of Health & Human Services,* which is currently stayed pending rulemaking. Two other cases—*Whitman-Walker Clinic v. HHS* and *Walker v. Azar*—resulted in nationwide preliminary injunctions that enjoined various parts of the rule.[6] In a fourth lawsuit—*Boston Alliance of Gay, Lesbian, & Bisexual Youth (BAGLY) v. HHS*—a federal district court denied the federal government's motion to dismiss claims related to the incorporation of Title IX's abortion exemption, the narrowing of the scope of covered entities, and the elimination on categorical coverage exclusions for gender affirming care.[7] And a fifth suit has also been filed specifically challenging the 2020 Rule's rollback of the LEP provisions in the 2016 Rule.[8]

Because the Proposed Rule will address the severe deficiencies in the 2020 Rule and "ensur[e] that Section 1557's robust civil rights protections apply" broadly, we urge you to finalize the Proposed Rule.

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[6] *Whitman-Walker Clinic, Inc. v. U.S. Dep't of Health & Human Servs.*, 485 F. Supp. 3d 1 (D.D.C. 2020) (enjoining enforcement of 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) and enforcement of the incorporation of Title IX's religious exemptions); *Walker v. Azar*, 480 F. Supp. 3d 417 (E.D.N.Y. 2020) (enjoining enforcement of the repeal of the definition of discrimination on the basis of sex). Both cases are stayed pending rulemaking.

[7] *Boston Alliance of Gay, Lesbian, Bisexual and Transgender Youth (BAGLY) v. U.S. Dep't of Health & Human Servs.*, 557 F. Supp. 3d 224 (D. Mass. 2021)(stayed pending rulemaking).

[8] *Chinatown Serv. Center v. U.S. Dep't of Health & Human Servs.*, No. 21-331 (JEB), 2021 WL 8316490 at *3 (D.D.C. filed on Feb 5, 2021) (stayed pending rulemaking).

II. THE PROPOSED RULE ADDRESSES DISCRIMINATION AND REINSTATES SECTION 1557'S PROPER SCOPE AND PROTECTIONS

A. Scope of Section 1557

1. Application of Section 1557 to Health Insurers and Other Entities

The States support HHS's decision to revise the definition of "health program or activity," which the 2020 Rule had limited to exclude some health insurers and other entities that were not "principally engaged" in providing medical treatments directly to patients. This has led to the exclusion of certain entities to which Section 1557 was plainly meant to apply, including many health insurers. The Proposed Rule, by contrast, adheres to the unambiguous statutory language, making the law's nondiscrimination mandate apply to "any health program or activity, *any part of which is receiving Federal financial assistance*." 42 U.S.C. § 18116(a) (emphasis added). As HHS notes in the Proposed Rule, Section 1557 "identifies three examples of Federal financial assistance, all of which pertain to health insurance," 87 Fed. Reg. at 47,829, and so it is logical to clarify its application to entities providing health insurance. *See Schmitt v. Kaiser Found. Health Plan of Wash.*, 965 F.3d 945, 948, 954-55 (9th Cir. 2020). The Proposed Rule accomplishes this clarification in part through defining "federal financial assistance" to include grants, loans, and other types of assistance from the HHS, as well as "credits, subsidies and contracts of insurance" in accordance with the text of Section 1557. *See* 87 Fed. Reg. at 47,842.[9] The Proposed Rule thus clarifies that entities receiving Federal financial assistance from HHS include those participating in Medicaid, the Children's Health Insurance Program, Medicare Parts A-D, as well as HHS grant programs. *See id*. The Proposed Rule would further clarify that financial assistance includes "advance payments of the premium tax credit and cost-sharing reductions . . . to ensure the affordability of health insurance coverage purchased through the Health Insurance Exchanges," *Id*. at. 47,843, thus applying when an insurer participating in a Health Insurance Exchange receives such payments on behalf of any of the issuer's enrollees. *See id*. The States further support HHS's change in interpretation to now specifically include Medicare Part B within the definition of Federal financial assistance. *See id*. at 47,887-90. The nature of payments made through Medicare Part B includes substantial subsidization of entities providing Part B services, and those providers should not be allowed to engage in discriminatory conduct. *See id*. at 47,888.

The Proposed Rule also reinstates a definition of "health program or activity" that adheres to the plain language of the statute and conforms with the reading of similar statutes such as Title IX. The Proposed Rule would apply to "any project, enterprise, venture or undertaking to provide or administer health-related services, health insurance coverage, or other health-related coverage;" providing "assistance to persons in obtaining health-related services, health insurance

[9] Although the Proposed Rule only covers entities receiving Federal financial assistance from HHS-administered programs, the States further encourage other Federal agencies to adopt conforming regulations that would mirror the Proposed Rule to clarify application of Section 1557 to those agencies' Federally assisted health programs and activities.

coverage, or other health-related coverage;" providing "clinical, pharmaceutical, or medical care;" or providing "health education for health care professionals or others." *See id*. at 47,844. The Proposed Rule further clarifies that all of the operations of such entities principally engaged in these activities are covered by Section 1557. *See id*. The States concur that all of these activities should appropriately fall within the scope of Section 1557.

The States support these changes because, among other reasons, ensuring that a broader swath of entities refrain from discrimination in the healthcare system will reduce adverse health outcomes, the costs of which would otherwise be borne by the States' public health systems. In addition, limiting the scope of Section 1557 as the 2020 Rule sought to do, increases the burden on the States to monitor and enforce nondiscrimination laws. For similar reasons, the States also support HHS's proposal to add specific nondiscrimination requirements in health insurance coverage and other health-related coverage, as discussed further below.

2. Application of Section 1557 to all HHS-Administered Health Programs and Activities

The States also support the Proposed Rule's inclusion of all HHS-administered health programs and activities in the scope of coverage. 87 Fed. Reg. at 47,838.[10] The 2020 Rule restricted the scope of covered federal programs to those "administered by [HHS] under Title I" of the Affordable Care Act. 45 C.F.R. § 92.3(a)(2). But this restriction contravened the language and intent of Section 1557, which states that it applies to programs and activities that are "administered by an Executive Agency *or* any entity established under [Title I of the ACA]." 42 U.S.C. § 18116(a) (emphasis added). The States concur with HHS that to the extent Section 1557's text leaves any ambiguity, a better and more reasonable reading of this language in line with Congress' intent to cover a broad swath of activities means that it should apply to all HHS-administered programs. *See* 87 Fed. Reg. at 47,829.[11] As with HHS's proposed changes regarding the definition of entities receiving Federal financial assistance, the States support this broadening of coverage for HHS-administered programs and activities because it will reduce confusion and prevent discrimination, reducing costs of adverse health outcomes that might otherwise be borne by the States' public health systems.

3. Exclusion of Employment Practices

The Proposed Rule clarifies that Section 1557 does not apply to employment practices, including the provision of employee health benefits. 87 Fed. Reg. at 47,838. The States agree

[10] The States concur with HHS that clarifying that Section 1557 applies to Federally administered "health" programs and activities appropriately conforms to the purpose and intent of Section 1557. *See* 87 Fed. Reg. at 47,838.

[11] Although the Proposed Rule only covers HHS-administered health programs and activities, the States encourage other Federal agencies to adopt conforming regulations mirroring the Proposed Rule to clarify Section 1557's application to Federal health programs and activities administered by other Federal agencies.

that allegations of discrimination in employment should be handled by other Federal agencies. This clarification of the 1557 regulation's coverage is logical, as persons seeking to file employment-related complaints of discrimination will need to abide by timing requirements of other Equal Employment Opportunity-related laws, and ambiguity in where such complaints may be filed increases the risk that these complainants will miss applicable deadlines. The States support the Office for Civil Rights' intent to refer employment-related complaints to other appropriate Federal agencies for adjudication under their jurisdiction. *See id.*[12]

B. Protecting LGBTQ Individuals from Unlawful Discrimination

The Proposed Rule expressly recognizes that discrimination "on the basis of sex" necessarily includes discrimination based on sex stereotypes, sex characteristics, sexual orientation, and gender identity. 87 Fed. Reg. at 47,858.[13] The States welcome this correction to the 2020 Rule and applaud HHS's return to proper statutory interpretation.

In the 2016 Rule, HHS recognized "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," and that "[e]qual access for all individuals without discrimination is essential to achieving this goal." 81 Fed. Reg. 31,379, 31,444. HHS expressly acknowledged the seriousness of continuing discrimination against LGBTQ individuals and the healthcare disparities caused by discrimination. *Id.* at 31,460. Accordingly, the 2016 Rule prohibited the blanket exclusion of transition-related healthcare services; the denial or limitation of coverage of services used for gender transition when those services would normally be covered when treating a non-transition related health condition; and the refusal to cover treatment that is typically associated with a particular gender because an individual identifies with another gender or is listed as having another gender in their medical records. *Id.* at 31,471–72. Further, if an insurance company covers a particular treatment of any condition, the carrier could not refuse to cover the same treatment because it is requested by a transgender or gender-nonconforming individual or because it is being utilized in a manner consistent with their gender identity. *Id.* at 31,435.

The 2020 Rule attempted to eviscerate these needed reforms. It stripped HHS's Section 1557 regulations of the express protections against discrimination based on gender identity, sex

[12] The States believe that the Section 1557's nondiscrimination requirements do apply to employment-related practices (and the Proposed Rule does not say otherwise). Indeed, as HHS recognized, eliminating employee health benefits from the provisions would leave over 55 percent of the U.S population—an unacceptably high number—without the protections of Section 1557. 87 Fed. Reg. at 47,838.

[13] It is settled law that federal civil rights statutes forbid discrimination on the basis of sex stereotypes and sex characteristics. *Price Waterhouse v. Hopkins*, 490 U.S. 228, 240 (1989) ("[G]ender must be irrelevant to employment decisions"). It is also settled law that "it is impossible to discriminate against a person for being homosexual or transgender without discriminating against that individual based on sex," because "homosexuality and transgender status [is] inextricably bound up with sex." *Bostock*, 140 S. Ct. at 1471.

stereotypes, and pregnancy-related conditions. These changes ignored nearly 200,000 comments to the 2020 Rule, many opposing the stark retreat from the 2016 Rule's protections that could result in LGBTQ individuals facing unreasonable barriers in obtaining appropriate medical care. In *New York*, several States sought to enjoin the 2020 Rule due to harms to their public health systems. Courts promptly enjoined elements of the 2020 Rule.[14]

The Proposed Rule is a necessary return to proper legal interpretations of the protections offered by Section 1557. Discrimination against transgender people violates Title IX. *See Grimm v. Gloucester Cty. Sch. Bd.*, 972 F.3d 586, 619 (4th Cir. 2020), *reh'g en banc denied*, 976 F.3d 399 (4th Cir. 2020), *cert. denied* 141 S.Ct. 2878 (2021). Even before the U.S. Supreme Court held that sex discrimination encompassed gender identity, courts interpreted Title IX's sex discrimination prohibition to ban discrimination against transgender students. *See*, *e.g.*, *Whitaker v. Kenosha Unified Sch. Dist. No. 1 Bd. of Educ.*, 858 F.3d 1034, 1049-50 (7th Cir. 2017). Federal appellate courts have also held that state restrictions on access to healthcare for transgender youth violate the Equal Protection Clause. *Brandt v. Rutledge*, 47 F.4th 661 (8th Cir. 2022).

1. Sexual Orientation and Gender Identity Discrimination Harms Patients

The Proposed Rule is an important step to address the "robust evidence that discrimination on the basis of sexual orientation or gender identity is associated with harms to the health of LGBTQI+ people". 87 Fed. Reg. at 47,834. LGBTQ persons report experiencing barriers to receiving medical services, including disrespectful attitudes, discriminatory treatment, inflexible or prejudicial policies, and even outright refusals of essential care, leading to poorer health outcomes and often serious or even catastrophic consequences.[15] LGBTQ individuals experience poorer physical health compared to their heterosexual and non-transgender counterparts, have higher rates of chronic conditions, and are at higher risk for certain mental health and behavioral health conditions, including depression, anxiety, and substance misuse.[16] HHS recognizes that these harms have been further exacerbated by the COVID-19 pandemic and limited healthcare resources. 87 Fed. Reg. at 47,834.

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[14] *See Whitman-Walker Clinic*, 485 F. Supp. 3d at 40–41, 64; *Walker*, 480 F. Supp. 3d at 429–30.

[15] Lambda Legal, *When Health Care Isn't Caring: Lambda Legal's Survey on Discrimination Against LGBT People and People Living with HIV* at 5–6 (2010) , https://www.lambdalegal.org/sites/default/files/publications/downloads/whcic-report_when-health-care-isnt-caring.pdf; *see also* Jennifer Kates, et al., Kaiser Family Found., *Health and Access to Care and Coverage for Lesbian, Gay, Bisexual, and Transgender (LGBT) Individuals in the U.S.* (May 3, 2018), https://www.kff.org/report-section/health-and-access-to-care-and-coverage-lgbt-individuals-in-the-us-health-challenges.

[16] *Lambda Legal*, at 5, 8.

Transgender people in particular face significant barriers to receiving both routine and gender-affirming care.[17] These barriers create serious consequences. Among transgender people, suicide attempts are nine times more common than in the overall U.S. population (41% versus 4.6%).[18] Unaddressed gender dysphoria can impact quality of life and trigger decreased social functioning.[19] Transgender people are more likely to experience income insecurity,[20] more likely to experience food insecurity,[21] and more likely to be uninsured or rely on state-run programs such as Medicaid.[22] State programs are likely to bear the financial burden of addressing the

[17] *See* Sandy E. James et al., Nat'l Ctr. For Transgender Equal., *The Report of the 2015 U.S. Transgender Survey*, at 96-99 . (2016), https://transequality.org/sites/default/files/docs/usts/USTS-Full-Report-Dec17.pdf; (transgender people in particular report hostile and disparate treatment from providers); *see also* Morning Consult & The Trevor Project, *How COVID-19 is Impacting LGBTQ Youth* at 25 (2020), https://www.thetrevorproject.org/wp-content/uploads/2020/10/Trevor-Poll_COVID19.pdf (finding that 28% of trans and nonbinary youth and 18% of LGBTQ youth overall reported wanting mental healthcare and not being able to receive it, compared with only 7% of white cisgender heterosexual youth).

[18] Ann P. Haas et al., Am. Found. For Suicide Prevention & The Williams Inst., *Suicide Attempts Among Transgender and Gender Non-Conforming Adults: Findings of the National Transgender Discrimination Survey* 2 (2014), https://williamsinstitute.law.ucla.edu/wp-content/uploads/Trans-GNC-Suicide-Attempts-Jan-2014.pdf.

[19] *See* Emily Newfield et al., *Female-to-Male Transgender Quality of Life*, 15(9) Quality of Life Research 1447 (2006), https://www.ncbi.nlm.nih.gov/pubmed/16758113 (observing that transgender men who received gender-affirming care reported having a higher health-related quality of life than those who had not).

[20] *See* Sharita Gruberg et al., Ctr. for Am. Progress, *The State of the LGBTQ Community in 2020* (Oct. 6, 2020), https://www.americanprogress.org/article/state-lgbtq-community-2020 (showing 54% of transgender respondents reported that discrimination moderately or significantly affected their financial well-being).

[21] Kerith J. Conron & Kathryn K. O'Neill, Univ. of Cal. Los Angeles, *Food Insufficiency Among Transgender Adults During the COVID-19 Pandemic* 2 (2021), https://williamsinstitute.law.ucla.edu/wp-content/uploads/Trans-Food-Insufficiency-Dec-2021.pdf.

[22] Jaime M. Grant et al., Nat'l Ctr. For Transgender Equal. & Nat'l Gay and Lesbian Task Force, *National Transgender Discrimination Survey Report on Health & Health Care* at 8 (2010), https://cancer-network.org/wp-content/uploads/2017/02/National_Transgender_Discrimination_Survey_Report_on_health_and_health_care.pdf (23% of transgender women and 13% of transgender men report relying on public health insurance); *see also* Kellan Baker et al., Ctr. for Am. Progress, *The Medicaid Program and LGBT Communities: Overview and Policy Recommendations* (Aug. 9, 2016), https://www.americanprogress.org/article/the-medicaid-program-and-lgbt-communities-overview-and-policy-recommendations (noting that the high prevalence of poverty in LGBTQ communities, especially among transgender people and LGBTQ people of color, makes Medicaid a critical program for the health and well-being of these communities)

significant consequences resulting from denying transgender people necessary healthcare.[23] Access to gender-affirming care improves wellbeing for transgender adults.[24]

a. Impacts on Transgender Youth

LGBTQ youth are especially vulnerable. These youth report a greater incidence of mental health issues and suicidal behaviors, suffer bullying and victimization to a greater extent than heterosexual youth, and have difficulty addressing concerns with their medical providers.[25] One study found that 56% of transgender youth reported a previous suicide attempt and 86% reported suicidal thoughts.[26] The Centers for Disease Control and Prevention found that transgender students are more likely to report feeling unsafe at or going to and from school, being bullied, threatened, or injured with a weapon at school, being forced to have sex, and experiencing physical and sexual dating violence.[27] Undergoing puberty that does not align with one's gender identity and developing permanent undesired secondary sex characteristics is "often a source of significant distress" for transgender adolescents.[28]

Access to gender-affirming care improves health outcomes for transgender youth. Transgender teens with access to social support and gender-affirming healthcare experience

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[23] *See* Christy Mallory & William Tentindo, Williams Inst., *Medicaid Coverage for Gender Affirming Care* (Oct. 2019), https://williamsinstitute.law.ucla.edu/wp-content/uploads/Medicaid-Gender-Care-Oct-2019.pdf (listing states that include gender affirming care in their Medicaid programs); *see e.g.*, Wash. Admin. Code § 182-501-0060 (listing program's benefits); Cal. Code Regs. tit. 22 § 51301 *et seq.* (same); N.Y. Comp. Codes R. & regs. tit. 18, § 505.1 *et seq.* (same).

[24] Michael Zaliznyak et al., *Effects of Gender-Affirming Hormone Therapy on Sexual Function of Transgender Men and Women*, 206 J. of Urology 637, 638 (2021), https://www.auajournals.org/doi/epdf/10.1097/JU.0000000000002045.06; What We Know Project, Cornell University, What Does the Scholarly Research Say about the Effect of Gender Transition on Transgender Well-Being? (2018) https://whatweknow.inequality.cornell.edu/topics/lgbt-equality/what-does-the-scholarly-research-say-about-the-well-being-of-transgender-people (online literature review); Newfield et al., *supra* fn. 20.

[25] Hudaisa Hafeez, et al., *Health Care Disparities Among Lesbian, Gay, Bisexual, and Transgender Youth: A Literature Review*, Cureus (Apr. 20, 2017), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5478215.

[26] Ashley Austin et al., *Suicidality Among Transgender Youth: Elucidating the Role of Interpersonal Risk Factors*, 37 J. of Interpersonal Violence 2696 (2022), https://pubmed.ncbi.nlm.nih.gov/32345113.

[27] *See* Michelle M. Johns et al., U.S. Ctrs. for Disease Control & Prevention, *Transgender Identity and Experiences of Violence Victimization, Substance Use, Suicide Risk, and Sexual Risk Behaviors Among High School Students*, 68 Morbidity Mortality Weekly Report 67, 69 (2019), http://dx.doi.org/10.15585/mmwr.mm6803a3.

[28] Ximena Lopez et al., *Statement on Gender-Affirmative Approach to Care from the Pediatric Endocrine Society Special Interest Group on Transgender Health*, 29 Current Op. Pediatrics 475, 480 (2017), https://pubmed.ncbi.nlm.nih.gov/28562420.

mental health outcomes equivalent to their cisgender peers.[29] And for teens under the age of eighteen, use of gender-affirming hormone therapy was associated with 39% lower odds of recent depression and 38% lower odds of attempting suicide compared to adolescents who wanted, but did not receive, such therapy.[30] Adolescents who begin gender-affirming treatment at later stages of puberty are over five times more likely to have been diagnosed with depression and over four times more likely to have anxiety disorders than adolescents who seek treatment in early puberty.[31]

In addition to improved mental health outcomes, access to gender-affirming treatment improves overall well-being in transgender teenagers and young adults. A longitudinal study that followed transgender adolescents from their intake at a gender clinic into young adulthood found that gender-affirming treatment resulted in significant improvement in global functioning and psychological wellbeing.[32] The study reported that post-treatment, participants had "rates of clinical problems that are indistinguishable from general population samples," and that their life

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[29] Dominic J. Gibson et al., *Evaluation of Anxiety and Depression in a Community Sample of Transgender Youth*, 4(4) J. Am. Med. Ass'n Open 1, 1–2 (Apr. 7, 2021), https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2778206 (finding no significant group differences in self and parent reported depressive and anxiety symptoms among "socially transitioned transgender youth, their siblings, and age- and gender-matched control participants"); Lily Durwood et al., *Social Support and Internalizing Psychopathology in Transgender Youth*, 50 J. of Youth and Adolescence 841 (2021), https://link.springer.com/article/10.1007%2Fs10964-020-01391-y ("Parents who reported higher levels of family, peer, and school support for their child's gender identity also reported fewer internalizing symptoms."); Kristina R Olson et al., *Mental Health of Transgender Children Who Are Supported in Their Identities*, 137(3) Pediatrics 1, 1 (2016), https://pubmed.ncbi.nlm.nih.gov/26921285 (similar); Anna I. R. van der Miesen et al., *Psychological Functioning in Transgender Adolescents Before and After Gender-Affirmative Care Compared with Cisgender General Population Peers,* 66 J. Adolescent Health 699, 703 (2020), https://pubmed.ncbi.nlm.nih.gov/32273193 (similar); *see also* Jack L. Turban et al., *Access To Gender-Affirming Hormones During Adolescence and Mental Health Outcomes Among Transgender Adults* 17 PLOS One 1, 8 (2022), https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0261039 (access to gender-affirming hormones during adolescence was associated with lower rates of past-month severe psychological distress, past-year suicidal ideation, past month binge drinking, and lifetime illicit drug use when compared to access to gender-affirming hormones during adulthood).

[30] Amy E. Green et al., *Association of Gender-Affirming Hormone Therapy with Depression, Thoughts of Suicide, and Attempted Suicide Among Transgender and Nonbinary Youth*, 70 J. Adolescent Health 643, 647–48 (2022), https://doi.org/10.1016/j.jadohealth.2021.10.036; *see also* Diana M. Tordoff, et al., *Mental Health Outcomes in Transgender and Nonbinary Youths Receiving Gender-Affirming Care*, 5 J. Am. Med. Ass'n Network Open 1, 1 (2022), https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2789423 (access to gender affirming care associated with improved mental health outcomes in youths).

[31] Julia C. Sorbara et al., *Mental Health and Timing of Gender-Affirming Care*, 146 Pediatrics 1, 5 (2020), https://publications.aap.org/pediatrics/article/146/4/e20193600/79683/Mental-Health-and-Timing-of-Gender-Affirming-Care.

[32] Annelou L.C. de Vries et al., *Young Adult Psychological Outcome After Puberty Suppression and Gender Reassignment*, 134 Pediatrics 696, 702 (2014), https://doi.org/10.1542/peds.2013-2958.

satisfaction, quality of life, and subjective happiness were comparable to their same-age cisgender peers.[33] Another study found significant improvement in teens' self-worth and perceived physical appearance after starting hormone replacement therapy.[34]

b. Impacts on Transgender Elders

LGBTQ elders are also particularly vulnerable to discrimination. In a survey of 2,560 LGBTQ older adults in the United States, nearly half of respondents were living at or below 200 percent of the federal poverty line.[35] More than one in ten LGBTQ older adults (13%) who participated in the project have been denied healthcare or provided with inferior care.[36] Fifteen percent of LGBTQ older adults fear accessing healthcare outside the LGBTQ community, and 8% fear accessing healthcare inside the community.[37] More than 21% of LGBTQ older adults have not revealed their sexual orientation or gender identity to their primary physician, and bisexual older women and men are less likely to disclose than lesbian and gay older adults.[38]

Nationally, 40% of transgender seniors reported being denied healthcare or facing discrimination by healthcare providers.[39] Transgender older adults are at significantly higher risk of poor physical health, disability, depressive symptomatology, and perceived stress, and suffer from fear of accessing health services, lack of physical activity, internalized stigma, victimization, and lack of social support.[40] Discrimination in a long-term care setting and the

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[33] *Id.*

[34] Marijn Arnoldussen et al., *Self-Perception of Transgender Adolescents After Gender-Affirming Treatment: A Follow-Up Study Into Young Adulthood*, 9 LGBT Health 238 (2022), https://www.liebertpub.com/doi/epdf/10.1089/lgbt.2020.0494; *see also* Mona Ascha et al., *Top Surgery and Chest Dysphoria Among Transmasculine and Nonbinary Adolescents and Young Adults*, JAMA Pediatr. (forthcoming 2022), doi:10.1001/jamapediatrics.2022.3424 (reconstructive chest surgery associated with statistically significant improvement in chest dysphoria, gender congruence, and body image at three months follow-up).

[35] Karen I. Fredriksen-Goldsen et al., *The Aging and Health Report: Disparities and Resilience Among Lesbian, Gay, Bisexual, and Transgender Older Adults Institute for Multigenerational Health* 4 (2011), https://www.lgbtagingcenter.org/resources/pdfs/LGBT%20Aging%20and%20Health%20Report_final.pdf ; *see also* Karen I. Fredriksen-Goldsen et al., *Iridescent Life Course: LGBTQ Aging Research and Blueprint for the Future: A Systematic Review* 65 Gerontology 253 (2019), https://pubmed.ncbi.nlm.nih.gov/30826811 (discussing state of literature).

[36] Fredriksen-Goldsen et al. (2011), *supra* note 35, at 4.

[37] *Id.*

[38] *Id*. at 4–5.

[39] *Id*. at 31; *see also* Annie Snow et al., *Barriers to Mental Health Care for Transgender and Gender-Nonconforming Adults: A Systematic Literature Review* 44 Health & Social Work 149–55 (2019), https://pubmed.ncbi.nlm.nih.gov/31359065.

[40] Karen I. Fredriksen-Goldsen et al., *The Physical and Mental Health of Transgender Older Adults: An At-Risk and Underserved Population* 54 The Gerontologist 488 (2014), https://pubmed.ncbi.nlm.nih.gov/23535500; *see also* Vanessa D. Fabbre & Eleni Gaveras, *The*

related anxiety anticipating it are associated with negative health outcomes.[41] At least one recent study has shown that LGBTQ older adults reported a higher likelihood of moving to a long-term care facility, as compared to heterosexual older adults.[42] A survey of LGBTQ elders and their families by Justice in Aging also found that 89% of respondents predicted that staff would discriminate against an openly LGBTQ elder.[43] A majority also thought that other residents would discriminate (81%) and, more specifically, that other residents would isolate an LGBTQ resident (77%).[44] More than half also predicted that staff would abuse or neglect the person (53%).[45]

These facts demonstrate the need for robust LGBTQ protections under Section 1557 and the harm caused by the 2020 Rule's departure from proper statutory interpretation. "[T]he unmistakable basis for HHS's action was a rejection of the position taken in the 2016 Rules that sex discrimination includes discrimination based on gender identity and sex stereotyping." *Walker*, 480 F. Supp. 3d at 430. "[W]hether by design or bureaucratic inertia, the fact remains that HHS finalized the 2020 Rules without addressing the impact of the Supreme Court's decision in *Bostock*." *Id.* Instead, the 2020 Rule drew "from the Government's losing litigating position in *Bostock*" to justify stripping away needed protections. *Whitman-Walker Clinic*, 485 F. Supp. 3d at 41 (citing 85 Fed. Reg. at 37,178-79). Abundant evidence of harm, discrimination, and health disparities experienced by LGBTQ people demands reversal. It is critical for HHS to finalize rules restoring the correct interpretation of "sex discrimination" under Section 1557.

Manifestation of Multilevel Stigma in the Lived Experiences of Transgender and Gender Nonconforming Older Adults 90 Am. J. of Orthopsychiatry 350 (2020), https://pubmed.ncbi.nlm.nih.gov/31971406; Kristen E. Porter et al., *Providing Competent and Affirming Services for Transgender and Gender Nonconforming Older Adults* 39 Clinical Gerontologist 366 (2016), https://pubmed.ncbi.nlm.nih.gov/29471769 Charles P. Hoy-Ellis & Karen I. Fredriksen-Goldsen, *Depression Among Transgender Older Adults: General and Minority Stress* 59 Am. J. of Cmty. Psychology 295 (2017), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5474152.

[41] Jaclyn White Hughto & Sari Reisner, *Social Context of Depressive Distress in Aging Transgender Adults* 37 J. of Applied Gerontology 1517 (2018), https://pubmed.ncbi.nlm.nih.gov/28380703; *see also* Dagfinn Nåden et al., *Aspects of Indignity in Nursing Home Residences as Experienced by Family Caregivers* 20 Nursing Ethics 748 (2013), https://pubmed.ncbi.nlm.nih.gov/23462504.

[42] Mekiayla Singleton et al., *Anticipated Need for Future Nursing Home Placement by Sexual Orientation: Early Findings from the Health and Retirement Study* 19 Sexuality Research & Soc. Policy 656 (2022), https://doi.org/10.1007/s13178-021-00581-y.

[43] Justice in Aging, *Stories from the Field: LGBT Older Adults in Long-Term Care Facilities* 8 (2d. ed. 2015), https://www.justiceinaging.org/wp-content/uploads/2015/06/Stories-from-the-Field.pdf.

[44] *Id.*

[45] *Id.*

C. Discrimination On The Basis Of Pregnancy-Related Conditions And the Impact of *Dobbs*

In the Proposed Rule, HHS correctly recognizes that discrimination on the basis of pregnancy or its related conditions is a form of sex discrimination that impacts healthcare access. 87 Fed. Reg. at 47,832. Where patients are denied medication, treatment, or even information, these actions can result in serious health consequences. *Id*. As HHS recognizes, access to healthcare is crucial, particularly for those who experience intersectional discrimination such as people of color and those with disabilities. *Id*.

The Proposed Rule does not expressly define sex discrimination or pregnancy-related conditions to include the termination of pregnancy, i.e., abortion. HHS endorses the view that abortion and other pregnancy-related conditions are already included in Section 1557 because it prohibits discrimination in health programs on the basis of any ground listed under Title IX. 42 U.S. Code § 18116. It therefore incorporates a Title IX regulation prohibiting discrimination on the basis of "pregnancy, childbirth, false pregnancy, termination of pregnancy or recovery therefrom." 45 CFR § 86.40(a). As HHS previously recognized, this long-standing interpretation is consistent with other Federal agencies and courts' interpretations of the scope of sex discrimination. 81 Fed. Reg. at 31,387-88.

The Proposed Rule should expressly incorporate this long-standing interpretation by including a standalone provision mirroring the specific prohibitions found in the Title IX regulations. The inclusion of a standalone provision would more effectively implement Section 1557's sex discrimination protections by expressly including all pregnancy-related conditions, including pregnancy termination, and by making clear that covered entities are prohibited from discriminating against a person on the basis of those conditions. Such a provision is particularly important in the wake of *Dobbs v. Jackson Women's Health Organization*, 597 U.S. __ (2022), which has caused widespread confusion among covered entities about their legal obligations related to abortion in the changed national landscape. A standalone provision would also provide an opportunity for HHS to clarify the interplay between Section 1557 and other federal statutes or regulations related to abortion that may apply to covered entities. Thus, we support HHS in including express language regarding the termination of pregnancy in defining sex discrimination.

By providing much need clarity to covered entities on the scope of sex discrimination protections, a strengthened definition of sex discrimination that enumerates specific forms of discrimination concerning pregnancy and its related conditions would also benefit patients. In the fallout of the *Dobbs* decision, people capable of becoming pregnant face numerous logistical and legal barriers to accessing care, particularly in the context of miscarriage management or pregnancy loss where there is a very real threat of arrest and prosecution as states seek to criminalize self-managed abortions.[46] Furthermore, there are many documented instances of

[46] *See* National Advocates for Pregnant Women, *Confronting Pregnancy Criminalization: A Practical Guide for Healthcare Providers, Lawyers, Medical Examiners, Child Welfare Workers, and*

providers refusing to provide care or engaging in other punitive measures against pregnant patients for behavior perceived as harming the fetus. For example, a provider may not report a non-pregnant patient for substance use disorder, but would report a pregnant person for similar conduct. A standalone provision could protect patients from experiencing discrimination from healthcare providers on the basis of a past termination of pregnancy when accessing a broad range of healthcare services in states that now ban abortion. For example, without clarification that sex discrimination includes past pregnancy, a provider could turn away a potential patient after reviewing their medical history—even if the termination was years prior or if the patient is seeking unrelated medical services. It is therefore essential that the Final Rule expressly identify this conduct as prohibited sex discrimination.

Providing clear direction that discrimination on the basis of sex includes pregnancy-related medical conditions such as past pregnancy and the termination of pregnancy further bolsters other HHS guidance to covered entities. Indeed, much of HHS's recent guidance to retail pharmacies made clear that discrimination based on adverse pregnancy outcomes could constitute a violation of the Proposed Rule. For example, if a pharmacy regularly fills contraceptive prescriptions but refuses to provide emergency contraceptives because they could prevent ovulation or block fertilization, this could constitute sex discrimination in violation of Section 1557.[47] Providing clear language to covered entities is invaluable in ensuring that patient care is not delayed or denied due to sex discrimination. 87 Fed. Reg. at 47,833.

Furthermore, a standalone provision would make clear to covered entities that pregnant persons are entitled to the same level of information about their medical condition and needs as any other non-pregnant person. Indeed, current federal conscience laws do not exempt healthcare providers from a responsibility to provide *information* about abortion. *See, e.g.*, Consolidated Appropriations Act of 2022, Pub. L. No. 117-103, § 507(d)(1), 136 Stat. 49, 496 (Weldon Amendment) (prohibiting discrimination against healthcare providers who refuse to "provide, pay for, provide coverage of, or refer for abortions"); 42 U.S.C. § 300a-7(b)(2)(A) (2012) (Church Amendment) (permitting religious healthcare entities to avoid "participat[ing] or assist[ing]" or "mak[ing] facilities available" for abortion). Under the Proposed Rule, healthcare providers, regardless of their religious exemption status, could not withhold information to patients on a discriminatory basis.[48]

Policymakers 9-11 (June 23, 2022), https://www.nationaladvocatesforpregnantwomen.org/wp-content/uploads/2022/06/1.Confronting-Pregnancy-Criminalization_6.22.23-1.pdf.

[47] U.S. Dep't of Health & Human Servs., *Guidance to Nation's Retail Pharmacies: Obligations Under Federal Civil Rights Laws to Ensure Access to Comprehensive Reproductive Health Care Service*s (Jul. 14, 2022), https://www.hhs.gov/civil-rights/for-individuals/special-topics/reproductive-healthcare/pharmacies-guidance/index.html.

[48] Moreover, the Proposed Rule would preclude the exercise of broader state conscience clauses that would allow healthcare providers to withhold information in a discriminatory manner. The preemption clause of the ACA makes clear that the ACA trumps conflicting state laws. *See* 42 U.S.C. § 18041(d) (2012). Moreover, while the ACA does not change federal conscience protection, it makes no similar proviso for state-level conscience laws. *See id*. § 18023(c)(2)(a)(i) (2012) ("Nothing in this Act

HHS has recognized that many patients live in communities "with limited options to access healthcare from non-religiously affiliated healthcare providers." 87 Fed. Reg. at 47,840. Further, HHS is aware that healthcare consumers do not know that their healthcare providers may limit care due to their religious affiliation. *Id*. at 47,840–41. This problem is exacerbated by the ever-increasing rate of consolidation in the U.S. healthcare industry, with the ten largest Catholic health systems having grown more than fifty percent in the last twenty years.[49] Today, one in every six hospital beds is in a Catholic facility.[50] These and other religiously-affiliated hospitals operate under the protection of federal conscience and religious objection laws that permit them to prohibit the provision of key reproductive health services, including contraception, sterilization, abortion, and infertility services.[51] But, providing information regarding these services is different from providing or directly referring for the services themselves. The Proposed Rule could ensure that patients in these covered entities are fully informed of their health status and medical choices and that physicians cannot discriminatorily withhold information.[52]

D. Protections for Individuals with Limited English Proficiencies

Over 67 million people in the United States speak a language other than English at home and of those, approximately 25 million may be considered LEP.[53] The States have an interest in ensuring that our populations of LEP individuals have meaningful access to health programs and activities despite language-related barriers.[54] Indeed, it well-known that language-related barriers

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shall be construed to have any effect on Federal laws regarding . . . conscience protection."). Indeed, while the statute does not preempt state laws regarding the "coverage, funding, or procedural requirements on abortions, including parental notification or consent" it omits "conscience protection." *Id*. § 18023(c)(1)-(2).

[49] *See* Tess Solomon et al., *Bigger and Bigger: The Growth of Catholic Health Systems* at 3 (2020) https://www.communitycatalyst.org/resources/publications/document/2020-Cath-Hosp-Report-2020-31.pdf.

[50] *Id*. at 4.

[51] *See, e.g.*,U. S. Conference of Catholic Bishops, Ethical and Religious Directives for Catholic Health Care Services 16–19 (6th Ed. 2018), https://www.usccb.org/about/doctrine/ethical-and-religious-directives/upload/ethical-religious-directives-catholic-health-service-sixth-edition-2016-06.pdf.

[52] These principles of informed consent are also reflected in federal conditions of funding, which require healthcare providers to meet certain health and safety standards. CMS Conditions of Participation are qualifications that healthcare organizations must meet in order to begin and continue participating in federally funded healthcare programs such as Medicare and Medicaid. 42 C.F.R. §§ 482.1 to 482.104. These conditions ensure patient rights: "the right to participate in the development and implementation of his or her plan of care" and the "right to make informed decisions regarding his or her care . . . includ[ing] . . . being involved in care planning and treatment." *Id*. at § 482.13(b)(1)-(2).

[53] *See* Karen Ziegler & Steven A. Camarota, Center for Immigration Studies, 67.3 Million in the United States Spoke a Foreign Language at Home in 2018, at 2 (2019), https://cis.org/Report/673-Million-United-States-Spoke-Foreign-Language-Home-2018.

[54] Several of the undersigned States are among the states with the highest share of populations speaking a foreign language at home, including California (45 percent), New Mexico (34 percent), New

can severely limit an individual's opportunity to access healthcare services, assess options, express choices, follow medication instructions, ask questions, and seek assistance.[55]

In promulgating the 2016 Rule, HHS recognized that national origin discrimination includes discrimination based on the "linguistic characteristics of a national origin group." 81 Fed Reg. at 31,467, 470-71. HHS emphasized that Congress intended, through Section 1557, to find effective ways to eliminate disparities in healthcare, including through the use of language services.[56] Therefore, in order to "ensure that [health programs and activities] aimed at the American public do not leave some behind simply because they face challenges communicating in English," *id.* at 31,410, HHS provided specific protections to guarantee meaningful access to healthcare for LEP individuals, *id.* at 31,470-71.[57] Yet, the 2020 Rule gutted the 2016 Rule's robust language access provisions. In particular, the 2020 Rule eliminated the notice and tagline requirements, removed a requirement that interpreters be "qualified," and eviscerated the "meaningful access" requirement. In doing so, HHS cited the financial and administrative burden associated with compliance, but ignored substantial evidence that this change would deny LEP individuals critical language assistance services and access to healthcare.

The Proposed Rule will restore "robust protections" for LEP individuals and help ensure that LEP individuals have meaningful access to health programs and activities in several key ways. 87 Fed. Reg. at 47,828. First, the Proposed Rule largely reinstates the requirement that covered entities take reasonable steps to provide meaningful access to each LEP individual eligible to receive services or likely to be directly affected by its health programs and activities. 87 Fed. Reg. at 47,860-63. The Proposed Rule continues to require that language assistance

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Jersey (32 percent), New York and Nevada (each 31 percent), Hawaii (28 percent), and Massachusetts (24 percent). *Id*. at 5. Several other States have experienced dramatic increases in the number of LEP individuals in their States, including Nevada (up 1,088 percent), North Carolina (up 802 percent), Washington (up 432 percent), and Oregon (up 380 percent). *Id* at 6.

[55] Nat'l Health Law Program & Access Project, *Language Services Action Kit* at 40 (2004), https://www.commonwealthfund.org/sites/default/files/documents/___media_files_publications_fund_report_2002_may_providing_language_interpretation_services_in_health_care_settings__examples_from_the_field_lep_actionkit_reprint_0204_pdf.pdf.

[56] Rose Chu et al., U.S. Dep't of Health & Human Servs., *ASPE Research Brief: The Affordable Care Act and Asian American and Pacific Islanders* at 2 (May 1, 2012), https://aspe.hhs.gov/sites/default/files/private/pdf/37346/rb.pdf; U.S. Dep't of Health & Human Servs., *HHS Action Plan to Reduce Racial and Ethnic Health Disparities* at 15, 17, 19-20 (2015), https://aspe.hhs.gov/reports/hhs-action-plan-reduce-racial-ethnic-health-disparities-implementation-progress-report-2011-2014-0.

[57] In connection with the 2016 Rule, HHS credited substantial evidence submitted to the agency that LEP individuals with access to adequate language assistance services "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," and that providers also benefit by the ability to "more confidently make diagnoses, prescribe medications, reach treatment decisions, and ensure that treatment plans are understood by patients." 81 Fed. Reg. at 31,459.

services be provided free of charge, be accurate and timely, and protect the privacy and independent decision-making ability of a LEP individual. 87 Fed. Reg. at 47,861, 47,915. Together, these provisions will increase LEP individuals' access to accurate, timely, and high-quality language access services that are necessary to navigate health services and coverage.

Second, the Proposed Rule contains a modified version of the 2016 Rule's notice and tagline requirements. In particular, the Proposed Rule requires covered entities to notify the public of the availability of language assistance services (replacing the "tagline" requirement with a Notice of Availability requirement that also requires a notice of the availability of auxiliary aids and services) in English and the top 15 most common languages spoken by LEP individuals in the relevant state or states. 87 Fed. Reg. at 47,853-56, 47,915. But rather than provide the required notices in all "significant" communications or publications as required by the 2016 Rule, HHS proposes that the notice of nondiscrimination and notice of availability be provided on an annual basis, displayed prominently on the covered entities' website and physical locations, and upon request. HHS also proposes that the notice of availability be provided on specifically identified documents and communications, including, for example, application and intake forms, Health Insurance Portability and Accountability Act (HIPAA) notices, notices of denial or termination of eligibility, benefits, or services, including Explanations of Benefits, notices of appeal and grievance rights, consent forms, communications related to a person's rights and benefits, among others. 87 Fed. Reg. at 47,855, 47,915-16.

This proposal strikes a reasonable balance between the 2016 Rule's efforts to improve access to health programs and services for LEP individuals and the 2020 Rule's concerns regarding cost and administrative burden. It also provides clear guidance to covered entities as to the information that must be conveyed, under what circumstances notices must be provided, and how the information must be provided or otherwise made available. Although the Proposed Rule does not include the 2016 Rule's broad requirement that taglines be provided in all "significant" communications or publications, the list of documents and communications in which the notice of availability must be provided is comprehensive, reduces ambiguity and confusion as to what constitutes a "significant" communication or publication, and will help ensure that LEP individuals have adequate notice of the availability of language assistance services to understand those documents or communications that are central to their rights, benefits, and healthcare services and coverage.

Third, the Proposed Rule requires that covered entities train staff on the provision of language assistance services and restores the requirement that covered entities must provide a "qualified" interpreter, which ensures that LEP individuals will have access to higher quality interpretation services than what is currently required under 2020 Rule. The Proposed Rule also addresses the use of machine translation and, in particular, proposes to require covered entities that utilize machine translation to have translated materials reviewed by a qualified interpreter when the underlying text is "critical to the rights, benefits, or meaningful access of a LEP individual." 87 Fed. Reg. at 47,861, 47,916. The States have some experience with machine

translation and found that it often produces inaccurate or misleading translations, which in turn can cause needless confusion or erect barriers for LEP individuals in navigating to care.[58] Scholarly research has also likewise found that machine translation can produce high error rates and that it is currently "unacceptable" for use in healthcare settings.[59] Given the well-documented issues with machine translation, the States support—at a minimum—HHS's proposal to require that materials translated by machine translation be reviewed by qualified interpreter where when the underlying text is "critical to the rights, benefits, or meaningful access of a LEP individual." 87 Fed. Reg. at 47,916. The States would further suggest that HHS collect data on the use of machine translation by covered entities to evaluate the circumstances in which it is used by covered entities and the accuracy of its results.

Finally, the Proposed Rule, for the first time, addresses nondiscrimination in the delivery of health programs and activities specifically through telehealth services. HHS proposes to require that telehealth services are accessible to individuals with disabilities and provide meaningful program access to LEP individuals. As discussed more fully below, the States welcome this focus on telehealth. Telehealth services have been essential to the delivery of healthcare services in the States during the COVID-19 pandemic, including across state lines, and use of telehealth continues to dramatically improve access to healthcare services for our most vulnerable residents, including people with disabilities and people who live in rural communities. But some aspects of telemedicine—including for example patient portals, the availability of real-time audio captioning or other video services necessary for interpretation, and the compatibility of telehealth platforms with screen reading software—have imposed barriers for LEP individuals and some people with disabilities.[60] Clarifying the application of the Proposed Rule to telehealth services would help reduce some of these barriers by ensuring that telemedicine platforms are accessible to individuals with disabilities and LEP individuals, and by ensuring that qualified interpretation services are available equally through telehealth platforms. It would also ensure needed consistency in access to telehealth services by LEP individuals and individuals with disabilities across state lines. Given the increasing use of telehealth platforms in our States and across the country, the States also agree that covered entities would benefit from specific provisions that address telehealth services for people with disabilities and LEP individuals to ensure that covered entities maximize access to telehealth services while preserving confidentiality, data privacy, and security.

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[58] Julie Zauzmer Weil, *D.C. Says Long-Awaited Translation of Vaccine Website Is Coming This Weekend*, Wash. Post (Apr. 9, 2021), https://www.washingtonpost.com/local/coronavirus-vaccine-translation-spanish/2021/04/09/40ed126a-9942-11eb-962b-78c1d8228819_story.

[59] Kristin N. Dew *et al., Development of Machine Translation Technology for Assisting Health Communication: A Systematic Review*, 85 J. of Biomedical Informatics 56, 57, 64 (2018), https://pubmed.ncbi.nlm.nih.gov/30031857/.

[60] Rupa S. Valdez *et al*., *Ensuring Full Participation of People with Disabilities in an Era of Telehealth*, 28 J. Am. Med. Inform. Ass'n 389 (Feb. 2021), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7717308/; Jorge Rodriguez, *et al*., *The Language of Equity in Digital Health: Prioritizing the Needs of Limited English Proficient Communities in the Patient Portal*, 32 J. of Health Care for the Poor & Underserved 211 (2021), https://muse.jhu.edu/article/789666.

E. Algorithm-Based Discrimination

The States welcome HHS's proposed regulation notifying covered entities that they "must not discriminate on the basis of race, color, national origin, sex, age, or disability in [their] health programs and activities through the use of clinical algorithms in decision making." 87 Fed. Reg. at 47,918. As the research cited in the NPRM demonstrates, this type of discrimination is increasingly prevalent, yet, based on the States' investigatory experiences, it is generally not transparent to consumers, and can be poorly understood even by providers.[61] The proposed regulation appropriately puts covered entities on notice of the relevance of Section 1557 to clinical algorithms, and is likely to increase the healthcare sector's attention and investment into review and auditing of these types of processes.

To ensure the success of these efforts, the States recommend the following clarifications, described in more detail below: (1) that a decision may be made "in reliance" on an algorithm even in circumstances where human judgment is involved; (2) that this regulation is exemplary and does not limit other types of automated decision making that may violate Section 1557; (3) that a clinical algorithm may be facially discriminatory even if protected characteristics are not explicit variables, and that disparate impact evidence is highly probative of discrimination; and (4) that HHS does not intend to limit other regulations or requirements that States may impose on covered entities to protect consumers against discrimination by clinical algorithms, or other automated decision making.

First, we commend HHS for its focus on decision making, since it is when algorithms and other automated systems are used to make decisions that impact care that they have the greatest potential to cause discrimination and harm. A decision may be made "in reliance" on an algorithm even if independent medical judgment is also an element of the decision.[62] HHS should clarify, and perhaps offer additional examples, explaining that merely adding an element of human clinical judgment on top of a discriminatory algorithm or system does not eliminate the covered entity's potential liability. Depending on the context, covered entities may need to implement policies and procedures in addition the use of individual judgment, in order to identify and eliminate bias resulting from use of a clinical algorithm.

Second, we agree with HHS's determination that this regulation does not represent a new prohibition, but a clarification and communication to covered entities of their responsibility regarding one specific form of discrimination. The field of algorithmic or computer-assisted

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[61] Although the States appreciate the American Medical Association's framework, which HHS describes on 87 Fed. Reg.at 47,883, our experiences to date have not demonstrated robust or widespread implementation of this framework.

[62] *See, e.g.*, Obermeyer et al., *Dissecting Racial Bias in an Algorithm Used to Manage the Health of Populations*, Science, 366, 447-453 (Oct. 25, 2019), https://pubmed.ncbi.nlm.nih.gov/31649194/ (noting that health program enrollment decisions "reflect how doctors respond to algorithmic predictions" in a way that reflects algorithmic bias).

decision making is fast-moving, and interacts in complicated ways with factors ranging from technology to payment policies. Accordingly, we suggest that HHS make clear in the preamble that despite the specificity of the (undefined) term "clinical algorithms in decision making," this regulation is exemplary, and does not represent the entire universe of algorithmic tools or automated decision making that may be used in a manner that violates Section 1557. Because Section 1557 applies to all "programs and activities" that could include pricing, financing, and other operational domains, it also reaches algorithms that may not be strictly "clinical" in nature, but that are used by providers, insurers, or other entities in non-clinical contexts that nonetheless impact consumers' access to healthcare.[63] For example, algorithms may be used to determine which patients get access to charity care or other financial support.[64]

Third, in this or future rulemaking, HHS may wish to consider elaborating the ways in which varying scienter requirements for the non-discrimination statutes underlying Section 1557 relate to algorithmic bias. Algorithms that were not designed with affirmative animus or invidious intent may nonetheless contain subtle, facial discrimination (or a deprivation of meaningful access) based on protected characteristics (including as a "proxy" for protected characteristics, as HHS describes, 87 Fed. Reg. at 47,881), even in the absence of use of race as a variable.[65] HHS should note that disparate impact evidence, while not necessarily determinative, can be highly probative evidence of algorithmic decision making that violates Section 1557. Conversely, the States strongly welcome HHS's explanation that use of racial or ethnic variables may be appropriate and justified when used to "identify, evaluate, and address health disparities." 87 Fed. Reg. at 47,881. Indeed, covered entities may use these variables as part of a proactive effort to ensure equity and ameliorate effects of past discrimination in healthcare.[66] HHS should make clear that Section 1557 does not interfere with such efforts.

Finally, the States urge HHS to make clear that its regulation addressing algorithmic discrimination by covered entities is intended to establish a floor, not a ceiling, for the protection of healthcare consumers. As HHS notes (87 Fed. Reg. at 47,884 n.578), several other federal

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[63] For one example of a list of categories of algorithms that may pose risks of discrimination to healthcare consumers, see Letter from California Attorney General Rob Bonta to Hospital CEOs (Aug. 31, 2022), https://oag.ca.gov/system/files/attachments/press-docs/8-31-22%20HRA%20Letter.pdf.

[64] *See, e.g.*, Samuel Davis et al., *Predicting a Need for Financial Assistance in Emergency Department Care*, 9 Healthcare 2021 556 (May 2021), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8150762/pdf/healthcare-09-00556.pdf.

[65] *See* Katie Palmer, *'It's Not Going to Work': Keeping Race Out of Machine Learning Isn't Enough to Avoid Bias*, STAT (June 28, 2022), https://www.statnews.com/2022/06/28/health-algorithms-racial-bias-redacting/ (citing research that algorithms based on clinical notes can predict patients' self-identified race despite explicit redaction of race data).

[66] *See, e.g.*, Samorani et al., *Overbooked and Overlooked: Machine Learning and Racial Bias in Medical Appointment Scheduling*, Manufacturing & Service Operations Management (Aug. 18, 2021), https://www.scu.edu/media/leavey-school-of-business/isa/research/Machine-Learning-and-Racial-Bias-in-Medical-Appointment-Scheduling-SSRN-id3467047.pdf (describing "race aware" changes to algorithm to alleviate waiting room times for Black patients who were otherwise more likely to be overbooked).

agencies are examining this issue in detail, on varied timelines. State agencies can and will address issues of algorithmic bias in ways that are more specific or broader than HHS.[67] In some cases, States may decide to offer broader protection to vulnerable groups than federal law provides.

F. Discrimination in the Delivery of Healthcare through Telehealth Services

In the wake of the COVID-19 pandemic, use of telehealth to deliver healthcare accelerated among health providers.[68] As a result, telehealth is increasingly instrumental in addressing chronic health issues, providing primary care for individuals living where services or specialties are lacking, and ensuring access for persons with income or transportation challenges.[69] At the same time, the recent expansion of telehealth highlights disparities in access based on race, language, disability, and economic status.[70] For example, African Americans and rural residents are more likely to lack broadband internet access, and a study found that patients who are either older, African-American, require an interpreter, use Medicaid, or live in areas with low broadband access were less likely to use video visits as compared to phone.[71] Accordingly, regulatory oversight of this growing treatment modality is necessary to ensure telehealth is not used discriminatorily, nor in a way that worsens existing inequities. Many states, including California, are in the process of enacting or proposing state legislation to address some of these issues, concurrent with proposed federal legislation and rulemaking.[72]

The States support the Proposed Rule's clarification that providers and covered entities must equitably provide telehealth services to patients, while prohibiting discriminatory practices in the delivery of telehealth services. 87 Fed. Reg. at 47,918. Equitable access to telehealth services requires that patients have proper technological equipment, knowledge and skills, and

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[67] *See, e.g.*, California Civil Rights Council, *Proposed Modifications to Employment Regulations Regarding Automated-Decision Systems* (Ver. July 28, 2022), https://calcivilrights.ca.gov/wp-content/uploads/sites/32/2022/07/Attachment-G-Proposed-Modifications-to-Employment-Regulations-Regarding-Automated-Decision-Systems.pdf.

[68] Verma S. Early Impact of CMS Expansion of Medicare Telehealth During COVID-19. Health Affairs Blog. 2020 (July 15, 2020) https://www.healthaffairs.org/do/10.1377/hblog20200715.454789/full/.

[69] Pei Xu et al., *Pandemic-Triggered Adoption of Telehealth in Underserved Communities: Descriptive Study of Pre- and Postshutdown Trends*, 24 J. Med. Internet Res. 7 (July 15, 2022), https://pubmed.ncbi.nlm.nih.gov/35786564/.

[70] *See*, *e.g.*, Lee Rainie, Pew Research Center, *Digital Divides — Feeding America*, (February 9, 2017), http://www.pewinternet.org/2017/02/09/digital-divides-feeding-america; Thiru M. Annaswamy et al., *Telemedicine Barriers and Challenges for Persons with Disabilities: COVID-19 and Beyond*, 13 Disability Health J. 4 (July 9, 2020), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7346769/.

[71] Julia Chen et al., *Predictors of Audio-Only Versus Video Telehealth Visits During the COVID-19 Pandemic*, 37 J. Gen. Intern. Med. 1138 (2022), https://doi.org/10.1007/s11606-021-07172-y.

[72] Center for Connected Health Policy and California Telehealth Policy Coalition, https://www.cchpca.org/california/pending-legislation/; https://www.cchpca.org/federal/pending-legislation/.

reliable internet or telecommunication services. Infrastructure and technological barriers in telehealth services differ by race, income, and geographic location, among other factors.[73] Recent guidance published by HHS provides examples of discriminatory acts in the delivery of telehealth services for covered entities and providers to consider in development of policies and processes.[74] Under the Proposed Rule, covered entities must ensure accessibility of telehealth platforms (87 Fed. Reg. at 47,864-65), communication for individuals with disabilities through auxiliary aids and services (*id*. at 47,863-64), and language assistance services for LEP individuals (*id*.). Consequently, the Proposed Rule helps protect consumers and providers from discrimination while encouraging improved access to telehealth. HHS should remind covered entities of all of their responsibilities regarding communication with individuals with disabilities, and auxiliary aids and services, including responsibilities set forth in prior HHS guidance.[75]

The Proposed Rule requires that covered entities implement policies and procedures to ensure compliance with Section 1557 and to provide training to staff interacting with patients. As part of those requirements and specifically for telehealth, the provisions should require covered entities to establish internal processes for communicating with patients before, during and after telehealth visits. This will allow for effective communication and continuity of care for patients who have challenges accessing follow-up or in-person care. For example, HHS could require development of pre-appointment screening and communication policies to ensure necessary equipment or technology for the appointment or to determine whether the patient has the requisite technological skills for participation. Provisions might also include planning and development of training resources for patients who lack skills or familiarity with telehealth prior to the appointment. Also, communication by the provider for follow-up care, whether for subsequent telehealth visits, referrals, or for in-person care, should occur in a timely manner to ensure continuity of care.

Finally, health practitioners providing abortion services now face increased risk of criminal prosecution, civil prosecution, or adverse licensing enforcement in states that prohibit abortion services. Fear of potential civil, criminal, or licensing consequences may lead some providers to refuse to provide abortion care or information about abortion care altogether. Further, although telehealth providers might provide telehealth abortion services to out-of-state patients where allowed, this raises concerns about the privacy of reproductive health information

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[73] Allison F. Perry et al., Institute for Healthcare Improvement, *Telemedicine: Ensuring Safe, Equitable, Person-Centered Virtual Care* (2021), https://www.ihi.org/resources/Pages/IHIWhitePapers/telemedicine-safe-equitable-person-centered-virtual-care.aspx.

[74] U.S. Dept. of Health and Human Servs., *Guidance on Nondiscrimination in Telehealth: Federal Protections to Ensure Accessibility to People with Disabilities and Limited English Proficient Persons* (July 29, 2022), https://www.hhs.gov/sites/default/files/guidance-on-nondiscrimination-in-telehealth.pdf.

[75] *See e.g.*, U.S. Dept. of Health and Human Servs., Example of a Policy and Procedure for Providing Auxiliary Aids for Persons with Disabilities (2013), https://www.hhs.gov/civil-rights/for-providers/clearance-medicare-providers/auxiliary-aids-persons-disabilities/index.html.

tracked through telehealth applications, including whether or not patients seek abortions across state lines.[76] To encourage and improve access to abortion services, the Proposed Rule might explicitly reference the security and privacy requirements under HIPAA pertaining to maintaining the security and privacy of protected reproductive health or abortion health services information created and stored for telehealth services or in telehealth applications. The Proposed Rule could further clearly note that these privacy requirements preempt any conflicting state laws that would seek to expose or remove the security protections of this information.

III. NEW PROCESS FOR SUBMISSION OF A CONSCIENCE OR RELIGIOUS EXEMPTION

The States support the notification procedures set forth in proposed § 92.302, which allow recipients to inform HHS of their views that the application of a specific provision or provisions of Section 1557 would violate federal conscience or religious freedom laws. The Proposed Rule recognizes that a blanket exemption from the provisions of Section 1557 is unattainable. 87 Fed. Reg at 47,886. While there may be fact-sensitive, case-specific instances when a covered entity is exempt due to federal conscience and religious freedom laws, no covered entity can be exempt from compliance with all provisions of Section 1557 in all circumstances. *Id*. [77] As such, the proposed notice provisions are superior to previous provisions regarding the application of federal conscience and religious freedom laws.

The Proposed Rule allows the recipient of federal funds to notify HHS of its belief that a specific provision or provisions of the regulation, as applied to it, would violate federal conscience or religious freedom laws. 87 Fed. Reg at 47,886. The notification will then prompt HHS to consider the relevant facts as applied to the covered entity in order to assess an exemption's applicability. *Id*. at 47,885-6. HHS's determination would be with respect to a particular recipient, certain provisions or modified application of certain provisions of the regulation, and certain contexts, procedures, or healthcare services. *Id*. at 47,886. Critically, the application of other provisions of Section 1557 to other contexts, procedures, or healthcare services, would remain. *Id*. This approach hews more closely to the Congressional intent of the ACA to expand healthcare access, while still recognizing that there may be circumstances when the application of federal conscience and religious freedom laws is appropriate.[78]

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[76] *See* Center For Connected Health Policy, Abortion Decision Impact on Telemedicine & Privacy (July 2022), https://mailchi.mp/cchpca/telehealth-policy-heats-up-with-abortion-decision-plus-telehealth-sud-recommendations-from-white-house-more (noting concerns about increased surveillance).

[77] For example, federal healthcare refusal laws do not override the Emergency Medical Treatment and Labor Act's protections that require that stabilization and treatment for a patient seeking emergency care.

[78] Even the most recent holding of *Franciscan Alliance v. Becerra*, 553 F. Supp. 3d 361 (N.D. Tex. 2021), supports this approach. The court's ruling applies only to the specific plaintiff and only with respect to a requirement that it perform or provide insurance coverage for services related to gender transition or abortion. 553 F. Supp. 3d at 375-78. The court never considered a wholesale exemption, such that the plaintiff and recipient of federal funds could discriminate against those seeking healthcare as it saw fit. (HHS has expressly confirmed it intends to abide by the injunctions upheld by the *Franciscan*

Moreover—and of critical importance to the States and their residents—the newly proposed provision allows HHS to assess the danger to individuals in need of healthcare, which is an essential consideration before exempting covered entities under federal conscience and religious freedom laws. 87 Fed. Reg. at 47,842, 46. Granting exemptions that affect underserved populations who already face a lack of healthcare access will only compound negative health outcomes. Careful consideration of these populations is thus essential.

This potential peril to individuals' health and wellbeing highlights why the healthcare context is fundamentally distinct from the education context, and why exemptions applicable in education should not be incorporated to apply to healthcare. A patient cannot always select an alternate healthcare facility or health plan with the forethought inherent in choosing an educational institution. 87 Fed. Reg. at 47,840-41. Scarcity of healthcare options is even more dangerous in emergencies. There is no life-or-death parallel in education. HHS addressed this singular aspect of healthcare when it incorporated only the bases of discrimination under Title IX, and not the Title IX exceptions. *Id*. HHS takes the same approach with Title VI, the Age Act, and Section 504, cleanly addressing any inconsistencies in past rules. *Id.* at 47,839. The States commend this approach of incorporating into Section 1557 only the grounds of discrimination, which tracks the plain language of Section 1557.

There are, however, some potential gaps in the notice provisions. Section 92.302 does not explicitly state that covered entities that notify HHS of their view that they are exempt from certain provisions due to the application of a federal conscience or religious freedom laws may not act as if exempted until receipt of a favorable determination from HHS. The Proposed Rule also does not expressly state that covered entities cannot refuse healthcare or coverage simply by deeming themselves exempt from Section 1557, but choosing not to notify HHS pursuant to § 92.302. In short, the notice requirements as currently drafted are permissive, not mandatory. The Proposed Rule could therefore benefit from clarification, and making explicit that the provisions are not optional for recipients who seek to refuse care.[79]

IV. PROHIBITION OF DISCRIMINATION—GROUP AND INDIVIDUAL HEALTH INSURANCE MARKETS: ENFORCEABILITY AND STATE AUTHORITY

In explaining its reasons for not relying on Section 1557 as authority for support of a proposed amendment regarding guaranteed issue of coverage (Section 147.104), HHS states, "Because states would not have authority to enforce Section 1557, CMS is of the view that partial reliance on Section 1557 could unnecessarily complicate enforcement efforts." 87 Fed. Reg. at 47,898. While the States do not dispute that HHS is the lead enforcement agency for

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Alliance court, in the event they remain in place.)

[79] Relatedly, there may also be some ambiguity by what is meant by an "open case." 87 Fed. Reg. at 47,886. The States assume that that HHS considers a notification pursuant to § 92.302 an open case, similar to if HHS had received a complaint of discrimination, or had an open investigation, but the States are concerned with any implication that covered entities that are not the subject of any open investigation or "case" may simply choose to refuse care.

Section 1557, we assume that HHS did not intend to express that states can never enforce Section 1557, only that states do not have the same primary enforcement authority with respect to Section 1557 comparable to states' responsibilities vis-a-vis state insurance markets, or the specific statutory jurisdiction accorded to federal grant-making agencies in 42 U.S.C. § 2000d-1. In practice, state agencies often play a role in oversight and enforcement of federal non-discrimination laws against subgrantees and other federal funds recipients in circumstances where there is joint federal/state administrative responsibility. And state Attorneys General generally have broad, independent authority to enforce consumer protection laws, both state and federal, when taking action to protect consumers within their own states against unlawful conduct, including discriminatory conduct. *See, e.g.*, *New York by Schneiderman v. Utica City Sch. Dist.*, 177 F. Supp. 3d 739, 747-48 (N.D.N.Y. 2016) (holding that New York Attorney General had authority to enforce Title VI to protect quasi-sovereign interests); *see also Munson v. Del Taco, Inc*., 46 Cal.4th 661, 676 (2009) (noting that under California's Unfair Competition Law or UCL, federal law violations may serve as a predicate for a state UCL claim).

Although the administrative procedures specified in the Section 1557 regulation itself would not be enforced or applied by states, the States may utilize their independent enforcement authorities that allow them to seek redress for violations of law, including federal laws, by entities within their jurisdictions. In addition, many states have passed enabling legislation to implement ACA provisions. HHS should clarify that states, including state Attorneys General, may enforce Section 1557 to the fullest extent granted by law. This will ensure that both state and federal law enforcement agencies have access to all available legal tools when attempting to identify and prevent discrimination against healthcare consumers, and preserve the States' role as "laboratories for democracy" in efforts to combat inequity in healthcare.

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The States applaud HHS for returning the protections against discrimination in healthcare clearly envisioned by the ACA. The Proposed Rule will help the States in their efforts to protect the health and well-being of our residents, and remain faithful to the Nation's values of equity for all. We urge the federal government to finalize this rule swiftly.

Sincerely,

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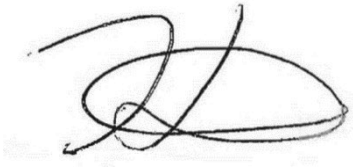

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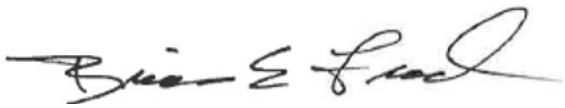

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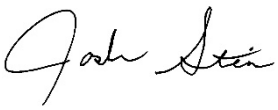

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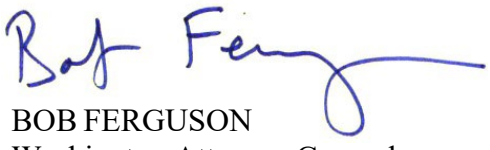

BOB FERGUSON
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January 28, 2022

ATTORNEY GENERAL RAOUL LEADS DEFENSE OF KEY PROVISIONS OF THE AFFORDABLE CARE ACT

Chicago — Attorney General Kwame Raoul today led a coalition of 20 attorneys general in filing an amicus brief in Kelley v. Becerra, defending key provisions of the Affordable Care Act (ACA) that guarantee access to preventive care for millions of Americans.

Raoul's brief, filed in the U.S. District Court for the Northern District of Texas, defends the ACA's preventive services provisions, which require private health insurers to cover certain preventive care services, including contraceptive care and prophylactic anti-HIV care, free of charge. In the brief, Raoul and the coalition argue that the preventive services provisions have improved health outcomes for residents and urge the court to reject the plaintiffs' challenges.

"Eliminating the preventive services provisions from the Affordable Care Act would have devastating consequences for both the individuals who utilize these services, the overall health and welfare of residents, and the stability of already overburdened statewide public health systems," Raoul said. "I will continue to fight attempts to repeal any part of the Affordable Care Act and diminish access to health care for Illinois residents."

The plaintiffs in the case are employers who wish to offer their employees health insurance that does not cover certain preventive services, most notably contraceptive care and prophylactic anti-HIV care, and employees who wish to purchase health insurance that does not cover such services. They argue that the provisions should be eliminated because they violate individuals' rights under the Religious Freedom Restoration Act (RFRA) and violate the U.S. Constitution's Appointments Clause.

The ACA's preventive services provisions require employers to cover certain preventive care services, and the provisions incorporate recommendations made by three expert bodies – the U.S. Preventive Services Task Force (PSTF), the CDC's Advisory Committee on Immunization Practices (ACIP), and the Health Resources and Services Administration (HRSA) – in defining the services that must be covered. The plaintiffs argue that the provisions violate the appointments clause because those expert bodies have not been appointed by the president and confirmed by the Senate. In today's brief, Raoul and the coalition argue that the federal government may rely on recommendations made by experts of this kind without violating the appointments clause. The attorneys general also argue that the plaintiffs have failed to establish that providing these preventive services substantially burdens private insurers' religious beliefs.

Raoul and the coalition further argue that, since being enacted in 2010, the ACA's preventive services provisions have had a positive impact on both residents' individual health and states' health care systems. Raoul and the attorneys general explain that millions of Americans have relied on the preventive services provisions to obtain no-cost preventive care, which has improved not only the health of those individuals, but public health outcomes more broadly. States have also come to rely on these provisions in building and strengthening their own public health systems. Raoul and the coalition argue that if the court were to invalidate the preventive services provisions, it could destabilize and overburden state public-health systems – including interfering with their abilities to effectively respond to the COVID-19 pandemic – which would have significant consequences for all Americans.

Joining Raoul in the brief are the attorneys general of California, Colorado, Connecticut, Delaware, the District of Columbia, Hawaii, Maine, Maryland, Massachusetts, Michigan, Nevada, New Jersey, New Mexico, New York, North Carolina, Oregon, Pennsylvania, Rhode Island, Vermont, and Washington.

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UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
FORT WORTH DIVISION

JOHN KELLEY, et al., Plaintiffs, v. XAVIER BECERRA, in his official capacity as Secretary of Health and Human Services, et al., Defendants.	Case No. 4:20-cv-00283-O Judge Reed O'Connor

BRIEF OF AMICI STATES ILLINOIS, CALIFORNIA, COLORADO, CONNECTICUT, DELAWARE, THE DISTRICT OF COLUMBIA, HAWAII, MAINE, MARYLAND, MASSACHUSETTS, MICHIGAN, NEVADA, NEW JERSEY, NEW MEXICO, NEW YORK, NORTH CAROLINA, OREGON, PENNSYLVANIA, RHODE ISLAND, VERMONT, AND WASHINGTON IN SUPPORT OF THE DEFENDANTS' MOTION FOR SUMMARY JUDGMENT PURSUANT TO LOCAL RULE 7.2(b)

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INTRODUCTION AND INTEREST OF AMICI STATES

The Amici States of Illinois, California, Colorado, Connecticut, Delaware, The District of Columbia, Hawaii, Maine, Maryland, Massachusetts, Michigan, Nevada, New Jersey, New Mexico, New York, North Carolina, Oregon, Pennsylvania, Rhode Island, Vermont, and Washington ("Amici States") submit this brief in support of Defendants Xavier Becerra, in his official capacity as Secretary of Health and Human Services; Janet Yellen, in her official capacity as Secretary of the Treasury; Martin Walsh, in his official capacity as Secretary of Labor; and the United States of America.

The Amici States have a vital interest in protecting the health and welfare of their citizens, an interest substantially advanced by the challenged provisions of the Affordable Care Act (the "Act"). The Amici States have directly benefitted from and continue to depend on the Act's preventive services provisions, 42 U.S.C. § 300gg-13(a)(1)-(4), which have improved public health outcomes for their residents. The Amici States also operate public health agencies and offer guidance to health insurers within their jurisdictions. They are therefore interested in the outcome of this litigation for the additional reason that they have expended considerable time and resources to implement the Act's requirements, and should the plaintiffs prevail, Amici States will be required to expend additional resources to provide guidance and healthcare if the challenged provisions are enjoined. If the Court were to invalidate the preventive services provisions, that result could destabilize the Amici States' public health systems—including interfering with their abilities to meaningfully respond to the COVID-19 pandemic—which would have a significant effect on their residents. The Amici States thus urge the Court to reject the plaintiffs' sweeping challenges to the Affordable Care Act's preventive services provisions.

ARGUMENT

I. The preventive services provisions have improved public health outcomes within the Amici States, engendered substantial reliance interests, and created a strong public interest weighing against an injunction.

The plaintiffs challenge the Affordable Care Act's preventive services provisions, which collectively require private insurers to "provide coverage for" and "not impose any cost sharing requirements for" certain preventive health services. 42 U.S.C. § 300gg-13(a)(1)-(4). As the plaintiffs seek to enjoin the federal government from enforcing those provisions, the Court must consider the equities, including the public's interest in the government's continued ability to enforce the provisions. *See Winter v. Natural Res. Def. Council*, 555 U.S. 7, 32 (2008) (explaining that "[a]n injunction is a matter of equitable discretion" and that courts must "pay particular regard for the public consequences in employing" that remedy). As this brief explains, the equities weigh strongly in favor of denying the plaintiffs' requested relief—particularly now, as the provisions strengthen the ability of the federal, state, and local governments to respond to the COVID-19 pandemic.

Since their enactment in 2010, these provisions have had a significant and positive impact on Amici States and their residents. Over the last decade, millions of Americans have relied on the preventive services provisions to obtain no-cost preventive care, improving not only their own health and welfare, but public health outcomes more broadly. The Amici States have likewise come to rely on these provisions in building their public health systems over the last decade. The plaintiffs' desired relief would turn back the clock on these reforms.

A. The preventive services provisions have improved public health outcomes for the Amici States' residents.

The preventive services provisions have achieved Congress's primary goal: They have expanded access to low-cost preventive services among people who need those services most and,

in doing so, shifted the national legal framework around public health. Prior to the enactment of the Affordable Care Act, that framework was largely individualized and reactive, focused on treating and curing disease rather than improving population health and preventing the contraction of illness. John Aloysius Cogan, *The Affordable Care Act's Preventive Services Mandate: Breaking Down the Barriers to Nationwide Access to Preventive Services*, 39 J. OF L. MED. ETHICS 355 (2011). This individualized, cure-focused model of healthcare was partially the result of a nationally fragmented legal landscape: Private insurers were regulated by a range of vertical and horizontal laws and rules from states and the federal government, none of which incentivized insurers to support public health considerations. *Id.* at 359-362.

Since the passage of the Act—and, in particular, the preventive services provisions challenged here—preventive services have become significantly more available and accessible to those individuals who need them most. Most basically, 71 million people now have access to free vaccines, cancer screenings, and primary care, among other services. Nadia Chait & Sherry Glied, *Promoting Prevention Under the Affordable Care Act*, 39 ANN. REV. PUB. HEALTH 507 (2018), at 514. A range of academic studies suggests that individuals who have access to no-cost preventive services use them: One study of over 60,000 insured adults, for instance, found a significant increase in the uptake of blood pressure checks, cholesterol checks, and flu vaccinations in the wake of the Affordable Care Act's implementation. Xuesong Han, et al., *Has Recommended Preventive Service Use Increased After Elimination of Cost-Sharing as Part of the Affordable Care Act in the United States?*, 78 PREVENTIVE MED. 85 (2015). The preventive services provisions, in other words, have had their intended effect: They have improved access to health services for the Amici States' residents and millions of others like them. Enjoining those provisions would significantly limit access to those important preventive services.

But the improvement in public-health outcomes the Amici States have witnessed is not limited to those Americans who directly use the preventive services covered by the Act. Rather, the preventive services provisions have also alleviated financial and other burdens placed on state public health systems, allowing those systems to better address and prevent other serious public health issues.

Most notably, the Amici States, like a majority of states, run and fund local public health clinics that serve their residents (primarily medically underserved or low-income residents). *See, e.g.*, D.J. Landry et al., *Public Health Departments Providing Sexually Transmitted Disease Services*, 28 FAMILY PLANNING PERSPECTIVES 161 (1995). Before the enactment of the preventive services provisions, states were required to devote substantial budgetary resources to supplying preventive services at such clinics. The preventive services provisions, however, have allowed state public health departments to bill insurance providers when insured people visit state-run health clinics providing vaccinations and other services. *See* Chait & Glied, *supra*, at 517 (citing a study showing that 42% of patients at one public health clinic were insured at the time of their visit but chose the health clinic for confidentiality and convenience purposes). Public health agencies that are able to bill insurance carriers for substantial portions of their caseloads "increase their capacity by allowing for the redirection of funds that would have previously been used on these services." *Id*. States have used this additional departmental capacity to focus on "more traditional public health functions, . . . including disease surveillance." *Id.* This, in turn, has allowed states' public health departments to develop and deploy additional health interventions, expanding and improving health outcomes for all residents.

Similarly, the inclusion of pre-exposure prophylaxis ("PrEP") medication, which helps prevent HIV and AIDS, in the list of preventive services covered by the Act—a medication the

plaintiffs specifically target, Pls.' MSJ, ECF 45, at 30—likewise has had substantial public health benefits for the Amici States and their residents. By the end of 2019, an estimated 1,189,700 people in the United States were HIV-positive, and over 10% of those HIV-positive individuals were unaware of their infection. U.S. Department of Health and Human Services, HIV.gov, *U.S. Statistics*.[1] That same year, over 15,000 HIV-positive individuals died. *Id.* As HIV is generally spread via close contact between individuals, the most effective measures of decreasing infection rates and managing care are at the local level, including through state public health departments. *See* Panagiotoglou et al., *Building the Case For Localized Approaches To HIV: Structural Conditions And Health System Capacity To Address The HIV/AIDS Epidemic In Six US Cities*, 22 AIDS BEHAV. 3071 (2018) (describing city-level "HIV microepidemics" and advocating for targeted, local HIV interventions). Many Amici States have established programs of this nature; for example, the Illinois Department of Public Health's HIV and AIDS Section maintains and funds a PrEP medication assistance program for individuals who need last-resort access to the medication. The preventive services provisions enable these programs by making insurers the first line of defense against HIV and AIDS; without these provisions, the demand placed on state and local governments for preventive services might disrupt their ability to provide safety-net services of this kind.

The result of the preventive services provisions has thus been, in part, to reduce the overall burden placed on state and local public health systems, freeing those systems to pursue other public health interventions. As an example, states with available resources were able to undergo rigorous contact-tracing programs at the start of the COVID-19 pandemic, while states and regions without public health resources or states experiencing other public health crises were not able to respond

[1] https://www.hiv.gov/hiv-basics/overview/data-and-trends/statistics (last updated June 2, 2021).

as quickly or thoroughly. *See, e.g.,* Melvin et al., *The Role of Public Health in COVID-19 Emergency Response Efforts from a Rural Health Perspective*, 17 PREVENTING CHRONIC DISEASE 1 (2020), at 3 (describing challenges of under-resourced and understaffed community health centers, including challenges with contact tracing and providing staff with personal protective equipment); *see also* Jennifer Seelig, *The Need for Contact Tracing Continues*, ABC NEWS10 (June 3, 2021) (describing New York's robust contract-tracing program, reaching 83% of people who tested positive and 88% of their contacts, with 7,430 contact-tracing staff statewide).[2] As states enter the third year of the pandemic, it is imperative that they do not lose the progress in improving public health outcomes that was made possible in part through the preventative services provisions.

B. States have expended time and resources implementing the preventive services provisions.

The preventive services provisions are important to the Amici States for a second reason: many have expended considerable resources creating legal and regulatory infrastructures to support the provisions. If the court were to invalidate the preventive services provisions, this infrastructure would be disrupted, frustrating the Amici States' efforts to help implement Congress' vision and requiring them to operate in limbo during a critical period for public health.

To take one example, many states have passed statutes and promulgated regulations expressly incorporating the recommendations of the advisory boards that the plaintiffs challenge. Illinois, for instance, has promulgated a regulation paralleling the challenged provision that requires insurers governed by state law to cover at no cost the same preventive services recommended by the United States Preventive Services Task Force (PSTF), Advisory Committee

[2] https://www.news10.com/news/local-news/the-need-for-contact-tracing-continues/. All websites last visited January 28, 2022.

on Immunization Practices (ACIP), and Health Resources and Services Administration (HRSA). *See* Ill. Admin. Code 2001.8(a)(1)(A)-(C). Other states have taken similar steps. *See, e.g.*, N.Y. Ins. Law § 3216(g)(17)(E); Cal. Health & Saf. Code, § 1367.002(a); 18 Del. Code § 3558(b); Va. Code Ann. § 38.2-3438-3442; D.C. Code § 31-3834.02(a)(2); N.J. Stat. § 17B:26-2.1mm; Md. Code Ann., Ins. § 15-1A-10.

If the plaintiffs' challenge to the preventive services provisions succeeds, these regulating bodies and advisory panels will be enjoined from performing the duties Congress gave them in the Affordable Care Act, necessitating costly and burdensome changes to the states' own regulatory frameworks for determining which services must be covered by those private insurers governed by state law.[3] Further, even states that have not implemented laws mirroring the Affordable Care Act's preventive services provisions have enjoyed the benefits afforded by those provisions. Invalidating the challenged provisions will require those states to reassess their regulatory frameworks for private insurers operating in their jurisdictions. This type of overhaul would impose significant burdens on states at a time when public health agencies and infrastructure can ill afford such disruption.

II. The plaintiffs' challenges to the preventive services provisions fail.

The plaintiffs seek to enjoin the preventive services provisions on two primary bases: that they violate the Appointments Clause and that, at least as applied to certain preventive services,

[3] The fact that some states have enacted provisions that, like those challenged here, require private insurers to cover certain preventive services does not mean that these states would not be affected by a judgment setting aside the Affordable Care Act's preventive services provisions. For example, these state-law insurance requirements do not apply to self-insured employer health plans, which cover more than half of all Americans. *See* 29 U.S.C. §§ 1144(a), (b)(2)(A); Sonfeld et al., *U.S. Insurance Coverage of Contraceptives and the Impact of Contraceptive Coverage Mandates, 2002*, 36 PERSP. SEXUAL & REPRO. HEALTH 72, 76 (2004). So many of the Amici States' residents are covered only by the Affordable Care Act's requirements, not by the state-law requirements those states have independently imposed.

they violate the plaintiffs' rights under the Religious Freedom Restoration Act ("RFRA"), 20 U.S.C. § 2000bb *et seq*.; Pls.' MSJ at 12–24, 30–37.[4] Each of these arguments fails on the merits and should be rejected. The plaintiffs' Appointments Clause claims fail because the members of the advisory committees Congress tasked with identifying preventive services are not "officers of the United States." And the plaintiffs' RFRA claims fail because the specific preventive services challenged by the plaintiffs do not substantially burden their religious rights and are, in any event, the least restrictive means to meeting a compelling government interest.

A. The plaintiffs' Appointment Clause claims fail because members of the PSTF, ACIP, and HRSA are not "officers of the United States."

The plaintiffs' primary argument is that the preventive services provisions are unconstitutional because they draw on "recommendations" issued by the members of the PSTF and ACIP—two advisory entities—and on "guidelines" issued by HRSA, a subdivision of the U.S. Department of Health and Human Services. Pls.' MSJ at 12–24. According to the plaintiffs, the members of PSTF and ACIP and the HRSA Administrator are "officers of the United States," but they have not been appointed in the manner required by the Appointments Clause. The plaintiffs' premise is incorrect. The members of PSTF and ACIP and the HRSA Administrator lack both the formal, continuous relationship with the federal government and the degree of authority necessary to be "officers" within the meaning of the Appointments Clause.

An individual "must occupy a 'continuing' position established by law" to qualify as an "officer" within the meaning of the Appointments Clause. *Lucia v. SEC*, 138 S. Ct. 2044, 2051 (2018). The Fifth Circuit has interpreted "officer" to require "a continuing and formalized

[4] The plaintiffs also argue briefly that the challenged provisions violated the nondelegation doctrine and the Vesting Clause. Pls.' MSJ 24-30. The Court should reject those arguments on the grounds identified by the defendants.

relationship of employment with the United States Government," *Riley v. St. Luke's Episcopal Hosp.*, 252 F.3d 749, 757 (5th Cir. 2001) (en banc). An "officer" must also "exercise significant authority pursuant to the laws of the United States." *Buckley v. Valeo*, 424 U.S. 1, 126 (1976) (per curiam); *accord Lucia*, 138 S. Ct. at 2051. Members of the PSTF and ACIP fail both requirements. They are neither federal employees, nor do they exercise "continuing" authority. In addition, none of the individuals identified by the plaintiffs exercise "significant authority pursuant to" federal law. The plaintiffs' Appointment Clause claims therefore fail.

1. Members of the PSTF, ACIP, and HRSA lack a formal, continuous relationship with the federal government.

The plaintiffs' challenges to the role entrusted to members of the PSTF and ACIP fail at the outset because the members of these advisory entities lack "a continuing and formalized relationship of employment with the United States Government." *Riley*, 252 F.3d at 757.

In *Riley*, the Fifth Circuit, sitting en banc, held that *qui tam* relators are not "officers of the United States" requiring appointment consistent with the Clause because relators "do not draw a government salary and are not required to establish their fitness for public employment." *Id.* at 758. In reaching that conclusion, the en banc panel relied in part on the Supreme Court's decisions in *Auffmordt v. Hedden*, 137 U.S. 310 (1890), and *United States v. Germaine*, 99 U.S. 508 (1878), each of which concluded that private individuals whose services were used by the federal government only intermittently were not "officers of the United States."

The same is true here. The volunteer members of the PSTF do not have a formalized relationship of employment with the United States. They are not afforded emoluments and do not draw a government salary; instead, they generally maintain full-time practices of medicine (or other professional activities) while lending their expertise to the federal government and the states. *See* 85 Fed. Reg. 711, 712 (Jan. 7, 2020) (PSTF members are all "volunteers and do not receive

any compensation beyond support for travel to in-person meetings."). Similarly, ACIP is comprised primarily of non-federal employees, who likewise do not receive salaries for their participation. *See* U.S. Ctrs. for Disease Control & Prevention, *Advisory Committee on Immunization Practices (ACIP): Charter*.[5] Both advisory entities likewise provide only intermittent services to the federal government, much like the individuals in *Auffmordt* and *Germaine*. *See Riley*, 252 F.3d at 757-58. The volunteer members of each entity by necessity do not have a "continuing and formalized relationship of employment with the United States," as *Riley* requires, *id.* at 757. The plaintiffs' challenge with respect to the PSTF and ACIP fails on that basis alone.

Recognizing that *Riley* requires dismissal of the bulk of their Appointments Clause claims, the plaintiffs ask the Court to ignore or rewrite it, insisting that it "finds no support in" the Supreme Court's recent opinion in *Lucia*. Pls.' MSJ at 16. As the plaintiffs acknowledge, however, *id.*, this Court lacks the power to decline to apply binding Fifth Circuit precedent, and the plaintiffs' suggestion that the Court merely "interpret[]" *Riley* in their preferred manner, *id.* at 16-17, fares little better.[6] *Riley*'s reliance on the fact that the *qui tam* relators there lacked a "formalized . . . employment" relationship with the federal government—in the Fifth Circuit's words, that they did not "draw a government salary" and were "not required to establish their fitness for public employment," 252 F.3d at 757-58—was an essential premise of its holding, not merely dictum that the Court may "interpret" away. Pls.' MSJ at 16. This Court is bound to apply *Riley*.

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[5] https://www.cdc.gov/vaccines/acip/committee/charter.html (last updated July 14, 2020).

[6] The plaintiffs also ask the Court to ignore or rewrite *Riley* because it "contradicts" a 2007 opinion of the Office of Legal Counsel. Pls.' MSJ 16 (citing *Officers of the United States Within the Meaning of the Appointments Clause*, 31 Op. O.L.C. 73, 78 (Apr. 16, 2007)). But the Office of Legal Counsel's opinions are, of course, not binding on the Court, so there is no need to read *Riley* in light of the 2007 opinion.

In any event, there is no tension between *Riley* and *Lucia*. *Riley* rests in large part on the Supreme Court's decision in *Germaine*, which, as the Court explained in *Lucia*, "held that 'civil surgeons' (doctors hired to perform various physical exams) were" not officers "because their duties were 'occasional and temporary' rather than 'continuing and permanent.'" 138 S. Ct. at 2051 (quoting *Germaine*, 99 U.S. at 511–12). The plaintiffs suggest that the Supreme Court's description of *Germaine* in *Lucia* establishes that there is no requirement that a federal officer "receive[] payment or emoluments for his work." Pls.' MSJ at 16. But this aspect of the analysis was not at issue in *Lucia*, which focused on whether the administrative law judges (ALJs) at issue in that case "exercised significant authority" under federal law. 138 S. Ct. at 2051; *accord id.* at 2053 (noting that "everyone . . . agree[d]" in *Lucia* that the ALJs held a "continuing office established by law"). Regardless, *Germaine*'s ultimate conclusion—that a private citizen empaneled for "occasional and intermittent" service to the federal government is not an officer of the United States, 99 U.S. at 512—is consistent with both *Lucia* and *Riley*. Under *Germaine*, *Lucia*, and *Riley*, the non-employee members of the PSTF and ACIP are not federal officers.

The plaintiffs' contrary argument would deem every advisory committee convened by statute to satisfy at least the first part of *Lucia*'s test. The federal government maintains an average of 1,000 advisory boards with varying duties, time commitments, and levels of required expertise. *See* Fed. Advisory Committee Act (FACA) Database, U.S. GSA (2021).[7] Some, like the National Advisory Council on Innovation and Entrepreneurship advising the Department of Commerce, are meant to function partially as community engagement boards and are tasked with facilitating federal dialogue with the innovation, entrepreneurship, and workforce development communities. *See* U.S. Economic Development Administration, National Advisory Council on Innovation and

[7] https://www.facadatabase.gov/FACA/FACAPublicPage.

Entrepreneurship (NACIE) (2021).[8] Others, like the Advisory Committee for Biological Sciences within the National Science Foundation, are bodies tasked with reviewing highly technical information and making recommendations to government agencies and branches. *See* National Science Foundation, Directorate for Biological Sciences Advisory Committee (BIO AC) (2021).[9] These committees reflect the federal government's recognition that elected officials often do not possess the level of specific, technical, or scientific expertise necessary to cover all topics that the federal government must regulate. But under the plaintiffs' view, the members of each of these committees—or, at the very least, any committee convened by statute—occupy "continuing positions" that are "established by law" and so are one step toward being deemed "officers of the United States." Pls.' MSJ 13. That cannot be right.

2. Members of the PSTF and ACIP, and the HRSA Administrator, lack the level of authority required to be "officers" within the meaning of the Appointments Clause.

Even if the plaintiffs were correct that "officers" need not have an employment relationship with the federal government, their Appointments Clause challenges would still fail because PSTF, ACIP, and HRSA do not exercise "significant authority" under federal law, *Lucia*, 138 S. Ct. at 2051. They merely issue recommendations or guidelines regarding the preventive services that private insurers must cover.

Lucia, which the plaintiffs heavily rely on, confirms that the "significant authority" requirement is not met here. At issue in *Lucia* was the constitutionality of the appointment of SEC ALJs—adjudicative officers that wielded "nearly all the tools of federal trial judges." 138 S. Ct. at 2053. The Court answered the question whether the ALJs exercised "significant authority" under

[8] https://www.eda.gov/oie/nacie/.

[9] https://www.nsf.gov/bio/advisory.jsp.

federal law by reference to its prior opinion in *Freytag v. Commissioner*, 501 U.S. 868 (1991), holding that the ALJs enjoyed substantially the same power as the "special trial judges" (STJs) at issue in *Freytag* and so were "officers of the United States." As evidence of the "significant" authority wielded by both kinds of adjudicative officers, the Court cited core responsibilities held by STJs and ALJs, such as receiving evidence and examining witnesses at hearings, taking pre-hearing depositions, administering oaths, ruling on motions, regulating the course of hearings and the conduct of counsel, ruling on the admissibility of evidence, and issuing subpoenas. 138 S. Ct. at 2053. The Court also relied on ALJs' and STJs' power to enforce compliance with certain orders and to punish contumacious conduct "by means as severe as excluding the offender from the hearing." *Id.*

Neither the PSTF and ACIP members nor the HRSA Administrator are given any authority comparable to that discussed in *Lucia*. They cannot compel individuals or businesses to appear anywhere or to answer any questions. They cannot issue definitive rulings with respect to rights and responsibilities. They cannot themselves regulate any conduct whatsoever. They have no enforcement authority at all—not even to enforce their own recommendations. As the Act reflects these entities merely issue "recommendations" and "guidelines." 42 U.S.C. § 300gg-13(a)(1)-(4). They and their members are not officers of the United States.

The plaintiffs' primary counterargument is that Congress has required private insurers to cover preventive services and has tasked the advisory entities and HRSA with identifying what those services are. Pls.' MSJ 14-15, 18-19. But Congress has not entrusted these entities with "significant discretion" on matters of policy or practice, as in *Lucia*, 138 S. Ct. at 2052. Instead, *Congress* has made the judgment that private insurers should have to cover certain preventive services at no charge. It has merely tasked the PSTF, ACIP, and HRSA with exercising their expert

judgment to make "recommendations" and issue "guidance" regarding the exact services that should be covered. 42 U.S.C. § 300gg-13(a)(1)-(4). In that sense, these entities' roles are no different than those of the private organizations whose standards Congress frequently incorporates into federal law. *See, e.g.*, 4 U.S.C. § 119(a)(2) (requiring certain databases to be "provided in a format approved by the American National Standards Institute's Accredited Standards Committee"); 42 U.S.C. § 6293(b)(8) (requiring certain test procedures to "be the test procedures specified in ASME A112.19.6–1990"). The plaintiffs' only response is that these standard-setting organizations are not chartered by federal statute. Pls'. MSJ, at 14 n.40. But the question whether an individual has a sufficiently formalized relationship with the federal government to constitute being an "officer" is distinct from whether he or she is entrusted with the authority that accompanies such a position. *See Lucia*, 138 S. Ct. at 2051. The plaintiffs' position appears to be that any private entity whose recommendations are incorporated into federal law has been delegated "significant authority" under federal law. *Id.* That would amount to an unprecedented incursion into Congress' ability to rely on expert entities in setting policy.

B. The plaintiffs' RFRA claims fail.

The plaintiffs' RFRA claims, which are levied only at the requirement that private insurers cover PrEP medication, *see* Compl. ¶¶ 108-111, also fail.[10] RFRA generally prohibits the federal government from "substantially burden[ing] a person's exercise of religion" unless it establishes that the practice in question "is in furtherance of a compelling governmental interest" and "is the least restrictive means of furthering" that interest. 42 U.S.C. § 2000bb-1(a), (b); *see Little Sisters*

[10] The plaintiffs' motion for summary judgment appears to cast a wider net, arguing that they have also asserted meritorious RFRA claims against a range of other preventive services, including "screenings and behavioral counseling for STDs and drug use." Pls.' MSJ, ECF 45, at 30. But the plaintiffs' complaint pleads an RFRA claim only against the requirement to cover PrEP, Compl. ¶¶ 108-111, and they cannot amend the complaint in their motion for summary judgment.

of the Poor Saints Peter & Paul Home v. Pennsylvania, 140 S. Ct. 2367, 2383 (2020). Here, the plaintiffs' RFRA claims fail on multiple grounds.

First, the plaintiffs have failed to establish that the requirement that private insurers cover PrEP medication "substantially burdens" their religious beliefs. The plaintiffs do not articulate any specific religious objection to PrEP medication itself. *See* Pls.' MSJ at 31; *see also, e.g.*, App. 36 (plaintiff Kelley's attestation regarding his religious beliefs). Rather, the plaintiffs explain that they object to "subsidizing lifestyles that violate their religious beliefs," Pls.' MSJ at 31—namely, "homosexual behavior, intravenous drug use, and sexual activity outside of marriage between one man and one woman," *id.* at 32—which they assert that providing PrEP medication does. But the plaintiffs provide no evidentiary support for their assertion that requiring insurers to cover PrEP medication without cost sharing in fact facilitates or encourages any of the identified conduct. Absent any such evidence, the plaintiffs cannot establish that any burden on their religious beliefs is "substantial," as required by RFRA. The plaintiffs' mere assertion that they believe such a connection to exist is not sufficient.

The plaintiffs analogize this case to *Burwell v. Hobby Lobby Stores, Inc.*, 573 U.S. 682 (2014), which upheld a RFRA claim brought against a requirement that private health insurers cover contraceptives. Pls.' MSJ at 31–32. But the plaintiffs in *Hobby Lobby* specifically objected to the medication that insurers were required to cover. *See* 573 U.S. at 691 (explaining that the plaintiffs had "religious objections to abortion," and held religious beliefs that the four contraceptive methods at issue terminated pregnancies). Here, by contrast, the plaintiffs at bottom object not to the actual covered medication, but to voluntary conduct that they assert—without

evidentiary support—is facilitated by the provision of that medication. *Hobby Lobby* provides no support for such an attenuated claim.[11]

The plaintiffs assert that, under *Hobby Lobby* and subsequent cases, the Court "*must* accept [their] complicity-based objections to unwanted health-insurance coverage," "no matter how attenuated" those objections may seem. Pls.' MSJ at 32. That is incorrect. Although Amici States do not question the sincerity of the plaintiffs' religious objections (at least understood as objections to certain "lifestyles" that they associate with HIV-positive status, Pls.' MSJ at 31), the sincerity of a RFRA plaintiff's belief is an analytically distinct question from whether challenged government conduct imposes a "substantial burden" on that belief. That much is evident from RFRA's text, which expressly requires that there be a "substantial[] burden" on a person's "exercise of religion." 42 U.S.C. § 2000bb-1(a), (b). *Cf. United States v. Lee*, 455 U.S. 252, 257 (1982) ("Not all burdens on religion are unconstitutional.").[12] The plaintiffs' suggestion appears to be that a substantial burden exists any time a litigant sincerely believes that it does. As multiple courts of appeals have explained, however, that argument "collapse[s] the distinction between beliefs and substantial burden, such that the latter could be established simply through the sincerity of the former." *Catholic Health Care Sys. v. Burwell*, 796 F.3d 207, 217 (2d Cir. 2015), *vacated*,

[11] The plaintiffs' speculation is also incorrect, as PrEP is used by many people for many reasons, including by married heterosexual people who are or may be HIV-positive and want to ensure that their children are not born with HIV. The plaintiffs make no argument as to how this situation—a recognized diagnostic purpose of PrEP, *see* U.S. Preventive Services Task Force, *Preexposure Prophylaxis for the Prevention of HIV Infection*, 321 J. AM. MED. ASS'N 2203, 2206 (2019) [hereinafter PSTF, *PrEP Recommendation*]—could be understood to encourage behavior to which they object.

[12] Nor does the legislative history of RFRA support the plaintiffs' assertions. *See Little Sisters of the Poor Home for the Aged v. Burwell*, 794 F.3d 1151, 1176 (10th Cir. 2015) (explaining that Congress "added the word 'substantially'" to RFRA's text during the drafting process "to clarify that only some burdens would violate the act"), *vacated sub nom. Zubik v. Burwell*, 136 S. Ct. 1557 (2016).

136 S. Ct. 2450 (2016); *see also, e.g.*, *Geneva Coll. v. Sec'y U.S. Dep't of Health & Human Servs.*, 778 F.3d 422, 442 (3d Cir. 2015) ("RFRA's reference to substantial burdens expressly calls for a qualitative assessment of the burden that the accommodation imposes on . . . the exercise of religion."), *vacated sub nom. Zubik v. Burwell*, 136 S. Ct. 1557 (2016); *Little Sisters of the Poor*, 794 F.3d at 1176; *Priests for Life v. HHS*, 772 F.3d 229, 247 (D.C. Cir. 2014), *vacated sub nom. Zubik v. Burwell*, 136 S. Ct. 1557 (2016). If "RFRA plaintiffs need only to assert that their religious beliefs were substantially burdened" in order to force the government to defend its actions through the strict-scrutiny lens, "federal courts would be reduced to rubber stamps." *Catholic Health Care Sys.*, 796 F.3d at 218. No court has required that result.

Second, the requirement that private insurers cover PrEP medication without cost sharing is justified by a "compelling governmental interest." 42 U.S.C. § 2000bb-1(b). As the PSTF has explained, over 30,000 individuals are diagnosed with HIV each year, and over 15,000 HIV-positive individuals died in 2019. PSTF, *PrEP Recommendation*, *supra*, at 2204, 2208; *see also U.S. Statistics*, *supra* note 1. PrEP medication is highly effective, yet it "is currently not used [by] many persons at high risk of HIV infection." PSTF, *PrEP Recommendation*, *supra*, at 2208-209. The government has a compelling interest in ensuring that individuals have access to life-saving medication. *See Medtronic, Inc. v. Lohr*, 518 U.S. 470, 475 (1996). The plaintiffs do not genuinely dispute that the federal government *could* have a compelling interest in requiring private insurers to cover the cost of preventive services of all kinds, including PrEP medication; their main objection is that Congress failed to specify that PrEP medication *in particular* must be covered by insurers. As explained, however, Congress reasonably and constitutionally asked a range of expert advisory entities to issue "recommendations" and "guidance" regarding the exact services that insurers should cover. That determination does not undercut the "compelling" nature of the federal

government's interest in ensuring that services like PrEP are made available without cost sharing to individuals who need them.

Finally, the preventive services provisions are the least restrictive means Congress could have chosen to ensure meaningful access to PrEP (and similar preventive services). The plaintiffs' only suggestion to the contrary is that Congress could establish an elaborate new program that would allow non-objecting providers to "seek reimbursement from the government for the services that they provide to uninsured or underinsured patients," Pls.' MSJ 36—that is, an entirely new system of public health insurance targeted only at preventive care. But plaintiffs identify no case to have imposed injunctive relief on the federal government on the thought that Congress could simply have established an entirely new administrative apparatus instead. *Cf. Sherbert v. Verner,* 374 U.S. 398, 408 (1963) (describing proposed exemption that, "while theoretically possible, appeared to present an administrative problem of such magnitude . . . that [it] would have rendered the entire statutory scheme unworkable"). The plaintiffs point to *Hobby Lobby* for the proposition that such an analysis is permissible, *see* Pls.' MSJ 36-37, but the language on which they rely is dicta on which the Court ultimately did "not rely . . . in order to conclude that" the regulations there violated RFRA, *Hobby Lobby*, 573 U.S. at 730. In any event, the reality is much starker: Granting the plaintiffs the relief they seek and allowing them to not provide (or pay for) insurance that would cover PrEP would deepen residents' financial reliance on state and local public health systems and upend progress made toward putting an end to the HIV epidemic. *Supra* pp. 2-7. RFRA does not require that result.

CONCLUSION

The plaintiffs' motion for summary judgment should be denied, and the defendants' cross-motion for summary judgment should be granted.

Date: January 28, 2022

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on January 28, 2022, the foregoing proposed *amicus* brief was filed on the Court's electronic filing system with a motion for leave of Court to file. Notice of this filing therefore will be sent to all parties for whom counsel has entered an appearance through the Court's electronic filing system, and Parties may access this filing through the Court's system.

Date: January 28, 2022

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