August 13, 2019

U.S. Department of Health and Human Services
Centers for Medicare and Medicaid, Office for Civil Rights, Office of the Secretary
Via Electronic Submission

Re: *Nondiscrimination in Health and Health Education Programs or Activities*
Docket RIN 0945-AA11; Docket Number: HHS-OCR-2019-0007

The City of New York (NYC) submits the following comment in response to Docket RIN 0945-AA11 ("Proposed Rule"). NYC's Department of Social Services, Department of Health and Mental Hygiene, Health and Hospitals Corporation, Commission on Human Rights, Mayor's Office of Immigrant Affairs, and Mayor's Office for People with Disabilities contributed to this comment.

Overview and Proposed Rule Changes

The Proposed Rule published by the U.S. Department of Health and Human Services (HHS) changes, without legitimate basis, regulations implementing Section 1557 of the Patient Protection and Affordable Care Act (ACA) (42 U.S.C. §18116) (Section 1557). Under Section 1557, Congress prohibited discrimination on the basis of race, color, national origin, sex, age, or disability in certain health programs or activities. Section 1557 builds on the following existing and long-standing Federal civil rights laws and explicitly applies them to health programs and activities for which any part is federally funded: Title VI of the Civil Rights Act of 1964 (Title VI), Title IX of the Education Amendments of 1972 (Title IX), Section 504 of the Rehabilitation Act of 1973 (Section 504), the Age Discrimination Act of 1975, and Section 794 of Title 29. Section 1557 also incorporates the enforcement mechanisms under those civil rights laws for violations of the statute. Section 1557 has been in effect since its enactment in 2010, and HHS issued the final rule implementing Section 1557 in May 2016 (2016 Regulations).

HHS submits the Proposed Rule seeking to substantially limit the scope of Section 1557 and eliminate or significantly revise key sections of the 2016 Regulations. Indeed, the Proposed Rule amounts to one of the most sweeping proposed regulations in history by aiming to strip away civil rights protections for tens of millions of individuals in the U.S. seeking access to health insurance and health care services.

HHS maintains that it is "committed to ensuring the civil rights of all individuals who access or seek to access health programs or activities of covered entities."[1] However, the proposed changes signal to the contrary by eliminating essential protections against discrimination that are mandated by Section 1557 and other federal civil rights laws, and contravening the Congressional intent for the ACA to expand access to affordable, quality health care across

[1] Proposed Rule at 27846.

health insurance markets. Essentially, entities would be permitted to withhold health care insurance and benefits as well as health care services from persons based upon their race, color, national origin, sex, age, or disability.

Specifically, HHS proposes to significantly narrow the reach of the statute by exempting numerous health care insurance plans, employee benefit programs, and even certain HHS-administered programs from nondiscrimination mandates even though they receive substantial federal funding. The Proposed Rule would also eliminate protections against discriminatory actions that Congress specifically intended to address through Section 1557 by:

- stripping away language access protections for individuals with Limited English Proficiency (LEP) and individuals with communication disabilities;
- creating blanket religious objection exemptions to allow insurance entities and health care providers and staff to deny health care services and coverage to persons, irrespective of emergencies or limited medical care options, if they seek, have had, are recovering from, or are experiencing a medical condition related to an abortion; and
- sanctioning discrimination and removing broad protections against lesbian, gay, bisexual, and queer (LGBQ) and transgender, gender non-conforming, non-binary (TGNCNB) individuals in accessing healthcare and prohibiting discrimination by healthcare and insurance providers.

Indeed, the Proposed Rule is the latest in a series of assaults on LGBQ and TGNCNB individuals as well as reproductive and pregnancy-related rights. This includes the so-called "conscience" rules that give medical professionals license to discriminate and refuse to provide reproductive, gender-affirming, and other medically necessary care; attempts to diminish a transgender persons' identity and access to medically necessary healthcare; the release of Department of Justice guidance stating Title VII does not protect individuals from discrimination on the basis of gender identity; and the Title X gag rule that interferes with reproductive health care providers ability to practice medicine.

These crusades against women, people with reproductive health care needs, and LGBQ and TGNCNB individuals is legally infirm and an affront to the basic human right to self-determination. That the Proposed Rule would eliminate protections under Section 1557 for women who make up half the U.S. population, more than 9.7 million lesbian, gay, and bisexual people, and approximately 1.3 million transgender people in the U.S.[2] – groups that already experience high levels of discrimination in health care settings and have resulting decreased

[2] Gallup, *In U.S., Estimate of LGBT Population Rises to 4.5%* (May 22, 2018) at https://news.gallup.com/poll/234863/estimate-lgbt-population-rises.aspx?g_source=link_NEWSV9&g_medium=TOPIC&g_campaign=item_&g_content=In%2520U.S.%2c%2520Estimate%2520of%2520LGBT%2520Population%2520Rises%2520to%25204.5% ; *see also* Andrew Flores et al., Williams Inst., UCLA Sch. of Law, How Many Adults Identify as Transgender in the United States? (2016) at https://williamsinstitute.law.ucla.edu/wp-content/uploads/How-Many-Adults-Identify-as-Transgender-in-the-United-States.pdf;

access to medical care and markedly poor health outcomes compared to the general population – is all the more repugnant.

Finally, the Proposed Rule seeks to gut Section 1557 by eliminating enforcement mechanisms that Congress mandated explicitly in the statute and HHS implemented through the 2016 Regulations. These mechanisms— grievance procedures and the investigation and enforcement authority held by HHS's Office for Civil Rights (OCR)— ensure health care entities are in compliance with the nondiscrimination mandates of Section 1557 and that people have redress when they are not. Through these changes, the Proposed Rule would roll back the ability of people to seek appropriate and affirming medical care, impede the ability of persons to access and advocate for health care, and increase the likelihood that they could be denied, delayed, or discouraged from seeking necessary medical care they are entitled to receive. Such circumstances would place individuals at risk of serious or life-threatening results in emergencies and other circumstances where the individual's choice of health care provider is limited.

Ultimately, the Proposed Rule would reverse the progress HHS has historically made in advancing its mission of enhancing the health and well-being of the U.S. public; albeit prior to recent attempts to stigmatize and discriminate against certain populations.

For the reasons that follow, we urge HHS to withdraw the Proposed Rule in its entirety because it is unlawful. Specifically, the Proposed Rule should not be finalized because it is: (1) not in accordance with governing law; (2) arbitrary and capricious; and (3) does not comply with Executive Order 13132, the Treasury General Appropriations Act, 1999, Public Law 105-277, and Executive Order 12866.

I. THE PROPOSED RULE VIOLATES THE ADMINISTRATIVE PROCEDURE ACT BECAUSE IT IS NOT IN ACCORDANCE WITH GOVERNING LAW.

An agency "does not have the power to adopt a policy that directly conflicts with its governing statute."[3] 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.[4] Section 1557, the underlying statute of the Proposed Rule, broadly mandates that except as otherwise provided for in the statute or amendments thereto, an individual shall not, on the grounds prohibited under title VI of the Civil Rights Act of 1964 (Title VI), title IX of the Education Amendments of 1972 (Title IX), the Age Discrimination Act of 1975, or section 794 of title 29 (Section 794), be excluded from participation in, be denied the benefits of, or be subjected to discrimination under, any health program or activity, any part of which is receiving Federal financial assistance, including credits, subsidies, or contracts of insurance, or under any program or activity that is administered by an Executive Agency or any entity established under this title (or amendments). The enforcement

[3] *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").

[4] *Pacific Northwest Generating Coop v. Department of Energy*, 580 F.3d 792, 806 (9th Cir. 2009).

mechanisms provided for and available under such title VI, title IX, section 794, or such Age Discrimination Act shall apply for purposes of violations of this subsection.[5]

The ACA has three primary goals: to make affordable health insurance available to more people, to expand the Medicaid program, and to support innovative medical care delivery methods to lower the costs of health care.[6] Pursuant to the foremost goal of the ACA, Section 1557 applies existing federal civil rights laws to health programs and facilities receiving Federal financial assistance to protected classes of people from discrimination based on race, color, national origin, sex, age, or disability. The Proposed Rule's interpretation of Section 1557 contradicts the statute and the ACA's explicit purposes.

Section 1557's Broad Nondiscrimination Mandates For Any Federally-Funded Health Program or Activity

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.[7] 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.

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[5] 42 U.S.C. §18116(a)(1).
[6] U.S. Centers for Medicare & Medicaid Services, "Affordable Care Act" at https://www.healthcare.gov/glossary/affordable-care-act/
[7] Valarie K. Blake, Civil Rights as Treatment for Health Insurance Discrimination, Wisconsin Law Review, March 26, 2019. http://wisconsinlawreview.org/civil-rights-as-treatment-for-health-insurance-discrimination/

The proposed exemptions run directly counter to the underlying statute that explicitly covers all health programs and activities if any part of them is receiving federal funding. The plain text of Section 1557 includes any and all federal financial assistance by the terms "any health program or activity, . . . that is administered by an Executive Agency or any entity established under this title." Moreover, according to HHS' 2003 LEP guidance, which HHS claims it intends to follow, "coverage extends to a recipient's entire program or activity, *i.e.*, to all parts of a recipient's operations. This is true even if only one part of the recipient receives the federal assistance."[8]

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."[9] 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. [10] 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.[11] 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.[12] Indeed, the federal government has regulated and continues to regulate the health insurance

[8] 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

[9] Proposed Rule at p. 27863.

[10] 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

[11] Proposed Rule at p. 27863.

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

industry, 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, the HHS's exemptions for these entities are irrational and are contradicted by significant evidence. *See, supra*, at pp. 19-21.

Section 1557, Title IX, and Title VII Prohibitions Against Sex Discrimination- Gender Identity and Sex Stereotyping

The 2016 Regulations interpret Section 1557 as prohibiting discrimination based upon gender identity and sex stereotyping. The Proposed Rule would remove these protections and permit health insurers, health care providers and other covered entities to engage in this discrimination, based upon HHS's erroneous assessment.

However, there is ample support for HHS to continue its interpretation that Section 1557 prohibits discrimination based on gender identity and sex stereotyping. For its definition of sex, Section 1557 incorporates Title IX, and Federal courts have repeatedly interpreted Title IX and Title VII and protections against sex discrimination to prohibit gender identity discrimination.[13] In addition, the Equal Employment Opportunity Commission interprets and enforces Title VII's prohibition of sex discrimination as forbidding "any employment discrimination based on gender identity or sexual orientation. These protections apply regardless of any contrary state or local laws."[14] Notably, Section 1557 mandates that nothing within the statute shall be construed to

[13] *See, e.g.*, *Glenn v. Brumby*, 663 F.3d 1312, 1317 (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, 575 (6th Cir. 2004) ("[A] label, such as 'transsexual,' is not fatal to a sex discrimination claim where the victim has suffered discrimination because of his or her gender non-conformity."); *Rosa v. Park West Bank & Trust Co.*, 214 F.3d 213, 215–16 (1st Cir. 2000) (holding that a transgender individual made a claim for sex discrimination under the Equal Credit Opportunity Act). In the upcoming term, the Supreme Court will review whether sex discrimination under Title VII includes gender identity. *Zarda v. Altitude Express, Inc.*, 883 F.3d 100, 108 (2d Cir. 2018), *cert. granted sub nom. Altitude Exp., Inc. v. Zarda*, 139 S. Ct. 1599 (2019); *See also, Prescott v. Rady Children's Hosp.-San Diego*, 265 F. Supp. 3d 1090, 1099 (S.D. Cal. 2017) ("Because Title VII, and by extension Title IX, recognize that discrimination on the basis of transgender identity is discrimination on the basis of sex, the Court interprets the ACA to afford the same protections."); *see also Flack v. Wis. Dep't of Health Servs.*, 328 F. Supp. 3d 931, 951 (W.D. Wis. 2018) (holding that denial of medically necessary treatments on the basis of transgender status amounts to discrimination on the basis of sex in violation of the ACA); *Whitaker By Whitaker v. Kenosha Unified Sch. Dist. No. 1 Bd. of Educ.*, 858 F.3d 1034, 1048 (7th Cir. 2017), *cert. dismissed sub nom. Kenosha Unified Sch. Dist. No. 1 Bd. of Educ. v. Whitaker ex rel. Whitaker*, 138 S. Ct. 1260 (2018) ("By definition, a transgender individual does not conform to the sex-based stereotypes of the sex that he or she was assigned at birth.") (citing *Price Waterhouse v. Hopkins*, 490 U.S. 228 (1989)).

[14] Equal Employment Opportunity Commission (EEOC), *What You Should Know About EEOC and the Enforcement Protections for LGBT Workers*, https://www.eeoc.gov/eeoc/newsroom/wysk/enforcement_protections_lgbt_workers.cfm#examples (last visited July 9, 2019); *see, e.g.*, Macy v. Holder, E.E.O.C. App. No. 0120120821, 2012 WL 1435995, *12

invalidate or limit the rights, remedies, procedures, or legal standards available to individuals aggrieved under Title VII.[15]

Despite this robust body of authority supporting the 2016 Regulations, HHS premises its Proposed Rule change on a single federal trial court's nationwide preliminary injunction in an ongoing case, *Franciscan Alliance, Inc. v. Burwell*.[16] That court's decision did not require HHS to make any regulatory changes, was not made on the merits, and both the preliminary order and any final decision are appealable. HHS's reliance upon *Franciscan Alliance* is misplaced because four appellate courts have held that Title IX must be construed to include gender identity discrimination.[17] Ignoring those precedents, the court in *Franciscan Alliance* erroneously stated that no federal court or agency had concluded sex should be defined to include gender identity.[18] Furthermore, the *Franciscan Alliance* court's conclusion that Title IX extends only to the binary, biological differences between cisgender men and women[19] is at odds with federal appellate precedents establishing that Title IX is meant to combat, not reinforce, sex stereotypes.[20]

(Apr. 20, 2012) ("intentional discrimination against a transgender individual because that person is transgender is, by definition, discrimination based on sex and such discrimination therefore violates Title VII.").

[15] 42 U.S.C. 18116(b).

[16] 84 *Fed. Reg.* 27846-27895, 27849 (June 14, 2019), https://www.federalregister.gov/documents/2019/06/14/2019-11512/nondiscrimination-in-health-and-health-education-programs-or-activities. (citing *Franciscan Alliance, Inc. v. Burwell*, 227 F. Supp. 3d 660 (N.D. Tex. 2016)).

[17] See e.g., *Whitaker v. Kenosha Unified School District No. 1*, 858 F.3d 1034, 1039-1047 (7th Cir. 2017); *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).

[18] *Franciscan Alliance, Inc.*, 227 F. Supp. 3d at 689.

[19] *Id.* at 688.

[20] *See, e.g., Whitaker*, 858 F.3d at 1039 (7th Cir. 2017) (holding that transgender student demonstrated a likelihood of success on his Title IX claim on a theory of sex stereotyping); *Wolfe v. Fayetteville, Arkansas Sch. Dist.*, 648 F.3d 860, 867 (8th Cir. 2011) (holding that to recover under Title IX, plaintiff had to prove "the harasser intended to discriminate against him 'on the basis of sex,' meaning the harassment was motivated by either [his] gender or *failure to conform with gender stereotypes*")(emphasis added); *Doe v. E. Haven Bd. of Educ.*, 200 F. App'x 46, 48 (2d Cir. 2006) (holding that Title IX supports a claim of sex discrimination where the alleged conduct included "verbal abuse that reflects sex-based stereotypes").

Section 1557, Title IX, and Title VII Prohibitions Against Sex Discrimination- Pregnancy, False Pregnancy, Termination Of Pregnancy, Or Recovery Therefrom, And Childbirth Or Related Medical Conditions

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, although the 2016 Regulations allow for a case-by-case assessment of burdens on a provider's religion pursuant to the Religious Freedom Restoration Act (RFRA), the Proposed Rule would extend it further and allow for blanket denial of service provision based upon the assertion of alleged religious and moral beliefs, irrespective of competing interests, including the health of people who may require emergency treatments.

Essentially, the proposed change means, due solely to a provider or insurer's purported religious or moral beliefs, persons in need of the termination of a pregnancy or other health care services to treat critical medical conditions resulting from that procedure could be denied, delayed, or discouraged from seeking necessary care completely. These refusals of care will ultimately place them at risk of serious or life-threatening conditions in emergencies and circumstances where the individual's choice of health care provider is limited. Should this lead to restrictions in health insurance coverage for abortions or the provision of related medical services, 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 and other medical services.[21]

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 of 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 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 NYC.[22]

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[21] https://www.kff.org/womens-health-policy/issue-brief/coverage-for-abortion-services-in-medicaid-marketplace-plans-and-private-plans/

[22] *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.

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.[23] Congress also considered and rejected broader religious and moral exemptions in the context of the Women's Health Amendment.[24]

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.[25]

Section 1557, Title VI and Section 794 of Title 29, Prohibitions Against Restricting Meaningful Access And Effective Communication To Obtain Health Care

(1) The Proposed Rule Weakens Language Access

The Proposed Rule waters down existing requirements on covered entities that ensure that 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. While this test may have value in certain circumstances, using this metric in the healthcare context would shift a healthcare entity's focus from providing language access *to each individual* as a matter of their right– consistent with the established standards of patient-centered care – to a looser consideration of language access on an institutional level.

The protections for LEP individuals encoded in Section 1557 build 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 is the only law extending this protection to federally administered programs and requires that healthcare institutions implement some of the basic standards and practices that are necessary to ensure every individual has equal access to health insurance and healthcare, regardless of the language patients and their families speak.

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[23] See, e.g., 155 CONG. REC. S13193-01 (2009).
[24] *See, e.g.*, 155 CONG. REC. S13193-01 (2009).
[25] *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").

The proposed changes 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. Such a change will mean that the needs of LEP individuals are more likely to be discounted when determining whether language access must be provided. Notably, the communities most likely to be neglected under the proposed changes would be those that are already marginalized as speakers of languages of lesser diffusion, who typically have less access to resources in their languages, and are often vulnerable due to their immigration and socio-economic status.

(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 and persons with communication disabilities eligible to be served or likely to be encountered. Requirements 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 the top 15 non-English languages for large-sized publications and the top two languages for small-sized publications.

The Proposed Rule would eliminate notice requirements about one's rights to translation and interpretation 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.

In addition, the changes would deprive persons with communication disabilities— such as individuals who are deaf or hard of hearing, use a foreign sign language as their preferred mode of communication, and read in a language other than English— with meaningful access to language services. HHS's suggested exemption from the auxiliary aids and services requirement for covered entities with fewer than 15 employees"[26] would similarly place an undue access barrier on individuals with sensory, manual and communication disabilities. 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.[27]

Even when LEP individuals have health insurance and/or access health care services, they often do not receive adequate translation and interpretation services, with particularly significant gaps in outpatient primary care and mental health services.[28] Research has shown that LEP individuals

[26] Federal Register, Vol. 84, No. 115, "Nondiscrimination in Health and Health Education Programs or Activities," RIN 0945–AA11, p. 27867.
[27] *Alexander v. Choate*, 469 U.S. 287, 301 (1985) (an otherwise qualified handicapped individual be provided with meaningful access to the benefit that the grantee offers…; to assure meaningful access, reasonable accommodations in the grantees program or benefit may have to be made).
[28] New York City Mayor's Task Force on Immigrant Health Care Access, Improving Immigrant Access to Health Care in New York City: a Report from the Mayor's Task Force on Immigrant Health Care Access, 2015. https://www1.nyc.gov/assets/cidi/downloads/pdfs/immigrant_health_task_force_report.pdf

who need but do not receive adequate interpretation services have low satisfaction with interpersonal aspects of health care services received.[29] The Proposed Rule would deter LEP individuals from seeking health care services and needed medical treatment and exacerbate health disparities for this population.

When linguistically appropriate care is not available to people who speak English "less than well," patients and healthcare providers alike are put at risk. Studies have shown that language barriers impede access to health insurance,[30] hinder utilization of health care services,[31] compromise quality of care, [32] and increase the risk of adverse health outcomes among LEP individuals. LEP individuals are more likely than others to report being in fair or poor health, defer needed medical care, or misunderstand medication instructions.[33] Even 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."[34]

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 services 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. 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 existing federal law, specifically Section 1557, Title VI and Section 794 of Title 29.

Section 1557- Enforcement Mechanisms

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.

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[29] D.W. Baker , R. Hayes, and J.P. Fortier, "Interpreter Use and Satisfaction with Interpersonal Aspects of Care for Spanish-Speaking Patients," Medical Care 36 , no. 10 (1998): 1461 –1470.
[30] Kaiser Family Foundation, August 2012, "Overview of Health Coverage for Individuals with Limited English Proficiency." https://www.kff.org/wp-content/uploads/2013/01/8343.pdf
[31] New York City Mayor's Task Force on Immigrant Health Care Access, Improving Immigrant Access to Health Care in New York City: a Report from the Mayor's Task Force on Immigrant Health Care Access, 2015. https://www1.nyc.gov/assets/cidi/downloads/pdfs/immigrant_health_task_force_report.pdf
[32] D.W. Baker , R. Hayes, and J.P. Fortier, "Interpreter Use and Satisfaction with Interpersonal Aspects of Care for Spanish-Speaking Patients," Medical Care 36 , no. 10 (1998): 1461 –1470.
[33] Ku, L., & Flores, G. (2005). Pay now or pay later: providing interpreter services in health care. Health Affairs, 24(2), 435-444.
[34] Federal Register, Vol. 84, No. 115, "Nondiscrimination in Health and Health Education Programs or Activities," RIN 0945–AA11, p. 27882.

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 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.

This proposed change 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. Additionally, removing the enforcement mechanisms that make 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.

II. THE PROPOSED RULE VIOLATES THE ADMINISTRATIVE PROCEDURE ACT BECAUSE IT IS ARBITRARY AND CAPRICIOUS.

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.[35] 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

[35] *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).

to a difference in view or the product of agency expertise.[36] Applying these standards demonstrates that, if finalized, the Proposed Rule would violate the APA.

A. 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

Eliminating gender identity and abortion anti-discrimination protections from the ambit of 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.

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.[37] 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,[38] would experience less support in accessing pregnancy termination related to their assault.

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[36] *See Motor Vehicle Mfrs. Ass'n*, 463 U.S. at 43-44.

[37] Sharita Gruberg and Frank J. Bewkes, *The ACA's LGBTQ Nondiscrimination Regulations Prove Crucial*, Center for American Progress (Mar. 7, 2018) https://cdn.americanprogress.org/content/uploads/2018/03/06122027/ACAnondiscrimination-brief2.pdf

[38] Dehlendorf, C. & Weitz, T. (2011). Access to Abortion Services: A Neglected Health Disparity. Journal of Health Care for the Poor and Underserved 22(2), 415-421. Johns Hopkins University Press. Retrieved July 8, 2019, from Project MUSE database.

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.[39] It includes a range of treatments, such as hormone replacement therapy, breast augmentation/reconstruction, mastectomy, facial feminization, voice training, or genital surgery,[40] and mental health care for 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.[41]

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 NYS and NYC, discrimination in the healthcare setting remains an unfortunate reality for transgender New Yorkers. 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. [42] 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.[43]

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

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[39] 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.")

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

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

[42] 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.

[43] 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.

injections place TGNCNB people at greater risk for HIV.[44] 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.[45]

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. 39% percent of respondents experienced serious psychological distress in the month prior to completing the survey compared to an estimated 5% percent of the U.S. population.[46] A meta-synthesis of 42 studies of suicidality among transgender populations similarly found lifetime suicidal ideation among 56% of participants, with 29% attempting suicide.[47] 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%).[48] 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 the 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.[49] In addition, gender-

[44] 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.
[45] Sevelius, J. M. (2013). Gender affirmation: A framework for conceptualizing risk behavior among transgender women of color. *Sex Roles, 68*(11-12), 675-689.
[46] 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.
[47] 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.
[48] Testimony delivered on June 19, 2019 to the 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
[49] Steve N. Du Bois et al., *Examining Associations Between State-Level Transgender Policies and Transgender Health*, 3:1 TRANSGENDER HEALTH 220-224 (2018).

affirming care has been shown to improve mental health disorders, including depression, anxiety, and gender dysphoria, and promote overall patient well-being.[50]

(2) HHS Failed To Account For Population Health Implications

Reduced access to health care resulting 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.[51] 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.[52] 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,[53] underscoring the importance of culturally competent and gender-affirming health care services to persons living with, or at risk of, HIV to the health of individuals and communities.

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—has population health implications. In 2017, there were 2.3 million recorded cases of chlamydia, gonorrhea, and syphilis in the U.S.—the highest number ever on record.[54] In NYC, there were 23,459 reported cases of gonorrhea in 2017, nearly double the number reported in 2010, and 71,830 cases of chlamydia. Research has shown that STI rates are often highest among populations whose access to health services are the most limited.[55] 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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[50] *See, e.g.*, WPATH, Position Statement (Dec. 21, 2016).

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

[52] 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

[53] 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.

[54] 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.

[55] 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.[56] Protecting against gender discrimination is thus integral to protecting and promoting community health. 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— again, undermining the federal goal to end the HIV epidemic.

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

HHS argues that the Proposed Rule will save costs, however, HHS's cost assessment fails to account for the 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 significant investment of resources are required, the failure to do so can be extremely costly to our healthcare system and to the people it serves. Studies have found that immigrants exhibited higher health care costs if there were language barriers between them and health care providers. Most of these increased costs were attributable to using more health care services and goods that could have been avoided with efficient communication.[57] Trained professional interpreters and bilingual health care providers positively affect LEP patients' satisfaction, quality of care, and outcomes, and can be ultimately more cost-effective.[58]

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.[59] 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).[60] 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.[61] Employers report very low costs from including coverage for gender-affirming care,

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[56] 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.

[57] Bischoff, A., & Denhaerynck, K. (2010). What do language barriers cost? An exploratory study among asylum seekers in Switzerland. *BMC health services research, 10*, 248. doi:10.1186/1472-6963-10-248

[58] Flores, G. (2005). The impact of medical interpreter services on the quality of health care: a systematic review. *Medical care research and review, 62*(3), 255-299.

[59] 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.

[60] 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.

[61] *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.[62] For example, a study on San Francisco's coverage of gender affirming care found that the cost was negligible.[63]

Despite the ample evidence supporting the cost-effectiveness of gender affirming health care and the increasing number of jurisdictions and plans moving to embrace such care due to the protections afforded under Section 1557, public and private health insurance companies continue to exclude gender-affirming health care from coverage, even in cases when a physician determines that they are medically necessary for a patient.[64] 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.[65]

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. While NYC has eliminated surgical-related requirements for changing gender identity on ID documents, many jurisdictions have not. 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.[66] These barriers also contribute to longer term economic instability for a population that experiences poverty at a much higher rate that non TGNCNB populations. According to the 2015 Survey, TGNCNB respondents were twice as likely to be in poverty than cisgender respondents.[67]

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[62] 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.

[63] 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.

[64] 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

[65] 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

[66] 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

[67] 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

(4) HHS Failed To Account For The Administrative Burdens And Significant Costs 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, including the NYC Health Department's eight Sexual 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.

B. 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 and foreign-born individuals 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); the number of uninsured women fell from 19 million in 2010 to 11 million in 2016 – 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). However, this progress would not have been possible without the robust non-discrimination protections in Section 1557. Thus, it is imperative that such protections continue to be extended to all forms of health insurance plans. The Proposed Rule's reduced scope of application would violate the goal of the ACA 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 has been designed to prevent by requiring guaranteed issue, renewability, and coverage of essential health benefits, and by prohibiting on pre-existing condition exclusions.

Second, HHS ignores the fact that, depending upon life, work, economic and social circumstances, individuals can move fluidly across health insurance markets, being insured for some period through the public options such as Medicaid, then getting employer sponsored coverage and possibly 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. [68] 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 persons 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 health insurance 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

HHS 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 or explanation to support this this policy shift. 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.[69]

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[68] 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.

[69] 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.

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.[70] Using HHS's erroneous logic, 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. HHS's conflicting justifications for the removal of various forms of sex discrimination from the 2016 Regulations are not rational.

(3) Arbitrary Elimination of Language Access Requirements

For the reasons set forth below, HHS's explanation for removing various language access requirements are irrational and runs counter to significant evidence.

NYC's Experience Providing Services to its Linguistically Diverse Population Demonstrates the Need for Robust Language Access Regulations in Healthcare

NYC is the largest and most culturally and linguistically diverse city in the United States, and its economic, cultural, and civic vitality depend on our immigrant communities. Of the City's 8.6 million residents, 3.1 million are immigrants (37.1% of the city's population). More than 200 languages are spoken by NYC residents across the five boroughs and approximately half of all New Yorkers speak a language other than English at home.[71] One in four – or two million New Yorkers – are considered LEP.[72] Protecting the well-being of all New Yorkers entails improving public health and emergency preparedness, as well as engagement across all communities. These, in turn, require clear communications with and trust in the government and healthcare institutions.

As a result of NYC's diversity, we have a unique understanding of how critical it is to ensure language access, particularly for essential services like healthcare. The city has found that language access is a fundamental requirement for meaningful access to healthcare. In fact, when LEP individuals are denied quality language services, they are less likely to seek preventative care, return to a healthcare institution for follow up care, comply with medical prescriptions, and are more susceptible to adverse outcomes. Furthermore, when an LEP individual must rely on unqualified staff, their own limited use of English, or a family member as an interpreter, they are less likely to share vulnerable but medically critical information, and the risk of miscommunication is high.

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[70] *See* Proposed Rule at p. 27856.
[71] U.S. CENSUS BUREAU. *QuickFacts New York city, New York*. (2000) https://www.census.gov/quickfacts/fact/table/newyorkcitynewyork/AGE295218.
[72] New York City Mayor's Office of Immigrant Health, State of Our Immigrant City: MOIA Annual Report for Calendar Year 2018, March 2019. https://www1.nyc.gov/assets/immigrants/downloads/pdf/moia_annual_report%202019_final.pdf

NYC advances English language learning and expanded language access for New Yorkers with LEP.[73] Since 2017, NYC requires that City agencies translate their most-commonly-distributed materials into ten languages, ensure all people have access to interpretation services when obtaining City services, and provide notification of free interpretation.[74] NYC's experience demonstrates that any minor administrative costs associated with printing information in additional languages is largely overshadowed by the benefits our communities receive when people are able to obtain the care they need.

NYC's experience with improving language access aligns with the broad efforts of the healthcare industry to improve outcomes. Over the last two decades, the healthcare industry has increasingly focused on the delivery of patient- and family-centered care as central components of quality care, patient safety, and health equity. This shift has been reflected in and driven by evolving requirements under the Joint Commission and the HHS standards for Culturally and Linguistically Appropriate Services. These initiatives are essential to advancing language access, and are also necessary to limit exposure to potential liabilities.

Nationwide, 25.1 million people are considered LEP and nearly 20% of them are U.S.-born citizens.[75] While the ACA has proven to be instrumental in supporting LEP individuals in obtaining health insurance coverage,[76] a disproportionately large percentage of LEP individuals remain uninsured,[77] 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.[78]

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[73] "State of Our Immigrant City: MOIA Annual Report for Calendar Year 2018," New York City Mayor's Office of Immigrant Affairs (2019), https://www1.nyc.gov/assets/immigrants/downloads/pdf/moia_annual_report%202019_final.pdf.

[74] Local Law 30 (2017)

[75] 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%)).

[76] 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 (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).

[77] 2017 ACS data (25.2% vs. 7.5%)

[78] 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 Contradicts 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.[79] 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. [80] Further, the Department of Justice's guidance for federally conducted or assisted programs explicitly recognizes the following: "[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;"[81]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."[82]

Thus, while federal agencies may have differing requirements regarding the content of notices and taglines, there is certainly agreement that the notices and taglines are necessary to provide meaningful access to health care and effective communication to LEP individuals. Eliminating these requirements entirely contradicts long-standing federal guidance.

Language Access Plans

The Proposed Rule also would eliminate a regulatory 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 when evaluating a covered entity's compliance means that entities will be disincentivized from devising systematic plans to guarantee access, which helps establish the infrastructure necessary to evaluate and apply equitable 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 services, which negatively affects both patients with LEP and healthcare systems.

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[79] *See* Proposed Rule at p. 27852

[80] The Department of Health and Human Services, Language Access Plan 2013, p. 13. https://www.hhs.gov/sites/default/files/open/pres-actions/2013-hhs-language-access-plan.pdf

[81] U.S. Department of Justice, "Common Language Access Questions, Technical Assistance, and Guidance for Federally Conducted and Federally Assisted Programs," August 2011, p. 6. https://www.lep.gov/resources/081511_Language_Access_CAQ_TA_Guidance.pdf

[82] LEP.gov Federal Interagency website, https://www.lep.gov/faqs/faqs.html#Two_EO13166_FAQ

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.[83] 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 include 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. We also note that 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 patients. Also, the use of underqualified language service providers can result in negative patient outcomes and miscommunication 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.

[83] 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

III. 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. *See, supra,* at p. 19. In addition, HHS has violated the APA by failing to consider and evaluate the federal implications of the Proposed Rule. 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, 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.[84] 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.[85] 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

[84] *See* Proposed Rule at p. 27886.
[85] *See, supra,* at p. 19.

Proposed Rule. This could force state and local governments to make significant expenditures to protect the health and well-being of their residents. [86]

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.[87]

In addition to violating the federal civil rights laws incorporated into Section 1557, the proposed changes also run 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 solely to their race, national origin, color, sex, or 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.[88]

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.[89] 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 some of the protections provided by Section 1557 are similar to those available New York State Human Rights Law and New York City Human Rights Law. Both New York State and New York City have a Human Rights Law prohibiting discrimination on the basis of gender identity and gender expression.[90] Further, 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.[91]

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[86] *See id*.
[87] Exec. Order No. 13,132, 64 Fed. Reg. 43,255 (Aug. 10, 1999).
[88] 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).
[89] 42 U.S.C. 18116(b).
[90] 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.
[91] 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).

NYC is committed to prohibiting unlawful discrimination in all of our programs, including, to the extent it has the authority to do so, 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 New Yorkers 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.

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.