EXHIBIT 10

Comments by the Cities of New York, Chicago, Baltimore, Bloomington, Los Angeles, Portland, Providence, and Seattle

August 13, 2019

U.S. Department of Health and Human Services
Office for Civil Rights
Hubert H. Humphrey Building, Room 509F
200 Independence Avenue SW
Washington, DC 20201

RE: Nondiscrimination in Health and Health Education Programs or Activities, RIN 0945-AA11, Proposed Rule, Fed. Reg. Vol. 84, No. 115, HHS Docket No. HHS-OCR-2019-0007.

The Cities of New York and Chicago, joined by the Cities of Baltimore, Bloomington, Los Angeles, Portland, Providence and Seattle, and the Town of Carrboro (together, the "Signatories") submit this Comment in opposition to Proposed Rule published by the Department of Health and Human Service ("HHS") on June 14, 2019.

THE PROPOSED RULE VIOLATES THE ADMINISTRATIVE PROCEDURE ACT

The APA requires courts to "hold unlawful and set aside agency action, findings, and conclusions that are, among other things, "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A); *see also Motor Vehicle Mfrs. Ass'n of United States v. State Farm Mut. Automobile Ins. Co.*, 463 U.S. 29, 41 (1983).

I. <u>The Proposed Rule Is Not In Accordance With Governing Law</u>.

An agency "does not have the power to adopt a policy that directly conflicts with its governing statute." *Maislin Indus., U.S. v. Primary Steel, Inc.*, 497 U.S. 116, 134-35 (1990); *see also United States v. Mead*, 533 U.S. 218, 228-29 (2001) (agency action cannot be "manifestly contrary to the statute"); *Chevron, U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 843 n.9 (1984) (courts "must reject administrative constructions which are contrary to clear congressional intent"). Thus, agency action is "not in accordance with law" where it "ignores the plain language of the statute," renders statutory language "superfluous," or "frustrate[s] the policy Congress sought to implement" in the statute. *Pacific Northwest Generating Coop v. Department of Energy*, 580 F.3d 792, 806 (9th Cir. 2009).

The Proposed Rule is in direct conflict with Section 1557 of the ACA in many ways. It conflicts with Section 1557 because it eliminates protections for discrimination based on gender identity and sex stereotyping. It conflicts with Section 1557 because it allows other forms of sex discrimination, such as discrimination based on termination of pregnancy. It conflicts with Section 1557's prohibitions on discrimination based on national origin, as incorporated into Section 1557 through Title VI, by weakening language notice and access requirements. It conflicts with Section 1557 by unlawfully limiting the scope and reach of Section 1557. And it

conflicts with Section 1557's explicit inclusion of enforcement mechanisms available under numerous civil rights laws. As such, the Proposed Rule is "not in accordance with law" and therefore invalid under the APA.

A. The Proposed Rule's Removal of Protections against Discrimination Based on Sex Stereotyping and Gender Identity Conflicts with Section 1557.

Section 1557 provides that "an individual shall not … be excluded from participation in, be denied the benefits of, or be subjected to discrimination under, any health program or activity, any part of which is receiving Federal financial assistance," on the grounds prohibited by Title IX of the Education Amendments of 1972, 20 U.S.C. § 1681 ("Title IX") (sex); Title VI of the Civil Rights Act of 1964, 42 U.S.C. § 2000d ("Title VI") (race, color, national origin); the Age Discrimination Act of 1975, 42 U.S.C. § 6101; and Section 794 of Title 29 (Rehab Act)(disability). *See* 42 U.S.C. § 18116. Thus, by its plain terms, Section 1557 was enacted to prevent discrimination in healthcare on any of the grounds recognized by federal civil rights and other statutes.

1. The Proposed Rule Conflicts with Congressional Intent to Protect Transgender and Gender Non-Conforming Individuals from Discrimination in Healthcare.

The ACA was enacted in 2010 "to increase the number of Americans covered by health insurance and decrease the cost of health care." *National Federation of Independent Business v. Sebelius*, 567 U.S. 519, 539 (2012); *see also King v. Burwell*, 135 S. Ct. 2480, 2485 (2015) (the ACA "adopts a series of interlocking reforms designed to expand coverage in the individual health insurance market."); *Morris v. California Physicians' Service*, 918 F.3d 1011, 1016 (9th Cir. 2019) (the purpose of ACA "as demonstrated by the content of its provisions and the implementing regulations, as well as its history, is to broaden access to health care."). One of the ways Congress sought to achieve this goal was through enactment of Section 1557, which aimed to decrease or eliminate many of the barriers felt by classes of individuals who routinely experienced discrimination in health care services, such as higher insurance premiums, denial of coverage for medically necessary procedures, or substandard care. By incorporating the non-discrimination provisions of other civil rights laws into the health care field, Congress sought to prevent discrimination and expand health care to all Americans, regardless of race, color, national origin, sex, age, and disability. As self- implementing, Section 1557 did not require regulations in order to take effect. 42 U.S.C. § 18116(c).

Importantly, by incorporating Title IX's provisions into Section 1557, Congress kept in place exemptions from compliance with the general prohibition against discrimination for covered entities that objected to providing coverage based on religious beliefs, or funding for

abortion services. Thus, Section 1557 struck a balance between protecting health care access for all, including reproductive and sexual health care, and religious liberty.

By allowing blanket discrimination against whole classes of individuals, however, the Proposed Rule tips the balance against health care access and in favor of discrimination, which frustrates the primary and essential purpose of the ACA. *See, e.g.*, *Sebelious*, 567 U.S. at 539. The Supreme Court has held that, under ordinary principles of statutory construction, distinct sections of the ACA must be interpreted in harmony with its overall purpose. *See King*, 135 S. Ct. at 2496 (looking at whole context of statute, Court found that Congress could not have possibly intended to eliminate one of its overarching reforms in a single provision); *see also Morris*, 918 F.3d at 1016 (purpose of ACA "strongly indicates" that provisions must be interpreted and applied in accord with this purpose). The Proposed Rule impermissibly conflicts with the very purpose of Section 1557—to prevent discrimination—and the ACA generally—to expand healthcare access to all Americans.

In 2012, the Department of Health and Human Service's Office of Civil Rights (OCR), the agency responsible for enforcing Section 1557, specifically held that gender identity and gender non-conformance was protected under Section 1557. OCR issued an opinion letter on July 12, 2012, stating that "[w]e agree that Section 1557's sex discrimination prohibition extends to claims of discrimination based on gender identity or failure to conform to stereotypical notions of masculinity or femininity and will accept such complaints for investigation." *See* Letter from Leon Rodriguez, Director, Office of Civil Rights, to Maya Rupert, Federal Policy Director, National Center for Lesbian Rights.[1] The letter also provided that "Section 1557 also prohibits sexual harassment or discrimination regardless of the actual or perceived sexual orientation or gender identity of the individual involved." *Id*.

Further advancing this purpose, and after an extensive due diligence period that included a request for information on August 1, 2013, proposed rules issued on September 8, 2015, and a thorough evaluation and response to nearly 25,000 comments, HHS promulgated regulations (the "2016 Regulations), which comprehensively set forth definitions, procedures, notice requirements, and enforcement mechanisms, for the implementation of Section 1557. *See* 45 C.F.R. § 92.1 *et seq*. (May 18, 2016).

The 2016 Regulations defined "on the basis of sex" to include "discrimination on the basis of pregnancy, false pregnancy, termination of pregnancy, or recovery therefrom, childbirth or related medical conditions, sex stereotyping, and gender identity." *Id*. at § 92.4. Gender identity was defined as "an individual's internal sense of gender, which may be male, female,

[1] Available at https://www.washingtonblade.com/2012/08/07/hhs-affirms-trans-protections-in-health-care-reform.

neither, or a combination of male and female, and which may be different from an individual's sex assigned at birth." In turn, "sex stereotyping" was defined as "stereotypical notions of masculinity or femininity, including expectations of how individuals represent or communicate their gender to others, such as behavior, clothing, hairstyles, activities, voice, mannerisms, or body characteristics" *Id.* While HHS noted that it supported banning discrimination on the basis of sexual orientation as policy, it did not expressly include it in the definition (noting that the law was mixed on this issue), but it did state that discrimination on the basis of sexual orientation was prohibited if it were based on sex stereotyping. 81 Fed. Reg. at 31389-90.

The 2016 Regulations also included a nondiscrimination provisions, stating that "[e]xcept as provided in Title I of the ACA, an individual shall not, on the basis of race, color, national origin, sex, age, or disability, be excluded from participation in, be denied the benefits of, or otherwise be subjected to discrimination under any health program or activity to which this part applies." 45 C.F.R. § 92.101(a)(1). In addition, the 2016 Regulations provided that covered entities "shall treat individuals consistent with their gender identity," except that they cannot "deny or limit health services that are ordinarily or exclusively available to individuals of one sex, to a transgender individual based on the fact that the individual's sex assigned at birth, gender identity, or gender otherwise recorded is different from the one to which such health services are ordinarily or exclusively available." *Id*. at § 96.206. In other words, the 2016 Regulations made clear that, for example, a transgender male could not be denied service or coverage for ovarian cancer due to the fact that he did not present as a woman. Thus, beyond the incorporation of Title IX, the 2016 Regulations affirmatively prohibited discrimination on the basis of gender identity and transgender status.

The 2016 Regulations emphasized, however, that "[i]nsofar as the application of any requirement under this part would violate applicable Federal statutory protections for religious freedom and conscience, such application shall not be required." *Id*. at § 92.2(b)(2). Accordingly, the 2016 Regulations continued to recognize that religious and moral objections to providing health care coverage and services could be legitimate bases for exemption from Section 1557.

HHS explained that the 2016 Regulations were written to "adopt formally this well-accepted interpretation of discrimination 'on the basis of sex.'" 81 Fed. Reg. 31387-88. HHS looked to other federal agencies, who had previously interpreted sex discrimination to include discrimination on the basis of gender identity, citing opinions from the Department of Labor, Department of Education, Department of Housing and Urban Development, and the Department of Justice. *Id*. at 31387 and note 56. HHS also noted that around the same time that Congress passed the ACA, it also passed two statutes that protected against discrimination on the basis of gender identity. *See* 18 U.S.C 249(a)(2)(A), the Matthew Shepard and James Byrd, Jr. Hate Crimes Prevention Act (HCPA) (criminalizing actions that cause harms based on persons' actual

or perceived sexual orientation, or gender identity, which in turn is defined as "actual or perceived gender-related characteristics"); 34 U.S.C. 12291(b)(13)(A) (2013), the Violence Against Women Reauthorization Act (adding "gender identity" as a protected characteristic in discrimination provision.). Perhaps most importantly, HHS emphasized that, at the time the ACA was enacted in 2010, federal courts had already interpreted sex discrimination to cover transgender people, and that, since that time, courts had interpreted Section 1557 specifically to cover such discrimination. *Id*. at 31387-90.

In removing these protections, through elimination of the definitions and antidiscrimination provisions, the Proposed Rule is—unlawfully—in direct conflict with Section 1557. The statutory purpose of the ACA generally, and Section 1557 in particular, as further reflected in the thoughtful and comprehensive 2016 Regulations, make clear that Congress intended to include gender identity and transgender status under the definition of "on the basis of sex." Congress did not intend to permit discrimination on the basis of sex for an entire class of individuals, those who are transgender, gender non-conforming, or otherwise non-binary (TGNCBN). Yet that is what the Proposed Rule allows. HHS now claims that Congress intended "sex" to refer solely to a person's biological sex assigned at birth,[2] but it offers no reasonable evidence to support this sudden turn-around, nor adequately explain its decision to reverse course in the face of the exhaustive record before HHS two years ago, when the 2016 Regulations were written.

Moreover, HHS's recent interpretation of Congress's meaning of term "sex," is too narrow in light of the ACA's goal to prohibit discrimination and provide equal access to health care and insurance and the statutory context of Section 1557. This narrow reading contravenes the U.S. Supreme Court's view that the interpretation of statutes "must not negate their own stated purposes," *New York State Dept. of Social Servs. v. Dublino*, 413 U.S. 405, 419–420 (1973) and "must not be guided by a single sentence or member of a sentence, but look to the provisions of the whole law, and to its object and policy." *Pilot Life Ins. Co. v. Dedeaux*, 481 U.S. 41, 51 (1987); *see also Util. Air Regulatory Grp. v. E.P.A.*, 134 S. Ct. 2427, 2441 (2014) (noting the "fundamental canon of statutory construction that the words of a statute must be read in their context and with a view to their place in the overall statutory scheme."). The ACA does, and must, protect all people from discrimination in healthcare, and the Proposed Rule conflicts with this plain Congressional intent.

[2] This position likewise ignores the ever-growing body of scientific data showing that sex is not always accurately assigned at birth. Sex assignment at birth, typically based on reproductive anatomy, often ignores the complexity of factors that determine a person's sex, including "genetic or chromosomal sex, gonadal sex, internal morphological sex, genitalia, hormonal sex, phenotypic sex, assigned sex/gender of rearing, and self-identified sex." Derek Waller, Recognizing Transgender, Intersex, and Nonbinary People in Healthcare Antidiscrimination Law, 103 Minn. L. Rev. 467, 472-79 (2018) (internal citations omitted).

2. The Proposed Rule Conflicts with Precedent Under Title IX and Similar Civil Rights Statutes Holding that Discrimination on the Basis of Sex Includes Gender Identity.

As discussed, Section 1557 incorporates the protections of Title IX, which prohibits discrimination on the basis of sex in federally-funded education programs and activities. *See* 20 U.S.C. § 1681. While Title IX does not contain an explicit definition of discrimination "on the basis of sex" in its text or regulations, courts have commonly interpreted the phrase to include discrimination on the basis of sex stereotyping and gender identity. Notably, Section 1557 explicitly prohibits an interpretation of the statute that would invalidate or limit the rights, remedies, procedures, or legal standards to individuals aggrieved under Title IX, Title VII and other civil rights statutes. The Proposed Rule is an abrupt and unlawful departure from this body of law.

In determining the scope of Title IX's protections against sex discrimination, courts traditionally looked to case law developed under Title VII, which prohibits discrimination "because of sex" in the employment context. *See* 20 U.S.C. §§ 2000e *et seq*. In 1989, the Supreme Court recognized that discrimination "because of sex" under Title VII included sex stereotyping, such that a woman who was denied a promotion because she did not exhibit feminine qualities typically associated with being female, had stated a Title VII discrimination claim. *Price Waterhouse v. Hopkins*, 490 U.S. 228, 251 (1989) ("[I]n forbidding employers to discriminate against individuals because of their sex, Congress intended to strike at the entire spectrum of disparate treatment of men and women resulting from sex stereotypes."), *superseded by statute*, Civil Rights Act of 1991, Pub. L. No. 102-166, 105 Stat. 1071. In so doing, the Court essentially rejected the reasoning, "and vitiate[d] the precedential value, of earlier Federal appellate court decisions that limited Title VII's coverage of 'sex' discrimination to the anatomical and biological characteristics of sex." 2016 Regulations, 81 Fed. Reg. at 31388.

A majority of appellate courts have held that the sex stereotyping recognized by *Price Waterhouse* extends to transgender individuals or discrimination based on sexual orientation. *See, e.g., EEOC v. R.G. & G.R. Harris Funeral Homes, Inc.*, 884 F.3d 560, 576 (6th Cir. 2018) (employer violated Title VII when it fired employee for being transgender; "[d]iscrimination on the basis of transgender and transitioning status is necessarily discrimination on the basis of sex"); *Zarda v. Altitude Express, Inc.*, 883 F.3d 100, 132 (2d Cir. 2018) (rehearing en banc) (Title VII prohibits discrimination based on sexual orientation), *cert. granted*, 139 S. Ct. 1599 (2019); *Hively v. Ivy Tech Cmty. Coll. of Ind.*, 853 F.3d 339, 350-52 (7th Cir. 2017) (describing plaintiff's sexual orientation as "the ultimate case of failure to conform to the female stereotype" and holding that sexual orientation discrimination is *per se* sex discrimination under Title VII); *Glenn v. Brumby*, 663 F.3d 1312, 1316-17 (11th Cir. 2011) ("[D]iscrimination against a transgender individual because of her gender-nonconformity is sex discrimination, whether it's described as being on the basis of sex or gender."); *Smith v. City of Salem*, 378 F.3d 566, 572-73

(6th Cir. 2004) (recognizing discrimination based on gender identity or gender non-conformity as actionable sex discrimination under Title VII); *Schwenk v. Hartford*, 204 F.3d 1187, 1202 (9th Cir. 2000) (holding that sex discrimination under Title VII encompasses both biological differences between men and women, and gender identity). *But see Bostock v. Clayton Cty. Bd. of Comm'rs*, 723 F. App'x 964, 965 (11th Cir. 2018) (denying employee's Title VII discrimination claim based on sexual orientation, citing earlier circuit precedent that "forecloses" employee's claim "regardless of whether we think it was wrong"), *cert. granted*, 139 S. Ct. 1599 (2019); *Etsitty v. Utah Transit Auth.*, 502 F.3d 1215, 1220-21 (10th Cir. 2007) (discrimination based on person's status as transsexual was not discrimination "because of sex" under Title VII).[3]

Relying in large part on these Title VII cases, appellate courts have consistently held that Title IX must be construed to include gender identity discrimination. For example, in *Whitaker v. Kenosha Unified School District No. 1*, 858 F.3d 1034, 1039-1047 (7th Cir. 2017), the Seventh Circuit held that discrimination against someone for being transgender is sex discrimination under the sex-stereotyping theory recognized in *Price Waterhouse*, and affirmed a preliminary injunction enjoining a school district from enforcing its policy barring transgender students from using school restrooms matching their gender identities against the plaintiff, a transgender boy. *Id*. at 1039, 1049-50 (policy that subjects transgender person to differential treatment because they are transgender "punishes that individual for his or her gender non-conformance" and is, therefore, form of sex discrimination prohibited by Title IX).

The three other federal appellate courts that have considered this issue under Title IX have likewise held that it protects against gender identity discrimination. *See Doe by & through Doe v. Boyertown Area Sch. Dist.*, 897 F.3d 518, 533-34 (3d Cir. 2018) (concluding that school district's sex-neutral bathroom policy allowing students to use bathrooms that align with gender identity did not discriminate against cisgender students on basis of sex, and further finding that "barring transgender students from restrooms that align with their gender identity would itself pose a potential Title IX violation"), *cert. denied*, 2019 U.S. App. LEXIS 3666; *Dodds v. U.S. Dep't of Educ*., 845 F.3d 217, 221(6th Cir. 2016) (affirming preliminary injunction that required school to allow transgender girl to use girl's bathroom); *G.G. ex rel. Grimm v. Gloucester Cty. Sch. Bd*., 822 F.3d 709, 720-23 (4th Cir. 2016) (Title IX's regulations protected transgender student from discrimination on basis of sex), *vacated and remanded*, 137 S. Ct. 1239 (2017), *dismissed as moot*, 2017 WL 9882602 (Dec. 12, 2017).

[3] On April 22, 2019, the Supreme Court granted certiorari to three of these cases—*Harris*, *Zarda*, and *Bostock*—to address whether Title VII's protections apply to transgender status and sexual orientation. *See* 139 Sp. Ct. 1599.

Against this landscape of Title VII and IX cases, HHS's position that "'sex' under Title IX does not include sexual orientation or gender," 84 Fed. Reg. at 27853, is flat out wrong, and cannot be used as a legitimate basis for writing these protections out of the Proposed Rule. And the hollow arguments put forth by HHS in an attempt to support its position reveal as much.

First, HHS dishonestly asserts that "Congressional activity" in this area "suggests" that sex under Title IX does not include sexual orientation or gender. *Id*. at 853. HHS cites the syllabus in *FDA v. Brown & Williamson Tobacco Corp*., 529 U.S. 120, 122 (2000), for the proposition that when "Congress several times considered and rejected bills" that would have granted the agency authority, "[it] evidenced a clear intent to [reject such authority]." 84 Fed. Reg. at 27853. Then, as evidence of Congress's intent here, HHS cites to: (1) a gender equity bill introduced in 2016 to amend Title IX, which never made it out of committee; and (2) proposed amendments to the Civil Rights Act over the last thirty years that likewise did not proceed past committee (except the Equality Act, which actually passed the House of Representatives in 2019). *Id*. & n. 38, 39.

The examples HHS relies on fail to support its version of Congressional intent. Unlike in *Brown & Williamson*, Congress has not repeatedly "considered and rejected" bills defining sex to include gender identity and sexual orientation; such bills either stalled in committee, or passed. *See also* 18 U.S.C. § 249(a)(2)(A) (the Hate Crimes Prevention Act) and 34 U.S.C. § 12291(b)(13)(A) (the Violence Against Women Reauthorization Act). And the Supreme Court has made clear that mere inaction by Congress is virtually meaningless. *See Whitaker*, 858 F.3d at 1049 ("Congressional inaction is not determinative" since it "'lacks persuasive significance because several equally tenable inferences may be drawn from such inaction, including the inference that the existing legislation already incorporated the offered change.'") (internal citation omitted). Thus, Congressional inaction could just as easily mean that Congress believed that "sex" under Title IX already included gender identity and sexual orientation. Furthermore, had HHS read the actual case and not just the syllabus, it would have known that *Brown & Williamson* actually states that "[w]e do not rely on Congress' failure to act—its consideration and rejection of bills that would have given the FDA this authority—in reaching this conclusion." 529 U.S. at 155. Rather, the Court stressed that its holding was based on the fact that "Congress has enacted several statutes addressing the particular subject of tobacco and health, creating a distinct regulatory scheme," while at the same time "Congress has persistently acted to preclude a meaningful role for *any* administrative agency in making policy on the subject of tobacco and health." *Id*. at 156.

Second, HHS misleadingly exaggerates the existence of a conflict of law, while wrongly implying that the weight of judicial authority aligns with its new interpretation. HHS states that "[w]hile four appellate courts have addressed the issue, a large volume of district court opinions have been inconsistent on the issue." 84 Fed. Reg. at 27855. HHS fails to mention that those

"four appellate courts" all recognized gender identity as a basis for discrimination under Title IX; indeed, it relegates them to a dismissive footnote only. While it is true that several district courts have ruled inconsistently on the issue, HHS impermissibly elevates the value and importance of these cases above the appellate court decisions.

Finally, HHS states that it is repealing the definitions for consistency's sake and to prevent "public confusion," citing the fact that DOJ's current position, as stated in *Franciscan Alliance* and other recent cases, conflicts with the 2016 Regulations. *Id*. at 27854-55, 856. This is nothing more than circular logic: Despite years of "sex" being interpreted to include gender identity and sexual orientation by DOJ, HHS, and the courts, DOJ decides unexpectedly last year to change its position, and HHS now relies on this new position as justification for its actions. This nonsensical explanation does not and cannot save the fact that the new position conflicts with Section 1557 itself. And if consistency were the true goal, it could have easily left untouched HHS and DOJ's prior interpretation. In fact, HHS goes on to say that it is not proposing its own definition of sex "because of the likelihood that the Supreme Court will be addressing the issue in the near future." *Id*. at 27857. Better then, HHS could have avoided even further confusion and litigation by holding off on issuing the Proposed Rule after the Supreme Court granted certiorari on April 22, 2019.

3. The Proposed Rule Conflicts with Case Law Interpreting Section 1557.

Finally, the Proposed Rule conflicts with every court—save one—that has directly considered whether Section 1557 prohibits discrimination based on gender identity and transgender status.

In the first case to address the issue, *Rumble v. Fairview Health Services*, 2015 WL 1197415 (D. Minn. Mar. 16, 2015), a transgender man claimed the local hospital and physicians violated Section 1557, alleging discriminatory treatment due to his transgender status. *Id*. at *3. Since HHS had not yet promulgated the 2016 Regulations, the court looked at the plain statutory language of Section 1557 and its incorporation of the four nondiscrimination statutes. *Id*. The court found that Section 1557 was ambiguous "insofar as each of the four statutes utilizes different standards for determining liability, causation, and a plaintiff's burden of proof." *Id*. at *9. Although it did not expressly find that Section 1557 was ambiguous with regard to the definition of sex, the court looked to agency interpretation—OCR's 2012 Opinion Letter—for guidance. *Id.* at *10. The court found that the OCR letter, while not controlling, was persuasive in "the thoroughness evident in its consideration, the validity of its reasoning, its consistency with earlier and later pronouncements." *Id*. Accordingly, it concluded that discrimination on the basis of sex under Section 1557 included transgender status. *Id*.

Next, in *Prescott v. Rady Children's Hospital*, 265 F. Supp. 3d 1090 (S.D. Cal. 2017), the court found that Section 1557 applied to protect transgender individuals in a lawsuit brought by a mother against a hospital, on behalf of her deceased minor transgender son. *Id.* at 1097. The defendant argued that the claim must be dismissed because the alleged conduct occurred before the 2016 Regulations (defining sex discrimination as including gender identity) had been promulgated, though they were in effect at the time the lawsuit was brought. *Id*. at *1098. The court rejected this claim, finding that Section 1557 affords protection against discrimination on the basis of gender identity "solely on the language of section 1557 itself," and not the 2016 Regulations. To support its finding, the court relied on Title VII and Title IX cases, *supra* at 6-9.

Two cases decided in 2018 from the district court in Wisconsin followed. In *Flack v. Wisconsin Department of Health Services*, 328 F. Supp. 3d 931 (W.D. Wis. 2018), the court granted a preliminary injunction to two plaintiffs who challenged the State of Wisconsin's Medicaid plan, which contained a categorical exclusion from coverage for all "[t]ranssexual surgery" and related procedures and medications. The Court found that the blanket exclusion, which prevented the two plaintiffs from getting medically necessary treatments, did so on the basis of both their assigned sex at birth and their transgender status, holding that "[e]ven accepting defendants' [narrow] definition of sex," the Wisconsin exclusion nevertheless denied plaintiffs coverage because of their natal sex," because the same procedure would be allowed for those seeking if gender matched natal sex, while not if it did not match gender identity. *Id*. at 947. The court concluded that the case was a "straightforward case of sex discrimination." *Id.* at 948.

Shortly thereafter, the same court also upheld a claim under Section 1557 brought by transgender women employees of the State of Wisconsin, wherein the state had excluded procedures and services related to gender reassignment from its health insurance coverage provided to employees. *See Boyden v. Conlin*, 341 F. Supp. 3d 979 (W.D. Wis. 2018). Following the reasoning in *Flack*, the court concluded holding that denying coverage for transsexual surgery fell within the ambit of the ACA's prohibition on "sex discrimination." *Id*. at 995.

Most recently, in *Tovar v. Essentia Health*, 342 F. Supp. 3d 947 (D. Minn. 2018), the Minnesota district court held that the plain language of Section 1557 prohibited discrimination on the basis of gender identity. There, plaintiff alleged that her transgender son was denied coverage for medically necessary care by defendant's health care plan, which categorically excluded all health services related to gender transition. *Id*. at 950-51. Following the Supreme Court's "expansive view" of sex discrimination in *Price Waterhouse v. Hopkins*, 490 U.S. 228, 251 (1989), as well as the decisions of "numerous courts" on the "precise question at issue here" under Section 1557, the court concluded based "solely on the plain, unambiguous language of the statute" that the plaintiff had stated a claim for sex discrimination under the ACA based on gender identity. *Id.* at 953, 957.

Thus, five out of the six cases that have interpreted sex discrimination under Section 1557 have held that it includes discrimination based on gender identity and transgender status.[4] Nevertheless, HHS claims that the Proposed Rule is "necessary," because the 2016 Regulation "is likely not constitutional." 84 Fed. Reg. at 27849. HHS supports this conclusion by relying entirely on *Franciscan Alliance*, despite the fact that it is an outlier and contrary to all of the other court decisions. Indeed, as it did with the Title IX cases that it disagrees with, HHS recognizes only that "other Federal courts have gender identity discrimination cases . . . pending on their dockets," *id*. at 27855, yet fails completely to acknowledge their holdings. HHS cannot escape the legal import of these cases by simply burying its head in the sand and ignoring them, while placing undue importance on a one-off decision it happens to agree with. Such wishful thinking does not eliminate the clear conflict between the Proposed Rule and the body of law interpreting Section 1557.

Furthermore, HHS's position conflates the 2016 Regulations with the statute itself. While *Franciscan Alliance* held that the definition of "on the basis of sex" in the 2016 Regulations went too far, the cases holding that Section 1557 extends to gender identity and transgender status did so on the basis of Section 1557 itself, and not the 2016 Regulations. Therefore, the Proposed Rule does not (and cannot) change the protections against discrimination that are part of Section 1557 as conferred by Congress, and act only to directly conflict with it.

In sum, HHS's attempt to rewrite Section 1557 by removing explicit protections under the 2016 Regulations is not only in direct contrast with existing law, but also marks an unlawful attempt to omit from discrimination protection an entire class of individuals. Congress directed HHS to bar sex discrimination in health care on the basis of sex; and it did so with clear intent to protect all individuals, including those who would encounter discrimination due to their transgender or gender non-conforming status. HHS's Proposed Rule, therefore, is in direct conflict with governing law, plainly violates the APA, *see Maislin Indus. v. Primary Steel, Inc.*, 497 U.S. 116, 134-35 (1990), and is an unlawful attempt to circumvent Congressional intent and well-established legal precedents through rule making.

[4] HHS also cites two consolidated cases from the North Dakota district court alleging that the 2016 Regulations were unlawful, but those cases were stayed in light of the injunction issued in *Franciscan Alliance*. *See Religious Sisters of Mercy v. Burwell*, No. 3:16-cv-386 (D.N.D. Nov. 7, 2016); *Catholic Benefits Ass'n v. Burwell,* No. 3:16-cv-432 (D.N.D. Dec. 28, 2016). HHS cites only to their dockets, however, because there are no published opinions or decisions in these cases.

B. The Proposed Rule's Blanket Removal of Protections For Persons Who Have Terminated a Pregnancy, Are Recovering Therefrom, or Suffering From Resulting Medical Conditions Conflicts With Section 1557.

The Proposed Rule would allow health care providers and other covered entities to invoke blanket abortion and religious objection exemptions from the 2016 Regulations' general prohibition on sex discrimination. Specifically, the Proposed Rule would allow for blanket denials of health care and insurance for persons based upon their termination of a pregnancy, recovery therefrom, or resulting medical conditions, irrespective of competing interests, including the health of people who may require emergency treatments. HHS notes that the statute will not apply if any part of it would "violate, depart from, or contradict definitions, exemptions, affirmative rights, or protections" under a wide range of provider conscience provisions set forth in HHS's recent rule "Statutory Conscience Rights in Health Care."

Essentially, under the Proposed Rule, people in need of abortion or other health care services that violate a provider's religious beliefs could be denied, delayed, or discouraged from seeking necessary care, placing them at risk of serious or life-threatening results in emergencies and other circumstances where the individual's choice of health care provider is limited. Should this lead to restrictions in abortion coverage by health insurers or abortion and related service provision by healthcare providers, the resulting gap in healthcare access would almost certainly disproportionately affect poor and low-income women who are unable to pay out-of-pocket for abortion services.

These proposed changes conflict with Section 1557 for numerous reasons. First, the text of Section 1557 is unambiguously clear as to the exemptions that apply to its antidiscrimination mandates. The statute explicitly extends nondiscrimination protections "except as otherwise provided for in [the] title (or an amendment made by [the] title)." 42 U.S.C. § 18116(a). Second, the Proposed Rule considers an overbroad universe of "conscience protections" separately established by HHS and not sanctioned by any federal laws or regulations. The expanded "conscience protections" would allow anyone "with an articulable connection to a procedure, health service, health program or research activity" to raise these alleged conscience objections. Meaning, the myriad participants in a health care encounter—from intake and billing staff to pharmacists, translators, radiology technicians, and insurance companies—could refuse to participate in service delivery to or provide coverage for patients, even under emergency circumstances. These expanded "conscience protections" would themselves amount to a violation of Section 1557 and the incorporated federal civil rights laws as they are nothing more than a new standard of selective and discriminatory treatment for many of the most vulnerable populations. HHS's rule seeking to expand "conscience protections" is currently being challenged in a California federal court by the city and county of San Francisco, and in a New

York federal court by a coalition of 23 states and municipalities, including signatories of this comment.[5]

Third, while debating the language of Section 1557, Congress considered and rejected broader exemptions similar to those now proposed by HHS. Congress refused to expand the federal conscience clause to prohibit "requir[ing] an individual or institutional health care provider to provide, participate in, or refer for an item or service to which such provider has a moral or religious objection, or require such conduct as a condition of contracting with a qualified health plan. *See, e.g.*, 155 CONG. REC. S13193-01 (2009). Congress also considered and rejected broader religious and moral exemptions in the context of the Women's Health Amendment. *See, e.g.*, 155 CONG. REC. S13193-01 (2009).

Finally, Congress has already included protections in the ACA to address religious concerns. Specifically, Title I of the ACA, in which Section 1557 is found, clearly incorporates existing federal conscience protections. *See e.g.*, 42 U.S.C. § 18023(c)(2)(a)(i) (2010) ("Nothing in this Act shall be construed to have any effect on Federal laws regarding . . . conscience protection."); 42 U.S.C.A. § 18113 (2010) (exemptions for objections to assisted suicide); 42 U.S.C.A. § 18023 (2010) (allowing states to prohibit abortion coverage in the state exchanges); 42 U.S.C. § 18023(c)(1)-(2) (the ACA shall not "preempt or otherwise have any effect on State laws regarding the prohibition of (or requirement of) coverage, funding, or procedural requirements on abortions, including parental notification or consent for the performance of an abortion on a minor").

Additionally, the ACA is already subject to the Religious Freedom Restoration Act (RFRA), and the 2016 Regulations allow for a case-by-case assessment of burdens on a provider's religion pursuant to the RFRA. The 2016 Regulations rejected incorporating Title IX's blanket religious exemption because Title IX is limited to educational institutions, which is significantly different from the health care context. While students and parents typically have a choice about whether to select a religiously affiliated educational institution, individuals' choice of health care provider or health care plan may be limited, especially in cases of emergency and in areas where hospitals are run by religious institutions. Notably, Congress has recognized the importance of ensuring the provision of emergency care to all persons without exception, and mandated that such care must be made available without exception. *See* 42 U.S.C. § 1395dd (hospitals that have an emergency room or department must provide to anyone requesting treatment an appropriate medical screening to determine whether an emergency medical condition exists, and to stabilize the condition or, if medically warranted, to transfer the person to another facility).

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[5] *State of New York v. U.S. Dep't of Health and Human Srvcs*, Case 1:19-cv-04676 at https://ag.ny.gov/sites/default/files/state_of_new_york_v_hhs_complaint.pdf; *City and County of San Francisco v. Azar*, Case No. 3:19-cv-2405 at https://www.sfcityattorney.org/wp-content/uploads/2019/05/1_Complaint.pdf.

Thus, HHS previously and more appropriately relied upon the RFRA to make individual case-by-base determinations about "whether a particular application of Section 1557 substantially burdened a covered entity's exercise of religion, and if so, whether there were less restrictive alternatives available." This means that, under the 2016 Regulations, there may be some instances in which a provider's religious beliefs will exempt it from providing services to which it objects to an individual, but other instances, based on the facts of a particular case, in which an individual must receive services despite a provider's religious objection.

The RFRA approach better balances the rights of all stakeholders and adheres to the ACA's purpose to provide equal access to health care and insurance; rather than prioritizing the purported religious and moral objections of providers and insurance companies over the rights of patients in need of critical medical care for time-sensitive health conditions. Indeed, the denials, delays, and inadequate medical care that individuals would face due to the assertion of overbroad "conscience objections could inflict significant and in some cases life threatening harm in the healthcare context.

C. The Proposed Rule's Weakening and Elimination of Language Assistance Conflicts with Section 1557.

(1) The Proposed Rule Makes Existing Language Access Mandates Discretionary

The Proposed Rule waters down existing requirements to ensure that low English proficiency ("LEP") individuals have access to translations and interpretation services. Specifically, the Proposed Rule would replace required steps to provide meaningful access "to each LEP individual eligible to be served or likely to be encountered" with a broader test that an "entity" apply a four-factor analysis to determine an organization's obligations to provide language assistance services. Using such a metric in the healthcare context would shift a healthcare entity's focus from providing language access to each individual – consistent with the established standards of patient-centered care – to a looser consideration of language access exclusively on an institutional level.

Section 1557's protections for LEP individuals builds upon pre-existing civil rights law, such as Title VI, which prohibits discrimination on the basis of race, color and national origin in programs and activities receiving federal financial assistance. Under governing U.S. Supreme Court case law, Title VI obligates recipients of Federal financial assistance to provide LEP individuals with meaningful access to Federally funded programs or activities. Section 1557 extends this protection to federally administered programs, and requires that healthcare institutions implement some of the basic standards and practices that are necessary for ensuring equal access to healthcare, regardless of the language patients and their families speak.

The Proposed Rule weakens language access because it will allow increased justifications for institutions to deny individuals language services, even when that information may be critical

to a patient's health and wellbeing. Health care entities will more likely discount LEP individuals when determining whether language access must be provided, and already vulnerable families and communities may experience disruptions and delays in the provision of their health care. Indeed, already marginalized communities are most likely to be neglected under the proposed changes—those who typically have less access to resources in their languages, and are often vulnerable due to their immigration and socio-economic status. Language access discrimination often overlaps with pre-existing barriers to access to health care, such as national origin, race, and color discrimination Thus, the Proposed Rule will put more vulnerable people at risk by making healthcare services more difficult to access or understand.

(2) The Proposed Rule Eliminates Notice and Taglines Requirements

The 2016 Regulations require covered entities to take reasonable steps to provide meaningful access to each LEP individual eligible to be served or likely to be encountered. Requirements also include posting a visibly-sized notice of non-discrimination and the availability of language access services in physical locations where the entity interacts with the public, on the entity's website, as well as in significant publications. The 2016 Regulations also require taglines on such publications, which must be translated into top 15 non-English languages for large-sized publications and top two languages for small-sized publications.

The Proposed Rule would eliminate notice requirements about one's rights to translation services, protections from discrimination, and directions concerning how to file a complaint. These proposed changes would result in a failure to provide meaningful access to language services for LEP individuals. These changes will also deprive persons with communication disabilities, such as individuals who are deaf or hard of hearing and use a foreign sign language as their preferred mode of communication of meaningful access to language services. Under governing U.S. Supreme Court case law, Section 794 of Title 29 (the Rehab Act) obligates recipients of Federal financial assistance to provide persons with disabilities with meaningful access to Federally funded programs or activities.

Ultimately, the Proposed Rule will undoubtedly weaken language access. In fact, in the Proposed Rule, HHS admits that repealing the requirements for taglines may "[decrease] access to, and utilization of, health care for non-English speakers by reducing their awareness of available translation services." 84 Fed. Reg. at 27855. When linguistically appropriate care is not available to people who speak English "less than well," patients, providers, and healthcare providers alike are put at risk. Studies have shown that language barriers impede access to health insurance, hinder utilization of health care services, compromise quality of care, and increase the risk of adverse health outcomes among LEP individuals. Cite? LEP individuals are more likely than others to report being in fair or poor health, defer needed medical care, or misunderstand medication instructions.

Essentially, when patients do not know they have the right to an interpreter, do not know how to request an interpreter, or cannot read important notices about their care or insurance, it is much more likely that they will not receive care or service in a language that they can understand. When communication between patients and providers is compromised, healthcare providers are unable to provide adequate patient care, and patients' health is put at risk. Simply put: If individuals do not know they can access language services, they will not access them, and their health will suffer. Thus, because the proposed elimination of the notice and tagline requirements will impede the ability of LEP individuals and persons with communication disabilities to meaningfully access health care and coverage programs and services, these proposed changes violate Section 1557 and the incorporated federal civil rights laws— Title VI and Section 794 of Title 29.

D. The Proposed Rule's Exemption of Numerous Health Care Insurance Entities Conflicts With the Scope of Section 1557.

Adding to protections against discrimination within the U.S. Constitution and federal civil rights laws, Section 1557 is the first civil rights statute to explicitly target discrimination in healthcare, including private insurance. Congress sought to advance the ACA's mission to expand coverage and to increase access to care through Section 1557, which broadly applies to "any health program or activity, any part of which is receiving Federal financial assistance," "any program or activity that is administered by an executive agency," and "any entity established under this title," and specifically enumerates "contracts of insurance" as a form of Federal financial assistance.

A previous regulatory analysis estimated that the 2016 Regulations would cover about 900,000 physicians, 133,343 facilities (such as hospitals and nursing homes), 445,657 clinical laboratories; 1,300 community health centers; 40 health professional training programs; Medicaid and public health agencies in each state and the territories; and at least 180 insurers.

The Proposed Rule severely limits the application of Section 1557 in health insurance by (1) entirely eliminating the definitions section of the 2016 Regulations and no longer defining "covered entity" and "health program or activity;" and (2) interpreting Section 1557 to apply only to an insurer's fully federally-funded or supported operations and those principally engaged in the business of providing healthcare.

Within this narrow scope, the Proposed Rule would entirely exempt Medicare Part B, group health plans established under ERISA, short-term plans, the Federal Employees Health Benefits Program, off-exchange products, and certain non-ACA health care programs administered by HHS from compliance with Section 1557.

The proposed exemptions run directly counter to the underlying statute that explicitly covers all health programs and activities if <u>any part of them</u> is receiving federal funding. The

plain text of Section 1557 includes any and all federal financial assistance by the terms "any health program or activity, . . . that is administered by an Executive Agency or any entity established under this title." Moreover, according to HHS' 2003 LEP guidance, which HHS claims it intends to follow, "coverage extends to a recipient's entire program or activity, *i.e.*, to all parts of a recipient's operations. This is true even if only one part of the recipient receives the federal assistance."[6]

More specifically, the Proposed Rule erroneously excludes ERISA plans from the scope of Section 1557 on the grounds that "such programs do not receive federal financial assistance from HHS and/or the entities operating them are not principally engaged in the business of providing health care." However, Section 1557 explicitly refers to "contracts of insurance," and thereby removes previous uncertainty about when civil rights law protections apply to health insurance coverage. The statute also makes it clear that all health insurers, so long as any part of their program or activity receives federal financial assistance, must not discriminate against individuals on the grounds of race, color, national origin, sex, or disability. Further, employer-sponsored plans, including self-funded group plans, heavily rely on federal financial assistance. In fact, as noted by the Commonwealth Fund, the government's largest expenditure in healthcare coverage outside of Medicare and Medicaid, is its subsidy of employer-sponsored coverage through the favorable tax treatment given to employer-sponsored plans, worth an estimated $146 billion in fiscal year 2018.[7] Health insurance companies, and employer-sponsored plans, also rely on government tax benefits.

HHS's proposal to exclude entities that are "principally or otherwise engaged in the business of providing health insurance," except for their specific operations that receive federal financial assistance, is similarly flawed. HHS seeks to justify this proposal by pointing to the Civil Rights Restoration Act of 1987 (CRRA), which did not explicitly refer to health insurance. However, even if that is true, Section 1557 expands the reach of the CRRA to "insurance contracts." And this was fully within Congress' authority to do so. The federal government has legal authority to regulate all health insurers and insurance plans, relying on the Commerce Clause or setting condition on the expenditure of federal funds. The condition does not have to be limited to activities specifically funded by the federal government so long as it is in pursuit of "the general welfare," related to a national concern, and done unambiguously.[8] Indeed, the federal government has regulated and continues to regulate the health insurance industry,

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[6] Federal Register, Vol. 68, No. 153, "Guidance to Federal Financial Assistance Recipients Regarding Title VI Prohibition Against National Origin Discrimination Affecting Limited English Proficient Persons," August 8, 2003 p. 47313. https://www.govinfo.gov/content/pkg/FR-2003-08-08/pdf/03-20179.pdf

[7] The Joint Committee on Taxation, 2018. "Estimates of Federal Tax Expenditures for Fiscal Years 2018-2022," JCX-81-18. Washington, DC; Congress of the United States, available at https://www.jct.gov/publications.html?func=startdown&id=5148

[8] *South Dakota v. Dole*, 483 U.S. 203, 207 (1987).

including ERISA plans, in numerous aspects. For example, the Health Insurance Portability and Accountability Act of 1996 limits the ability of employer-sponsored health plans to engage in certain risk selection practices, including discriminating on the basis of pre-existing health conditions in determining eligibility for enrollment or level of premiums for plan members. Finally, as explained below in Section II(A)(1), the exemptions are irrational and are contradicted by significant evidence. *See, supra*, at pp. 19-21.

E. The Proposed Rule's Elimination of Mandated Enforcement Mechanisms Conflicts With Section 1557.

The Proposed Rule would eliminate the enforcement mechanisms available to HHS's OCR and protected individuals. However, Section 1557 unambiguously mandates that "the enforcement mechanisms provided for and available under such Title VI, Title IX, section 794, or such Age Discrimination Act shall apply for violations of [Section 1557]." 42 U.S.C. §18816(a). This statutory mandate provides OCR with centralized authority to monitor and enforce civil rights laws in the health care sector.

The Proposed Rule removes most provisions supporting OCR's enforcement authority under the statute, including its power to request information from a covered entity, access the books, records, and facilities of HHS to evaluate compliance of the agency's own programs, order remedial action, ban retaliatory action against an individual making a complaint, and/or take legally permissible disciplinary actions for those in non-compliance, including suspension or termination of funds.

These proposed changes run counter to both the statute and the very purpose of OCR. Indeed, OCR was created to provide the area-specific knowledge and expertise for effective government oversight and civil rights law enforcement in the health sector, which is a specialized industry requiring specialized knowledge. Removing enforcement authorities delegated to OCR under the 2016 Regulations would essentially eliminate the OCR's primary means to serve the mission of the office.

The Proposed Rule would also repeal mandates within the 2016 Regulations that require covered entities to hold themselves accountable under Section 1557, including requirements to designate an employee responsible for coordinating the responsibilities under the 2016 Regulations and to establish grievance procedures that allow individuals to allege discrimination. It would also eliminate a provision explicitly providing a private right of action to individuals who allege discrimination in violation of Section 1557, and a provision that requires covered entities to notify individuals of their rights under Section 1557 and the 2016 Regulations.

In other words, under the Proposed Rule, an individual being discriminated against would no longer be informed of whether and how they can file their grievances or lawsuits. A covered entity would no longer need to take concrete actions to address such grievances.

Combined with removal of much of OCR's enforcement authority, the Proposed Rule would virtually eliminate all avenues that allow the individuals' voices to be heard and enable OCR to hold stakeholders accountable.

Additionally, removing the institutionalized enforcement mechanism that makes it easier for individuals to raise their voices when they believe that their civil rights have been violated will impact populations that have been historically marginalized, already experience significant barriers to health care, and have disproportionately poor health outcomes, including people of color and immigrants. These are the individuals who are least likely to know their rights or how to exercise their rights, and whose limited resources make it difficult to file a lawsuit under the underlying statute or utilize other means to file their grievances and challenge the discrimination they experience.

This proposed regulatory rollback runs directly counter to the clear goal of Section 1557 to provide equal access to health care and insurance and essentially renders the statute meaningless.

II. The Proposed Rule is Arbitrary and Capricious

An agency rule is arbitrary and capricious if the agency has: relied on factors that Congress did not intend it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise. *See Motor Vehicle Mfrs. Ass'n*, 463 U.S. at 43-44.

Under the "arbitrary and capricious" standard, HHS is required to examine relevant data and articulate a satisfactory explanation for its action, including a "rational connection between the facts found and the choice made," based upon relevant factors. *See Motor Vehicle Mfrs. Ass'n*, 463 U.S. 29 at 43; *Burlington Truck Lines, Inc. v. United States*, 371 U.S. 156, 168 (1962). Applying these standards demonstrates that, if finalized, the Proposed Rule would violate the APA.

A. HHS's Explanations for the Proposed Rule Are Not Rational and Run Counter to Significant Evidence.

(1) Arbitrary Exemptions of Certain Health Care Insurance From Section 1557

As previously noted, the Proposed Rule would dramatically limit the scope of the ACA non-discrimination protections, by effectively removing many of the currently covered health care insurance programs from the statute's reach. For the reasons below, HHS's justifications for these exemptions are irrational and unsupported by evidence.

As an initial matter, determining the civil rights obligations of insurers and employers based on whether the federal government provides financial assistance directly through subsidies or indirectly through tax benefits is illogical, especially since disparities for racial minorities[9] and foreign-born individuals[10] in obtaining employer-sponsored insurance continue to exist. The ACA was instrumental in reducing racial, ethnic, sex, and disability-based disparities in health insurance coverage. Indeed, studies have found that after the implementation of the ACA: people of color experienced large coverage gains, with an 11 percentage point decline in the uninsured rates for Hispanics and Asians and 8 percentage point decline for Blacks and American Indians, compared to Whites (5 percentage points);[11] the number of uninsured women fell from 19 million in 2010 to 11 million in 2016[12] -- notably the uninsurance rate for Latinas, decreased by more than 10 percentage points from 30.4% in 2013 to 19.9% in 2017 (4.8% for White women during the same period).[13] However, this progress would not have been possible without the robust non-discrimination protections in Section 1557. It is imperative that such protection continue to be extended to all types of health insurance plans. The Proposed Rule's reduced scope of application would violate the goal of ACA broadly and Section 1557 to expand equal access to health care.

HHS arbitrarily limits which entities should be considered "covered entities" and subject to non-discrimination mandates based on the reasoning that "[h]ealth insurance is distinct from health care." This flawed judgment ignores two important facts. First, a person's access to health care is often dramatically limited by their access to, or lack of access to, adequate health insurance coverage. Prior to the enactment of the ACA, health insurers could effectively restrict coverage for certain classes of people through decisions about issuance, cost-sharing, and benefit-design—tactics that the ACA was designed to prevent by requiring guaranteed issue, renewability, and coverage of essential health benefits, and by prohibiting pre-existing condition exclusions.

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[9] Waidmann, T. A., Garrett, B., & Hadley, J. (2004). Explaining Differences in Employer Sponsored Insurance Coverage by Race, Ethnicity, and Immigrant Status. Economic Research Initiative on the Uninsured Working Paper, 42.

[10] Buchmueller, T. C., Lo Sasso, A. T., Lurie, I., & Dolfin, S. (2007). Immigrants and employer-sponsored health insurance. Health Services Research, 42(1p1), 286-310.

[11] Artiga S., Orgera K., Damico A (2019). Changes in Health Coverage by Race and Ethnicity since Implementation of the ACA, 2013-2017. Kaiser Family Foundation Issue Brief, available at https://www.kff.org/disparities-policy/issue-brief/changes-in-health-coverage-by-race-and-ethnicity-since-implementation-of-the-aca-2013-2017/

[12] Gunja M.Z., Collins S.R., Doty M.M., Beutel S. (2017). How the Affordable Care Act Has Helped Women Gain Insurance and Improved Their Ability to Get Health Care. The Commonwealth Fund Issue Brief, available at https://www.commonwealthfund.org/publications/issue-briefs/2017/aug/how-affordable-care-act-has-helped-women-gain-insurance-and

[13] National Partnership for Women & Families Fact Sheet, 2018. "Women's Health Coverage: Stalled Progress," analysis based on the U.S. Census Bureau's 2018 Current Population Survey Annual Social and Economic Supplement. http://www.nationalpartnership.org/our-work/resources/health-care/womens-health-coverage-sources-and-rates-of-insurance.pdf

Next, depending upon life, work, economic and social circumstances, individuals can move fluidly across health insurance markets, being insured for some period through the public programs such as Medicaid, then getting employer sponsored coverage and later becoming self-employed. According to a Health Affairs study, one in four Americans changed their health insurance coverage at least once in 2015. After omitting the newly insured, the three most common reasons for churning were job-related insurance changes, loss of eligibility for Medicaid or ACA marketplace subsidies, and inability to afford a previous plan.[14] Given the frequency of insurance "churning," meaningful civil rights protections for individuals accessing health insurance cannot be achieved without granting the same protections regardless of their insurance types or products. Under the Proposed Rule, the same person protected from discrimination if insured through Medicaid might not receive comparable protections through employer-sponsored coverage. Section 1557's protections were not designed to be subject to the "luck of the draw" of selecting coverage in the "right" insurance market. Thus, it is vital that Section 1557 continue to apply to all health programs and activities that interact with individuals at various points in their overall pursuit of health insurance and health care services.

(2) Arbitrary Removal of Termination of Pregnancy, Recovery Therefrom and Related Medical Conditions as Forms of Sex Discrimination

As noted above, HHS now claims that, under Section 1557, Congress intended "sex" to refer solely to a person's biological sex assigned at birth, but offers no reasonable evidence to support this this policy shift nor adequately explains its decision to reverse course in the face of the exhaustive record previously before HHS, when the 2016 Regulations were written. In addition to running counter to governing law, this policy reversal conflicts with the interpretation of Title IX by other federal agencies. In fact, since 2012, the Department of Education has recognized and enforced discrimination against students and employees based upon termination of pregnancy, recovery therefrom and resulting medical conditions as sex discrimination under Title IX in the education settings.[15]

This conflict is notable because, within the same Proposed Rule, HHS justifies removing gender identity as a form of sex discrimination because such a reading it is inconsistent with those of other federal agencies. *See* Proposed Rule at p. 27856. Using HHS's erroneous logic,

[14] Sommers, B. D., Gourevitch, R., Maylone, B., Blendon, R. J., & Epstein, A. M. (2016). Insurance churning rates for low-income adults under health reform: lower than expected but still harmful for many. Health Affairs, 35(10), 1816-1824.

[15] 34 C.F.R. § 106.40(b) (defining sex discrimination to reach discrimination against students on "the basis of such student's termination of pregnancy or recovery therefrom."); § 106.51(b)(6) (barring employment discrimination with respect to "[g]ranting and return from leaves of absences for termination of pregnancy); § 106.57(b)(prohibiting illicit discrimination against employees or prospective employees "on the basis of termination of pregnancy or recovery therefrom."); *see generally*, Office for Civil Rights, Pregnant or Parenting? Title IX Protects You from Discrimination at School, U.S. Dep't of Educ. http://www2.ed.gov/about/offices/list/ocr/docs/dclknow-rights-201306-title-ix.html.

termination of pregnancy, recovery therefrom and resulting medical conditions should continue to be considered sex discrimination in the health care and insurance context under Section 1557 to align with the regulations of another federal agency governing the provision of education and employment in education settings. HHS's conflicting justifications for the removal of various forms of sex discrimination from the 2016 Regulations are clearly not rational.

(3) Arbitrary Elimination of Language Access Requirements

HHS contends that the 2016 Regulations concerning language access must be eliminated in their entirety because the notice and tagline requirements were inconsistent with those required by other components of HHS, and provided relatively minimal benefit to LEP individuals.[16] For the reasons set forth below, HHS's explanation is irrational and runs counter to significant evidence.

There is a Need for Robust Language Access Regulations in Healthcare

The importance of addressing the language needs of LEP individuals is prevalent throughout the United States. The Migration Policy Institute estimates that 25.1 million people in the U.S. are considered LEP, and nearly 20% of them are U.S.-born citizens.[17] The ACA has proven to be instrumental in supporting LEP individuals in obtaining health insurance coverage. In fact, the insurance coverage rate among LEP individuals has increased from 61.7% in 2010 to 74.8% in 2017, with a noticeable jump in 2014, when various ACA insurance expansion provisions went into effect.[18] However, a disproportionately large percentage of LEP individuals remain uninsured (25.2% vs. 7.5% according to the 2017 ACS data), and targeted outreach and assistance are crucial in closing the coverage gap within this population. Given the high need, the government has a duty to ensure that LEP individuals receive appropriate language assistance services when they seek insurance coverage, utilize benefits, or receive health care services.[19]

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[16] Proposed Rule at p. 27852

[17] Migration Policy Institute (MPI) tabulations from the U.S. Census Bureau's 1990 and 2000 Decennial Censuses and 2010 and 2013 American Community Surveys (ACS), Migration Policy Institute, July 2015. https://www.migrationpolicy.org/article/limited-english-proficient-population-united-states (Between 1990 and 2013, the LEP population in the U.S. grew 80% from nearly 14 million (6% of the total U.S. population) to 25.1 million (8%)).

[18] SHADAC analysis of the American Community Survey (ACS) Public Use Microdata Sample (PUMS) files, State Health Compare, SHADAC, University of Minnesota, accessed on June 28, 2019, available at http://statehealthcompare.shadac.org/table/15/health-insurance-coverage-type-by-limited-english-proficiency#1/5,4,1,10,86,9,8,6,18,19/24/29,30

[19] NY State of Health: The Official Health Plan Marketplace, 2019 Open Enrollment Report, May 2019. https://info.nystateofhealth.ny.gov/sites/default/files/NYSOH%202019%20Open%20Enrollment%20Report_0.pdf

The Proposed Rule Runs Contrary To Long-Standing Federal Guidance To Ensure Meaningful Access

Notice and Taglines Requirements

HHS contends that the notice and tagline requirements in the 2016 Regulations must be eliminated entirely because they are inconsistent with those required by other components of HHS, and provided relatively minimal benefit to LEP individuals. However, in HHS's own Language Access Plan, the agency notes that the taglines in non-English languages are used to inform LEP clients of their right to free language services and the nondiscrimination practices of the relevant agency. Further, the Department of Justice's guidance for federally conducted or assisted programs explicitly recognizes that "[w]hen…an LEP individual does not know about the availability of language assistance services, [they] will be less likely to participate in or benefit from an agency's programs and services," that notices and taglines serve as a temporary measure to promote better language access when documents deemed "vital" have yet to be translated, and that "agencies should provide notice about its language assistance services in languages LEP persons will understand."

Language Access Plans

The Proposed Rule also would eliminate the provision that allows HHS to consider whether the covered entity has an effective written language access plan. However, developing and implementing an effective written language access plan is an important factor in evaluating a covered entity's compliance under the 2016 Regulations, and is crucial to providing effective language access services in a sustainable manner.

Removing the consideration of whether an entity has an effective written language access plan evaluating a covered entity's compliance means that entities will be disincentivized from devising systematic plans to guarantee access, which provide the architecture necessary to evaluate and apply a systematically equal delivery of service across an institution and its service population. Ad hoc provision of language services results in inequality and a reduction in the quality of language access available, which negatively affects both patients with LEP and healthcare systems.

Moreover, similar to Section 1557, Federal Executive Order 13166 (EO13166) requires federal agencies to implement a system and plan to ensure improved access to services for LEP individuals, and New York State Executive Order 26 (EO26) requires state agencies to appoint a Language Access Coordinator and publish a language access plan. A recent independent analysis of the EO26 concluded that such mandates would benefit both NYS LEP residents and government agencies and improve access to and quality of services provided by state agencies. In addition, the report concluded that the EO would reduce health disparities among LEP

populations, without materially affecting the operations of the covered entities.[20] The 2016 Regulations encourage health insurers, researchers, and health care providers to take similar action to accommodate LEP individuals' language needs. The proposal to remove this consideration could discourage use of an important planning tool that helps entities better comply with the law and ensure that language access services are implemented in a cost-efficient manner to benefit both LEP individuals and covered entities themselves.

The Proposed Rule Eliminates or Weakens Major Tools that Facilitate Language Access, Which Will Result in Negative Health Outcomes.

HHS also proposes eliminating the current remote video interpreting standards and instead includes standards only for remote audio interpreting services. However, because healthcare institutions are increasingly relying on remote video interpretation services, it is vital that there are high standards for any language service provider that provides medical interpretation. The removal of standards for remote video interpretation means that healthcare institutions will have a compromised ability to budget for high quality video remote interpretation. Indeed, the rapid development and integration of new technologies into the delivery of interpretation continue to expand the availability and lower costs for video remote interpretation.

The proposed change further eliminates "qualified" from the proposed description of interpreters and translators that can provide language services under the law, and eliminates "above average familiarity with" from the definition. This weakens the qualifications required of language service providers that provide interpretation and translations for healthcare institutions, thereby jeopardizing the quality of communication possible between providers and LEP patients. Also, the use of underqualified language service providers can result in negative patient outcomes and miscommunications that can result in liability for the institution and increased costs due to inefficiencies such as unnecessary tests and procedures. In short, by undermining this valuable tool for effective communication, the Proposed Rule undermines access to quality healthcare for individuals with LEP.

B. HHS Failed to Consider Important Aspects of the Problem Underlying the Proposed Rule.

(1) HHS Failed To Account For The Need to Address Existing Discrimination in Health Care And The Resulting Negative Impact on Health Care Outcomes

[20] New York Lawyers for the Public Interest, Letter to U.S. Department of Health and Human Services Office for Civil Rights, RE: Request for Information Regarding Nondiscrimination in Certain Health Programs or Activities, October 1, 2013. https://nylpi.org/wp-content/uploads/bsk-pdf-manager/33_NYLPI_section_1557_comments_final_hardcopy.pdf

Section 1557 will have a detrimental and far-reaching impact on the health of LGBQ and TGNCNB people, women, and our communities. Indeed, HHS' futile distinction between health insurance and health care ignores the direct role of insurers in care access and health outcomes. HHS also disregards the deleterious impact of discrimination on care access and health, particularly where, as here, the discrimination is state-sanctioned.

For patients across the United States who lack state and local protections against discrimination based on gender identity and termination of pregnancy, the Proposed Rule poses a significant threat to their dignity and general and emergency health care needs. In short, the Proposed Rule would permit health care providers and insurance companies— who are not being asked to cover or participate in abortion procedures or gender affirming care or transitions— to refuse to provide treatment or coverage for basic and essential medical care which is, without exception, made available to other persons. HHS essentially contends that such refusal of care is warranted and lawful if a health care provider or insurance company takes issue with a person's gender identity or the fact that they have undergone an abortion procedure.

In fact, an analysis of HHS complaints before the nationwide preliminary injunction issued in *Franciscan Alliance* found that the majority of complaints filed with HHS's OCR under the 2016 Regulations addressed denials of medical care or insurance coverage for generally available healthcare services— and unrelated to gender affirming care or gender transition. For example, a health care provider could refuse to treat a patient for the flu solely based on the person's gender identity or refuse to accept a new transgender patient in favor of a person who is not transgender. Furthermore, under the Proposed Rule, women could be denied preventative and emergency care medical care or insurance coverage solely because they have terminated a pregnancy, are recovering therefrom or are suffering from a medical condition related to an abortion. Even survivors of sexual assault, particularly women of color who already experience difficulty in accessing reproductive health care, would experience less support in accessing pregnancy termination related to their assault.

In addition, the Proposed Rule would eliminate the prohibition on categorical denials, automatic exclusions, and limited coverage for gender-affirming care. Gender-affirming care is medically necessary and, in many cases, life-saving for TGNCNB people.[21] It includes a range of treatments, such as hormone replacement therapy, breast augmentation/reconstruction, mastectomy, facial feminization, voice training, or genital surgery,[22] and mental health care for

[21] World Professional Association for Transgender Health (WPATH), *Position Statement on Medical Necessity of Treatment, Sex Reassignment, and Insurance Coverage in the U.S.A.* ("Position Statement") (Dec. 21, 2016) ("The medical procedures attendant to gender affirming/confirming surgeries are not 'cosmetic' or 'elective' or 'for the mere convenience of the patient.' These reconstructive procedures are not optional in any meaningful sense, but are understood to be medically necessary for the treatment of the diagnosed condition.")

[22] WPATH, The Standards of Care, 9-10 (2012).

gender dysphoria. The country's leading medical associations have affirmed almost uniformly that access to these services leads to better overall health outcomes and should be deemed medically necessary.[23]

The protections afforded by Section 1557 to LGBQ and TGNCNB people have served as a critical tool in closing the healthcare gap facing many members of these communities. However, under the Proposed Rule, health care providers could roll back their protections or discontinue their compliance efforts that are already underway under the 2016 Regulations, leading to further deleterious healthcare outcomes for this population.

Even with protections under other federal laws and robust legal protections in place in states and localities, discrimination in the healthcare setting remains an unfortunate reality for transgender residents of our localities. The inability to obtain such medical care under the Proposed Rule will further marginalize LGBQ and TGNCNB communities that already experience rampant discrimination in health care settings, inhibiting care-seeking and reducing the availability of culturally competent and affirming health care. [24] Studies consistently show that transgender people face high rates of discrimination when seeking health care. According to the Report of the 2015 U.S. Transgender Survey, which included 27,715 participants, 25% of respondents reported experiencing a problem with their insurance in the past year that was directly related to their gender identity, including being denied health care coverage; and 23% of respondents did not see a doctor when they needed care because of fear of being mistreated.[25]

The risk of adverse health outcomes is compounded by the likelihood that some TGNCNB persons unable to obtain gender-affirming care through their insurance will engage in risky behaviors in order to meet their health needs. For example, sharing used needles for hormone injections place TGNCNB people at greater risk for HIV.[26] Other risky behaviors may include taking a higher hormone dosage than prescribed, purchasing hormones through unsafe underground markets, or injecting dangerous substances, like silicone, to bring one's body in line with the one's innate sense of their gender.[27]

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[23] https://transcendlegal.org/medical-organization-statements

[24] Jaime M. Grant, Lisa A. Mottet, Justin Tanis, National Gay and Lesbian Task Force & National Center for Transgender Equality, *Injustice at Every Turn: A Report of the National Transgender Discrimination Survey*, 6 (2011) https://transequality.org/sites/default/files/docs/resources/NTDS_Report.pdf.

[25] James, S. E., Herman, J. L., Rankin, S., Keisling, M., Mottet, L., & Anafi, M. (2016). *The Report of the 2015 U.S. Transgender Survey*. Washington, DC: National Center for Transgender Equality.

[26] Neumann, M. S., PhD., Finlayson, T. J., PhD., Pitts, N. L., B.S., & Keatley, J., M.S.W. (2017). Comprehensive HIV prevention for transgender persons. *American Journal of Public Health, 107*(2), 207-212.

[27] Sevelius, J. M. (2013). Gender affirmation: A framework for conceptualizing risk behavior among transgender women of color. *Sex Roles, 68*(11-12), 675-689.

Reduced access to mental health services for TGNCNB people resulting from the rule is also concerning given astounding rates of mental health issues among TGNCNB persons that result from interpersonal and systemic discrimination. According to the 2015 U.S. Transgender Survey, 40% of those surveyed had attempted suicide in their lifetime, compared to an estimated 4.6% of the general U.S. population. Thirty-nine percent of respondents experienced serious psychological distress in the month prior to completing the survey (based on the Kessler 6 Psychological Distress Scale) compared to an estimated five percent of the U.S. population.[28] A meta-synthesis of 42 studies of suicidality among transgender populations similarly found lifetime suicidal ideation among 56% of participants, with 29% attempting suicide.[29] In addition, LGBTQ youth disproportionately experience mental and behavioral health challenges compared to their heterosexual/cisgender peers. According to the NYC data, they are more likely to feel sad or hopeless (50% vs. 25%), more likely to attempt suicide (20% vs. 6%), more likely to drink alcohol (35% vs. 20%) and twice as likely to misuse both prescription and illicit drugs (16% vs. 8%).[30] By rolling back civil rights protections of the population already reluctant to seek care, the Proposed Rule could further exacerbate mental health disparities between LGBTQ youth and their heterosexual/cisgender peers as they may face additional barriers in accessing care without meaningful anti-discrimination protections in place.

Ultimately, by eliminating rigorous rules that require federally assisted health programs to respect and promote rights of the individuals that our civil rights laws were intended to support, the Proposed Rule will likely increase these individuals' social isolation and lead to poorer health outcomes. In contrast, a recent study found that state-level policies providing protections to transgender people from discrimination in schools and the ability to change name and gender on identifying documents led to better mental health, less alcohol consumption, and more recent health care utilization among transgender individuals.[31] In addition, gender-affirming care has been shown to improve mental health disorders, including depression, anxiety, and gender dysphoria, and promote overall patient well-being.[32]

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[28] James SE, Herman JL, Rankin S, Keisling M, Mottet L, Anafi M. The Report of the 2015 U.S. Transgender Survey. Washington, DC: National Center for Transgender Equality. 2016. https://www.transequality.org/sites/default/files/docs/USTS-Full-Report-FINAL.PDF.

[29] Adams N, Hitomi M, Moody C. Varied reports of adult transgender suicidality: synthesizing and describing the peer-reviewed and gray literature. *Transgend Health*. 2017; 2(1):60-75.

[30] June 19, 2019 testimony to New York City Council Committees on Youth Services and Mental Health, Addiction and Disabilities, Oversight – Mental Health Services for LGBTQ Youth. Testimony delivered by: Ashe McGovern, J.D. Executive Director, NYC Unity Project, Senior Policy Advisor, LGBTQ Initiatives; Hillary Kunins, MD, MPH, MS, Executive Deputy Commissioner, Division of Mental Hygiene, New York City Department of Health and Mental Hygiene

[31] Steve N. Du Bois et al., *Examining Associations Between State-Level Transgender Policies and Transgender Health*, 3:1 TRANSGENDER HEALTH 220-224 (2018).

[32] *See, e.g.*, WPATH, Position Statement (Dec. 21, 2016).

(2) HHS Failed To Account For Population Health Implications

Reduced health care access flowing from the Proposed Rule also has significant population health implications, including in compromising HIV prevention efforts. In 2017, approximately 38,700 people living in the U.S. were diagnosed with HIV, and transgender people received an HIV diagnosis at a rate three times higher than the national average.[33] People at risk for HIV must have access to pre-exposure prophylaxis (PrEP), which reduces the risk of sexual transmission of HIV by well over 90%. For persons with HIV, retention in care not only enables them to live healthy lives, but is a necessary component of ending the epidemic, as persons with an undetectable viral load for six months or longer who remain on treatment cannot transmit HIV through sex. Secretary Azar himself said ensuring PrEP access was "a major step" in the administration's promise to end the HIV epidemic in America by 2030.[34]

Crucial to ensuring everyone's access to HIV prevention and treatment tools, however, is not only the affordability and availability of drugs and healthcare services but also an inclusive care environment. Research has established a negative association between the impact of perceived discrimination and adherence to HIV antiretroviral therapy,[35] underscoring the importance to individual and community health of culturally competent and gender-affirming health care services to persons living with, or at risk of, HIV.

Similarly, delays in accessing testing and treatment for sexually transmitted infections (STIs)—for which many transgender persons are at higher risk as compared to the general population—will compound the already alarming rates of STIs nationally and locally. There were 2.3 million recorded cases of chlamydia, gonorrhea, and syphilis in the U.S. in 2017—the highest number ever on record.[36] Research has shown that STI rates are often highest among populations whose access to health services are the most limited.[37] In a recent study of HIV and STIs among transgender youth ages 15-24, respondents who reported having a provider knowledgeable on transgender health were significantly more likely to report being tested for

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[33]CDC. HIV among transgender people. 2019. Available at www.cdc.gov/hiv/group/gender/transgender/index.html Accessed July 1, 2019.

[34] HHS Press Office, "Trump Administration Secures Historic Donation of Billions of Dollars in HIV Prevention Drugs", May 9, 2019. https://www.hhs.gov/about/news/2019/05/09/trump-administration-secures-historic-donation-of-billions-of-dollars-in-hiv-prevention-drugs.html

[35] Turan, B., Rogers, A. J., Rice, W. S., Atkins, G. C., Cohen, M. H., Wilson, T. E., . . . Weiser, S. D. (2017). Association between perceived discrimination in health care settings and HIV medication adherence: Mediating psychosocial mechanisms. *AIDS and Behavior, 21*(12), 3431-3439.

[36] Centers for Disease Control and Prevention. NCHHSTP Newsroom: 2018 STD Prevention Conference. https://www.cdc.gov/nchhstp/newsroom/2018/2018-std-prevention-conference.html. Published August 28, 2018.

[37] Geisler WM, Chyu L, Kusunoki Y, et al. Health insurance coverage, health-care-seeking behaviors, and genital chlamydia infection prevalence in sexually active young adults. Sex Transm Dis. 2006 Jun;33(6):389-96.

HIV and STIs.[38] Protecting against gender discrimination is thus integral to protecting and promoting community health. Thus, HHS's proposal to reduce health care access by TGNCNB individuals—a group known to have high rates and risk factors for HIV—is irresponsible and entirely counter to the federal initiative to end the HIV epidemic, which would not be possible without prompt diagnosis, use of PrEP, viral suppression, and community support to achieve plan goals. In addition, if people of color are denied or dissuaded from receiving necessary prophylaxis, screening, and treatment for HIV and other STIs, existing disparities will widen—once again, undermining the federal administration's plan to end the HIV epidemic.

(3) HHS Failed To Account For The Cost Savings Attributable to the 2016 Regulations

HHS's cost assessment fails to account for cost-savings attendant to persons receiving timely and appropriate health care and averting the downstream costs of untreated health conditions. With respect to language access mandates, while it is true that a significant investment of resources is required, the failure to do so can be extremely costly to a healthcare system and to the people it serves. Furthermore, it has been shown that medically necessary health care for transgender individuals is cost-saving by reducing the risk of negative "end points," such as depression, suicidality, substance abuse, drug abuse, and HIV.[39] Averted HIV infections from appropriate prophylaxis, testing, and treatment can save tens of millions of dollars in medical costs attendant to HIV, including costs for daily medication and treatment of opportunistic infection, with the medical costs saved by avoiding just one HIV infection in the U.S. being conservatively estimated at $229,800 (2015 USD).[40] And each new HIV infection is a step backwards in the federal plan to end the epidemic.

Moreover, gender-affirming care is cost-effective and, when averaged with a pool of insured people, is typically less expensive than routine procedures, like those connected with childbirth.[41] Employers report very low costs from including coverage for gender-affirming care,

[38] Sharma, A., Kahle, E., Todd, K., Peitzmeier, S., & Stephenson, R. (2019). Variations in testing for HIV and other sexually transmitted infections across gender identity among transgender youth. *Transgender Health, 4*(1), 46-57.

[39] Padula WV, Heru S, Campbell JD. Societal implications of health insurance coverage for medically necessary services in the U.S. transgender population: a cost-effectiveness analysis. *J Gen Intern Med.* 2016;31(4):394-401.

[40] Oh P, Pascopella L, Barry P, Flood J. A system synthesis of direct costs to treat and manage tuberculosis disease applied to California, 2015. *BMC Research Notes*. 2017;10(434):1-7.

[41] *See* Letter from WPATH to Roger Severino, Director, Office of Civil Rights (OCR), U.S. Department of Health and Human Services (HHS) (Aug. 15, 2017).

with many employers reporting no costs at all.[42] For example, a study on San Francisco's coverage of gender affirming care found that the cost was negligible.[43]

However, public and private health insurance companies exclude transition-related health care from coverage, even in cases when a physician determines them medically necessary for a patient.[44] In the 2015 LGBT Health and Human Services Needs Assessment Survey ("2015 survey"), which examined the nexus between economic insecurity and health for TGNCNB New Yorkers, 61.3% of nearly 4000 respondents reported that their insurance does not cover transition-related care.[45] Based upon multiple studies, Lambda Legal has noted that denials of insurance coverage for medically necessary care can cause serious harm to TGNCNB people, including depression, suicide, or potentially harmful self-surgery or self-medication.[46]

Covering care improves people's life opportunities and capacity for self-sufficiency. Without access to these vital surgical, hormonal or other treatments, fewer TGNCNB individuals will be able to change their identity documents. This inability to have identity documents that match one's gender identity and expression will make employment, travel, housing and other social needs much harder to navigate for TGNCNB individuals.[47] These barriers also contribute to longer term economic instability for a population that experiences poverty at a much higher rate than non-TGNCNB populations. According to the 2015 Survey, TGNCNB respondents were twice as likely to be in poverty than non-transgender respondents.[48]

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[42] Jody L. Herman, Williams Institute, *Costs and Benefits of Providing Transition-Related Health Care Coverage in Employee Health Benefits Plans* (Sept. 2013) https://williamsinstitute.law.ucla.edu/wp-content/uploads/Herman-Cost-Benefit-of-Trans-Health-Benefits-Sept-2013.pdf.

[43] Economic Impact Assessment, Gender Nondiscrimination in Health Insurance, State of California (2012), available at https://transgenderlawcenter.org/wp-content/uploads/2013/04/Economic-Impact-Assessment-Gender-Nondiscrimination-In-Health-Insurance.pdf.

[44] Lambda Legal, "Creating Equal Access to Quality Health Care for Transgender Patients: Transgender Affirming Hospital Policies," Revised May 2016. https://www.lambdalegal.org/sites/default/files/publications/downloads/fs_20160525_transgender-affirming-hospital-policies.pdf May 2016

[45] Somjen Frazer and Erin Howe, "Transgender Health and Economic Insecurity: A report from the 2015 LGBT Health and Human Services Needs Assessment Survey," Empire State Pride Agenda: New York, NY. http://strengthinnumbersconsulting.com/wp-content/uploads/2017/06/TG-health-and-economic-insecurity-report-FINAL.pdf

[46] Lambda Legal, "Creating Equal Access to Quality Health Care for Transgender Patients: Transgender Affirming Hospital Policies," Revised May 2016. https://www.lambdalegal.org/sites/default/files/publications/downloads/fs_20160525_transgender-affirming-hospital-policies.pdf May 2016

[47] Somjen Frazer and Erin Howe, "Transgender Health and Economic Insecurity: A report from the 2015 LGBT Health and Human Services Needs Assessment Survey," Empire State Pride Agenda: New York, NY, p. 8. http://strengthinnumbersconsulting.com/wp-content/uploads/2017/06/TG-health-and-economic-insecurity-report-FINAL.pdf

[48] Somjen Frazer and Erin Howe, "Transgender Health and Economic Insecurity: A report from the 2015 LGBT Health and Human Services Needs Assessment Survey," Empire State Pride Agenda: New York,

Ultimately, improving access to medically necessary treatment of gender dysphoria, including the wide range of services to bring a transgender person's body into congruence with their gender, will improve an array of health and economic outcomes for TGNCNB persons.

(4) HHS Failed To Account For The Administrative Burdens And Significant The Proposed Rule Will Impose On States And Cities

HHS is silent regarding the negative financial impact the Proposed Rule will have on state and local health departments. In fact, additional human and financial resources will be needed for community outreach and other programming to combat increases in LGBQ and TGNCNB-related stigma and discrimination. Moreover, public health clinics may have increases in patient volume and in uncompensated care. And this is to say nothing of the resources required to counter any increases in HIV, STIs, or other diseases resulting from the Proposed Rule.

HHS HAS NOT COMPLIED WITH EXECUTIVE ORDER 13132, THE TREASURY GENERAL APPROPRIATIONS ACT, OR EXECUTIVE ORDER 12866.

Executive Order 13132

As explained above, HHS's failure to consider all aspects of the problem – specifically, the significant costs that the Proposed Rule would shift to state and local governments – violates the APA. In addition, HHS has violated the APA by failing to consider and evaluate the federal implications. The requirement that HHS consider the costs to state and local governments and federalism implications associated with the Proposed Rule violates not only the APA but also Section 6 of Executive Order 13132, which mandates that:

> no agency shall promulgate any regulation that has federalism implications, that imposes substantial direct compliance costs on State and local governments, . . . unless (1) funds necessary to pay the direct costs incurred by the State and local governments in complying with the regulation are provided by the Federal Government; or (2) the agency, prior to the formal promulgation of the regulation, (a) consulted with State and local officials early in the process of developing the proposed regulation; (b) in a separately identified portion of the preamble to the regulation as it is to be issued in the Federal Register, provides to the Director of the Office of Management and Budget (OMB) a federalism summary impact statement, which consists of a description of the extent of the agency's prior consultation with State and local officials, a summary of the nature of their concerns and the agency's position supporting the need to issue the regulation,

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NY. http://strengthinnumbersconsulting.com/wp-content/uploads/2017/06/TG-health-and-economic-insecurity-report-FINAL.pdf

> and a statement of the extent to which the concerns of State and local officials have been met; and (c) makes available to the [OMB] Director any written communications submitted to the agency by State and local officials.

Exec. Order No. 13,132, 64 Fed. Reg. 43,255 (Aug. 10, 1999)

HHS ignores this requirement, stating in conclusory fashion and without data, analysis or any other evidentiary support, that the Proposed Rule "does not have federalism implication and does not impose substantial direct compliance costs on State and local governments."[49] HHS is incorrect.

As explained above, the Proposed Rule will require states and local governments to expend additional human and financial resources for community outreach and other programming to combat increases in LGBQ and TGNCNB-related stigma and discrimination. Moreover, public health clinics may have increases in patient volume and in uncompensated care, and resources would be required to counter any increases in HIV, STIs, or other diseases resulting from the Proposed Rule. This could force state and local governments to make significant expenditures to protect the health and well-being of their residents. *See id*.

Moreover, the Proposed Rule has federalism implications. Policies and regulations that have federal implications include those that have substantial direct effects on States and local governments, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.[50]

In addition to violating the federal civil rights laws incorporated into Section 1557, the Proposed Rule also runs counter to the U.S. Constitution and other federal laws. Specifically, the proposal to permit health care insurance companies and providers to deprive persons of health care coverage and services due to their race, national origin, color, sex and disability status is a violation of the Equal Protection Clause of the Fourteenth Amendment. Further, the proposal to remove enforcement mechanisms through which persons may challenge a discriminatory denial of health care services and insurance is a violation the Due Process Clause of the Fifth and Fourteenth Amendments. Finally, HHS's proposal to allow providers to deprive certain persons of medical care, despite the existence of emergency circumstances, is a direct violation of the Emergency Medical Treatment & Labor Act.[51]

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[49] Proposed Rule at p. 20592

[50] Exec. Order No. 13,132, 64 Fed. Reg. 43,255 (Aug. 10, 1999).

[51] 42 U.S.C. § 1395dd (requiring hospitals that have an emergency room or department to provide to anyone requesting treatment an appropriate medical screening to determine whether an emergency medical condition exists, and to stabilize the condition or, if medically warranted, to transfer the person to another facility).

Notably, pursuant to Section 1557, Congress explicitly specified that the statute may not be construed to invalidate or limit the rights, remedies, procedures, or legal standards available to individuals aggrieved under Title VI, Title VII, or Title IX, in part, or to supersede State laws that provide additional protections against discrimination on any basis set forth in Section 1557.[52] However, as set forth above, the Proposed Rule seeks to set new regulations implementing Section 1557 that would ignore the very mandates within the statute. In addition, the protections under Section 1557 are similar to those available in other states and localities, including New York State Human Rights Law, New York City Human Rights Law, and Chicago Human Rights Law.

For example, both New York State and New York City have a Human Rights Law prohibiting discrimination on the basis of gender identity and gender expression.[53] Chicago's Human Rights Ordinance likewise prohibits discrimination on the basis of gender identity and gender expression. *See* Chicago Mun.Code § 2-160-010 *et seq*. And in 2016, the NYC Commission on Human Rights published legal enforcement guidance explicitly prohibiting employers from offering employee benefits that discriminate on the basis of gender identity, and NYC laws prohibit discrimination in public accommodations, health care, and other settings.[54]

The Signatories are committed to prohibiting unlawful discrimination in all of our local programs, including the administration of health insurance which serves the fundamental purpose of ensuring that vital health care services are broadly available to all individuals throughout the country. In addition, NYC upholds a sexual and reproductive justice framework in city programs and services. We recognize that sexual and reproductive justice exists only when all people have the power and resources to make healthy decisions about their bodies, sexuality, and reproduction. This framework includes the right to: choose to have or not have children; choose the conditions under which to give birth or create a family; care for one's children with necessary social support in a safe and healthy environment; and control one's own body and self-expression, free from any form of sexual, reproductive, or gender based oppression.

The Proposed Rule poses a serious impediment to these protections by giving license to health insurers and providers to discriminate against our residents by excluding coverage of medically necessary care in violation of Section 1557 and federal civil rights laws. Due to the compliance costs and federalism concerns implicated by the Proposed Rule, a federalism summary impact statement should be provided.

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[52] 42 U.S.C. 18116(b).

[53] NYS Human Rights Law § 296(2)(a) (prohibiting health care entities and providers from withholding or denying health care services to any person because of their sexual orientation, gender identity or expression, or the marital status of any person); N.Y.C. Admin. Code § 8-107.

[54] 10 N.Y.C.R.R. § 405.7 (c)(2) (prohibiting discrimination against patients in NYC health care facilities based on sexual orientation, gender, gender identity, and marital status).

The Treasury General Appropriations Act of 1999

HHS does not address the affirmative obligations imposed on it by the Treasury General Appropriations Act of 1999. That Act provides that:

> before implementing policies and regulations that may affect family well-being, an agency shall assess whether the action — (1) strengthens or erodes the stability or safety of the family and, particularly, the marital commitment; (2) strengthens or erodes the authority and rights of parents in the education, nurture, and supervision of their children; (3) helps the family perform its functions, or substitutes governmental activity for the function; (4) increases or decreases disposable income or poverty of families and children; (5) is warranted because the proposed benefits justify the financial impact on the family; (6) may be carried out by State or local government or by the family; and (7) establishes an implicit or explicit policy concerning the relationship between the behavior and personal responsibility of youth, and the norms of society.

Pub. L. No. 105–277, §654(c)(1-7), 112 Stat. 2681- 528-30 (1998).

Because HHS has not assessed the impact of the Proposed Rule on family well-being in any fashion, the Proposed Rule should not be finalized.

Executive Order 12866

Finally, HHS's assertion that the Proposed Rule is compliant with the Regulatory Flexibility Act is incorrect and incomplete. For the reasons discussed above, contrary to HHS's analysis, implementation of the Proposed Rule would impose an administrative and financial burden on states and localities. *See, supra*, at p. 31.

For all of the reasons set forth above, the Signatories object to the Proposed Rule and call on HHS to withdraw it.

Sincerely,

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