

November 9, 2015

The Honorable Sylvia Matthews Burwell Secretary U.S. Department of Health and Human Services Hubert H. Humphrey Building 200 Independence Avenue SW Washington, D.C. 20201

Dr. Jocelyn Samuels Director, Office for Civil Rights U.S. Department of Health and Human Services Hubert H. Humphrey Building, Room 509F 200 Independence Avenue, SW Washington, D.C. 20201

RE: Nondiscrimination in Health Programs and Activities, Proposed Rule RIN 0945-AA02

Dear Secretary Burwell and Director Samuels:

The National Partnership for Women & Families represents women across the country who are counting on successful continued implementation of the Affordable Care Act (ACA). We look forward to continuing to work with the Department of Health and Human Services (HHS) to ensure that the ACA delivers on its promise to guarantee equitable access to affordable, comprehensive health coverage for women and their families. We appreciate the opportunity to comment on the Nondiscrimination in Health Programs and Activities proposed rule.

Section 1557's prohibition against discrimination on the grounds of race, color, national origin, sex, age, or disability in health programs and activities will provide women with the legal protection they need to ensure and enforce their ability to receive equitable and timely access to a full range of health care services. A landmark provision, Section 1557 marks the first time that federal civil rights law has prohibited discrimination on the basis of sex in health programs or activities, thus significantly expanding the protections afforded to individuals seeking and receiving health care. We thank the Department for issuing this proposed regulation, and look forward to working with the Department to ensure robust implementation of Section 1557's protections. The comments that follow provide a range of recommendations relating to the proposed regulation, with a particular focus on sex discrimination.

If you have any questions about our comments and recommendations, please contact Theresa Chalhoub, Health Policy Counsel, at tchalhoub@nationalpartnership.org or (202) 986-2600.

§ 92.2 Applications

Enforcement Authority

HHS has the authority to promulgate government-wide regulations for the implementation of Section 1557's antidiscrimination protections for all health programs and activities that receive federal financial assistance from any federal agency. Congress explicitly delegated rulemaking authority to HHS¹ and as such HHS's rulemaking will be given *Chevron* deference.²

HHS suggests that its regulations should reach only health programs and activities funded and administered by HHS and entities established under Title I of the ACA. However, consistent with its broad congressionally-delegated authority, HHS should apply its Section 1557 regulations to *all* federally-administered health programs and activities and all health program and activities, any part of which receive federal funding. Such broad application is not only permitted by the text of Section 1557; it is wholly appropriate as a matter of policy. Given HHS' expertise in health care, in administration of nondiscrimination laws in the context of health programs and activities, and in the implementation of Section 1557 since the ACA's passage, it is the agency best suited to issue regulations that ensure that Section 1557's intended protections be put into effect. Consistent regulations across all agencies also promote the equal and uniform application of the provision's protections to all health programs and activities that receive federal financial assistance.³

If HHS nevertheless chooses not to use its clear rulemaking authority to apply the final rule government-wide, then as lead agency for enforcement of Section 1557, it must collaborate expeditiously with other federal agencies to effect its provisions, in cooperation with the Department of Justice (DOJ) in its role as coordinating agency for implementation and enforcement of antidiscrimination rules applicable to recipients of federal financial assistance.⁴ HHS and DOJ should ensure that other agencies enter into delegation agreements or memoranda of understanding granting HHS interpretation and enforcement authority over agency-funded and agency-administered health programs; or, alternatively, move quickly to adopt the standards set out by HHS through their own rulemaking procedures. We note that delegation agreements or formal statements of policy agreement between agencies, such as Memoranda of Agreement, are far more efficient than many separate rulemakings and will ensure that Section 1557's protections are efficiently and uniformly implemented for all health programs and activities that receive federal financial assistance from any federal department. In these collaboration efforts, HHS should

² See Chevron U.S.A., Inc. v. Natural Res. Def. Council, Inc., 467 U.S. 837, 842-43 (1984).

¹ 42 U.S.C. § 18116(c) (2010). This delegation of authority specifically to HHS differs markedly from other civil rights statutes wherein Congress has directed agencies to separately develop their own implementing rules. See Title VI, Civil Rights Act, 42 U.S.C. § 2000d-1 (1964) (*"Each federal department and agency* which is empowered to extend Federal financial assistance to any program or activity . . . is authorized and directed to effectuate the provisions of section 2000d of this title"); Title IX, Education Amendments, 20 U.S.C. § 1682 (1972) (*"Each federal department and agency* which is empowered to extend Federal financial assistance to any program or activity . . . is authorized and directed to effectuate the provisions of section 2000d of this title"); Title IX, Education Amendments, 20 U.S.C. § 1682 (1972) (*"Each federal department and agency* which is empowered to extend Federal financial assistance to any program or activity . . . is authorized and directed to effectuate the provisions of section 1681 of this title"); Age Discrimination Act, 42 U.S.C. § 103(a)(4) (1998) ("[A]fter the Secretary publishes final general regulations under paragraph (a)(3), the head of each Federal department or agency which extends Federal financial assistance to any program or activity . . . shall transmit to the Secretary and publish in the Federal Register proposed regulations to carry out the provisions of section 6102 of this title"); Rehabilitation Act, 29 U.S.C. § 794(a) (2014) ("The head of each such [Executive] agency [and United States Postal Service] shall promulgate such regulations as may be necessary to carry out the amendments to this section made by the Rehabilitation, Comprehensive Services, and Developmental Disabilities Act of 1978").

³ 40 C.F.R. § 1500.3 (stating that regulations issued pursuant to the National Environmental Policy Act by the Council on Environmental Policy are "applicable to and binding on all federal agencies."); United States Merit Sys. Prot. Bd. v. FLRA, 286 U.S. App. D.C. 210 (1990) (holding that regulations promulgated by OPM pursuant to the Civil Service Reform Act are "binding on all federal agencies.").

⁴ Exec. Order No. 12,250, 3 C.F.R. 298 (1980) ("The Attorney General shall coordinate the implementation and enforcement by Executive agencies of various nondiscrimination provisions of . . . [a]ny other provision of Federal statutory law which provides, in whole or in part, that no person in the United States shall, on the ground of race, color, national origin, handicap, religion, or sex, be excluded from participation in, be denied the benefits of, or be subject to discrimination under any program or activity receiving Federal financial assistance.").

prioritize those agencies with significant involvement in health care, such as the Department of Veterans Affairs.

Exceptions from the Sex Discrimination Prohibition

The proposed rule appropriately does not incorporate any of the exceptions from Title IX. The preamble to the proposed rule seeks comment as to whether exceptions such as those set out in Title IX's protection from sex discrimination in education programs and activities should be added.⁵ HHS further asks if the rule "appropriately protects religious beliefs" and if any additional exception should be included to protect religious beliefs.⁶ No such exceptions are appropriate and we strongly object to their inclusion.

Section 1557 does not by its terms import any exceptions from Title IX or from any of the referenced statutes. It references Title VI, Title IX, Section 504, and the Age Act solely for the grounds on which they prohibit discrimination (race, color, national origin, sex, disability, and age) and for their enforcement mechanisms.⁷ Section 1557's ban against discrimination in health programs or activities includes a single exception – that it applies "[e]xcept as otherwise provided" in Title I of the ACA. The plain language of the statute bars incorporating the Title IX exceptions or any other exceptions to the prohibition of sex discrimination.

Exceptions to general rules like Section 1557's ban on discrimination must be read strictly and narrowly. For example, in considering the same "except as otherwise provided" language in the Americans with Disabilities Act (ADA), the Eleventh Circuit limited the exceptions to only those expressly mentioned in the statute. In that case, the Eleventh Circuit held that the limiting language of "except as otherwise provided" precluded the importation of more restrictive language from the Rehabilitation Act into the ADA. The same principle applies here. While the proposed regulations incorporate "exceptions" from Title VI, Section 504, and the Age Discrimination Act set out at 45 C.F.R. §§ 80.3(d), 84.4(c), 85.21(c), 91.12 through 91.15, and 91.17 through 91.18, these incorporated provisions by and large do not actually set out exceptions from the relevant antidiscrimination mandates. Rather, they clarify that certain programs targeted to meet the particular needs of specific protected groups within the protected class are not properly considered discrimination.⁸ ("The exclusion of nonhandicapped persons from aids, benefits, or services limited by Federal statute or executive order to handicapped persons or the exclusion of a specific class of handicapped persons from aids, benefits, or services limited by Federal statute or executive order to a different class of handicapped persons is not prohibited by this part.") This is different in kind from, for example, Title IX's exception completely carving out educational institutions training individuals for military service from its otherwise applicable nondiscrimination mandate.9

Moreover, as the preamble to the proposed rule states, Title IX's exceptions, which are narrowly focused on the educational context, make little sense in the context of health

⁵ Nondiscrimination in Health Programs and Activities, 80 Fed. Reg. 54,172, 54,173 (proposed Sept. 8, 2015) (to be codified at 45 C.F.R. pt. 92).
⁶ Id. at 54,173.

⁷ The Supreme Court held in a similar context that the incorporation by reference of protections from one civil rights statute into another does not mean that the limitations of the first apply to the second. *See Consolidated Rail Corp. v. Darrone,* 465 U.S. 624 (1984) (holding that Section 504's reference to Title VI's remedies, procedures, and rights did not import limitations from Title VI not expressly provided in Section 504).

⁸ See, e.g., 45 C.F.R. § 84.4(c).

⁹ See 20 U.S.C. 1681(a)(4).

programs and activities.¹⁰ For all these reasons, the final rule should not incorporate Title IX exceptions into the prohibition against discrimination on the basis of sex. The only exceptions permitted to Section 1557's sex discrimination prohibition are those exceptions expressly stated in Title I of the ACA.

We are deeply troubled by the Department's suggestions that a religious exemption may be warranted. The text of 1557 provides no authority for HHS to create an exemption on the basis of religious objection. As noted above, the statute incorporates non-discrimination protections from existing federal statutes and explicitly stipulates that Section 1557 may not invalidate state laws that provide additional protections against discrimination, demonstrating clear intent by Congress to improve access to health care services – without exception.

Any religious exemption from Section 1557's antidiscrimination requirement in general, and from the sex discrimination prohibition in particular, would be contrary to the express purpose of Section 1557. Prior to Section 1557 there were no broad federal protections against sex discrimination in health care. Section 1557 was intended to provide robust protection against discrimination on the basis of sex, as evidenced not only by the first of a kind protection provided by Section 1557 itself, but also by Congress's particular focus on addressing sex discrimination throughout the ACA.¹¹ Indeed, several ACA provisions were enacted specifically to correct insurer practices that discriminated against women either on their face or in their effect.¹² The suggestion that the Department might impose an exception only with respect to sex discrimination is particularly concerning. There is no justification for providing lesser protections from discrimination on the basis of sex, than on the bases of race, national origin, disability, and age; indeed, doing so would undermine the very purpose of Section 1557.

Establishing strong and effective regulations when implementing and enforcing Section 1557 of the ACA is key to ending sex discrimination in health care, including outright denials of health care services. These types of refusals cause great harm to women's health, safety, and autonomy. Health care providers and facilities should not be able to disregard medical standards of care and evidence-based practices, or withhold information about other providers or treatment options that could meet a patient's needs. Accordingly, not only should HHS refuse to create a specific exemption to Section 1557, HHS should – in line with Congressional intent to improve non-discrimination protections in health care – look to Section 1557 as a way to mitigate the discriminatory impact existing religious exemptions and accommodations have on women and lesbian, gay, bisexual, and transgender (LGBT) individuals.¹³

¹⁰ Nondiscrimination in Health Programs and Activities, 80 Fed. Reg. at 54,173.

¹¹ *E.g.*, 156 Cong. Rec. H1632-04 (daily ed. March 18, 2010) (statement of Rep. Lee) ("While health care reform is essential for everyone, women are in particularly dire need for major changes to our health care system. Too many women are locked out of the health care system because they face discriminatory insurance practices and cannot afford the necessary care for themselves and for their children"); 156 Cong. Rec. H1891-01 (daily ed. March 21, 2010) (statement of Rep. Pelosi) ("It's personal for women. After we pass this bill, being a woman will no longer be a preexisting medical condition."); 155 Cong. Rec. S12026 (daily ed. Oct. 8, 2009) (statements of Sen. Mikulski) ("[H]ealth care is a women's issue, health care reform is a must-do women's issue, and health insurance reform is a must-change women's issue because . . . when it comes to health insurance, we women pay more and get less."); 155 Cong. Rec. S12026-01 (daily ed. Oct. 8, 2009) (statement of Sen. Boxer) ("Women have even more at stake. Why? Because they are discriminated against by insurance companies, and that must stop, and it will stop when we pass insurance reform."); 156 Cong. Rec. H1854-02 (daily ed. March 21, 2010) (statement of Rep. Maloney) ("Finally, these reforms will do more for women's health . . . than any other legislation in my career.").

¹² 42 U.S.C. § 300gg(a) (2015) (allowing rating based only on family size, tobacco use, geographic area, and age but not based on gender, thereby eliminating a long-standing discriminatory practice); 42 U.S.C. § 300gg-3 (2012) (prohibiting preexisting condition exclusions, which were often used to discriminate against women in part because several of the conditions excluded by insurers primarily affect women and because women are more likely than men to suffer from chronic conditions), 45 C.F.R. § 147.104(e) (2015) (prohibiting discrimination in marketing and benefit design, including on the basis of sex).

¹³ See National Health Law Program, Health Care Refusals: Undermining Quality Care for Women (2010), available at <u>http://www.healthlaw.org/issues/reporductive-health/health-</u> care-refusals-undermining-care-for-women#.Vip5U9KrTIW.

The importance of non-discrimination laws and the potential harm to individuals if religious exemptions are allowed are the bases for why courts have long rejected arguments that religiously affiliated organizations can opt out of anti-discrimination requirements.¹⁴ Instead, courts have held the government has a compelling interest in ending discrimination and that anti-discrimination statutes are the least restrictive means of doing so. Indeed, the majority opinion in *Burwell v. Hobby Lobby Stores, Inc.* makes clear that the decision should not be used as a "shield" to escape legal sanction for discrimination in hiring on the basis of race because such prohibitions further a "compelling interest in providing an equal opportunity to participate in the workforce without regard to race," and are narrowly tailored to meet that "critical goal."¹⁵ The same principles apply here. Section 1557 was narrowly tailored to end longstanding discrimination in health care and must not include a religious exemption.

§92.4 Definitions

Definition of Federal Financial Assistance

We support the definition of "federal financial assistance" in the regulation, particularly the recognition that tax credits under the ACA are included. Further, we support the recognition that funding includes both payments to a covered entity as well as to individuals obtaining health insurance coverage from that entity. As is noted in our comments, this definition also supports the conclusion that Medicare Part B providers should be subject to Section 1557.

Section 1557 differs from the civil rights laws to which it refers by expressly identifying "credits, subsidies, [and] contracts of insurance" as federal financial assistance to make clear that each triggers its application. For example, Section 1557's inclusion of "contracts of insurance" as federal financial assistance means that it has broader application than some of the other civil rights laws it references. Unlike Section 1557, Title VI, Title IX, and the Rehabilitation Act either explicitly exclude or have been interpreted in some circumstances to exclude contracts of insurance as a form of federal financial assistance.¹⁶ A contract of insurance that is federal financial assistance is any contract of insurance that is funded, entered into, administered, or guaranteed by the federal government. Thus, for example, an insurance company in a marketplace that receives federally-subsidized payments such as through premium tax credits is covered by Section 1557. In addition, contracts for health insurance entered into by the federal government to provide coverage for federal employees are also federal financial assistance to the contracting insurance company. Because contracts of insurance are explicitly included in Section 1557, its

¹⁴ See e.g., Bob Jones Univ. v. United States, 461 U.S. 574 (1983) (holding that the government's interest in eliminating racial discrimination in education outweighed any burdens on religious beliefs imposed by Treasury Department regulations); *Newman v. Piggie Park Enters., Inc.,* 390 U.S. 400 (1968) (holding that a restaurant owner could not refuse to comply with the Civil Rights Act of 1964 and not serve African-American customers based on his religious beliefs); *Dole v. Shenandoah Baptist Church,* 899 F.2d 1389, 1392 (4th Cir. 1990) (holding a religious school could not compensate women less than men based on the belief that "the Bible clearly teaches that the husband is the head of the house, head of the wife, head of the family"); *Hamilton v. Southland Christian Sch., Inc.,* 680 F.3d 1316 (11th Cir. 2012) (reversing summary judgment for religious school that claimed a religious right to fire teacher for becoming pregnant outside of marriage).

¹⁵ Burwell v. Hobby Lobby Stores, Inc., 134 S. Ct. 2751, slip op. at 46 (2014).

¹⁶ Because "contracts of insurance" are not excluded in the statutory text of Section 504 but in its regulations, there are conflicting decisions about whether the regulations properly exclude it. *Compare Moore v. Sun Bank of North Florida*, 923 F.2d 1423, 1429-32 (11th Cir. 1991) (finding that because Section 504 did not expressly exclude contracts of insurance or guaranty, the regulations containing the exclusion were invalid as inconsistent with congressional intent and that the contract at issue did in fact constitute federal financial assistance) with Gallagher v. Croghan Colonial Bank, 89 F.3d 275 (6th Cir. 1996) (holding that based on the Section 504 regulation's exclusion of contracts of insurance or guaranty as federal financial assistance, a bank's receipt of reimbursement for default loans was not federal financial assistance and thus the bank was not subject to the Rehabilitation Act).

regulations must recognize this and ensure that these federal funds are not used to finance discrimination.

We do not agree, however, with the statement in the preamble that implies that a covered entity subject to Section 1557 could contract away the requirement to comply with Section 1557. The preamble states:

A health services provider that contracts with such an issuer does not become a recipient of Federal financial assistance by virtue of the contract, but would be a recipient if the provider otherwise receives Federal financial assistance.¹⁷

It seems this was written in the context of a qualified health plan (QHP) that participates in a marketplace. The result of such a policy would be that a QHP would be subject to Section 1557 while the myriad of network providers who directly provide the health services to the QHP's enrollees would not. We believe this interpretation counters prevailing understanding and is also bad policy. The result in this case would be that a QHP would have to ensure that its activities – primarily administrative in nature – do not discriminate, but it would not have to ensure its network providers do not discriminate. Since there is ample documentation of health disparities in healthcare provider settings, the potential result would be to allow a QHP to essentially gut the nondiscrimination requirements of Section 1557.

Indeed, longstanding case law in the Medicaid arena precludes this absurd result. Courts have repeatedly held that a state Medicaid agency cannot disclaim responsibility by contracting away its duties under federal law.¹⁸

Given the precedents in Medicaid and the essential need to prevent discrimination in the provision of all healthcare services, we strongly recommend that HHS explicitly require subcontractors of federal fund recipients to comply with Section 1557. Federal financial assistance does not stop being federal financial assistance once the primary recipient of federal funds cashes the payment check. It is only because that primary entity receives federal financial assistance that it will build a network of secondary providers or subcontractors to undertake additional services for which the primary entity received the federal funds. Thus, the secondary recipients must also be subject to the same nondiscrimination requirements as the primary recipient – otherwise, the nondiscrimination requirements may have no practical impact.

We recommend that the sentence in the preamble be rewritten as follows:

A health services provider that contracts with such an issuer *a covered entity* not becomes a recipient of Federal financial assistance by virtue of the contract, but would be a recipient if the provider otherwise receives Federal financial assistance.

Additionally, we are dismayed that the proposed rule continues the exclusion of Medicare Part B providers from the definition of federal financial assistance and has extended this exclusion to compliance with Section 1557. We believe the statutory text of Section 1557

¹⁷ Nondiscrimination in Health Programs and Activities, 80 Fed. Reg. at 54,174.

¹⁸ See, e.g., K.C. v. Shipman & Cansler, 716 F.3d 107, 119 (4th Cir. 2013); Carr v. Wilson-Coker, 203 F.R.D. 66, 75 (D. Conn. 2001).

specifically includes Part B providers and that the prior HHS policy excluding Part B providers from compliance with Title VI is based on an antiquated definition of federal financial assistance and thus should not be extended (and indeed should be rescinded for Title VI). We strongly urge the Department to delete the exemption for Medicare Part B providers from compliance with Section 1557 (and Title VI). For a comprehensive analysis of why Medicare Part B providers should be included in the definition of federal financial assistance, we refer the Department to comments submitted by the Leadership Conference for Civil and Human Rights.

Definition of Sex Stereotypes

Read together, HHS's proposed definitions of sex stereotypes and gender identity recognize that protections against sex discrimination should extend to people of all gender identities—including transgender and non-transgender men and women, as well as people of non-binary genders.

With regards to the definition of sex stereotypes, we commend HHS for clearly stating that discrimination based on sex stereotypes constitutes discrimination on the basis of sex, including discrimination on the basis of gender identity. Title IX has consistently been interpreted to bar discrimination based on sex stereotyping—including discrimination based on the assumption that someone conforms to a sex stereotype and discrimination against an individual because he or she departs from a sex stereotype—and Section 1557 must be understood to ban such discrimination.¹⁹ Indeed, HHS's Office for Civil Rights (OCR), charged with accepting and investigating complaints under Section 1557, has already received and resolved complaints of sex discrimination based on sex stereotypes.²⁰

The current language in the proposed rule, however, could be misread to imply that sex stereotyping discrimination only includes discrimination based on gender identity. The final rule should affirm that any form of discrimination on the basis of sex stereotypes constitutes sex discrimination – whether or not it also constitutes discrimination on the basis of gender identity – and provide examples illustrating discrimination based on sex stereotypes related to sexual orientation, traditional gender roles and family responsibilities, the diagnosis and treatment of pain, and other examples that demonstrate the range of stereotypes that can form the basis of sex discrimination.²¹ We also note that the proposed rule's definition of sex stereotypes, while accurate in describing the types of assumptions that may motivate discrimination against non-binary individuals, is cumbersome and may not be readily understood by readers unfamiliar with the issue.

Finally, to ensure that covered entities are aware of the full ramifications of § 1557's protections from sex discrimination, we also urge HHS to clarify the relationship between sex stereotypes and sexual orientation discrimination by adding language to the proposed

²⁰ OCR Enforcement under Section 1557 of the Affordable Care Act Sex Discrimination Cases, U.S. DEP'T OF HEALTH & HUMAN SERV.

http://www.hhs.gov/ocr/civilights/understanding/section1557/casesum.html/ (last visited Oct. 30, 2015).
 ²¹ See, e.g., OCR Enforcement under Section 1557 of the Affordable Care Act Sex Discrimination Cases, U.S. DEP'T OF HEALTH & HUMAN SERV.

http://www.hbs.gov/ocr/civilrights/understanding/section1557/casesum.html (last visited Nov, 5, 2015): Cheryl B. Travis, Dawn M. Howerton, & Dawn M. Szymanski, Risk Uncertainty, and Gender Stereotypes in Healthcare Decisions, 35 WOMEN & THERAPY 207-220 (2012).

¹⁹ See Dep't of Educ., Office for Civil Rights, Revised Sexual Harassment Guidance: Harassment of Students by School Employees, Other Students, or Third Parties: Title IX (January 19, 2001), available at http://www2.ed.gov/ about/offices/list/ocr/docs/shguide.html; Dep't of Educ., "Dear Colleague," 7-8 (October 26, 2010), available at http://www2.ed.gov/about/offices/list/ocr/letters/ colleague-201010 pg8.html. See also Price Waterhouse v. Hopkins, 490 U.S. 228 (1989); Lewis v. Heartland Inns of America, LL.C., 591 F.3d 1033 (8th Cir. 2010); Bibby v. Phila Coca Cola Bottling Co., 260 F.3d 257, 2652-63 (3d Cir. 2001); Smith v. City of Salem, 378 F.3d 566 (6th Cir. 2004). See also Doe v. Brimfield Grade School, 552 F. Supp. 2d 816, 823 (C.D. III. 2008); Theno v. Tonganoxi Unified School District, 377 F. Supp. 3d 952 (D. Kansas 2005); Schroeder v. Maumee Bd. Of Educ., 296 F. Supp. 2d 869, 880 (N.D. Ohio 2003); Montgomery v. Indep. Sch. Dist. No. 709, 109 F. Supp. 2d 1081, 1090-91 (D. Minn. 2000).

definition of sex stereotypes in § 92.4 that illustrates how discrimination on the basis of sex stereotypes can target individuals not only on the basis of gender, but also on the basis of sexual orientation. Indeed, federal courts and the Equal Employment Opportunity Commission (EEOC) have consistently extended sex discrimination protections to individuals treated adversely because of their sexual orientation or manifestations of that orientation.²²

Thus, we recommend revising the definition of sex stereotypes in § 92.4 as follows:

Sex stereotypes refers to stereotypical notions of gender, including expectations of how an individual represents or communicates gender to others, such as behavior, clothing, hairstyles, activities, voice, mannerisms, or body characteristics. These stereotypes can include *the* expectations that gender can only be constructed within two distinct opposite and disconnected forms (masculinity and femininity), and that gender cannot be constructed outside of this gender construct (individuals who identify as neither, both, or a combination of male and female genders) *that individuals* permanently identify with one and only one of two genders (male or *female*), and that they act in conformity with the gender expressions stereotypically associated with that gender. Sex stereotypes also include gendered expectations related to the appropriate roles or behavior of men and women, such as the expectation that women are primary caregivers, and gendered expectations related to aspects of an individual's sexual orientation identity, such as the sex of an individual's sexual or romantic partners.

Definition of Gender Identity

We also strongly support the clear affirmation of what has already been recognized across the federal government and by many federal courts: discrimination based on gender identity, gender expression, gender transition, transgender status, or sex-based stereotypes is necessarily a form of sex discrimination. Numerous federal courts have found that federal sex discrimination statutes reach these forms of gender-based discrimination.²³ In 2012, the EEOC likewise held that "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."²⁴ The Attorney General affirmed this interpretation in a 2014 memorandum.²⁵ The Office of Personnel Management and the

²² Following the decision in *Price Waterhouse v. Hopkins*, which determined that discrimination based on sex stereotypes is unlawful under the sex discrimination protections of Title VII, federal courts and the EEOC have consistently extended these protections to individuals treated adversely because their appearance, mannerisms, or conduct—including an individual's sexual orientation identity and manifestations of that identity such as being in a relationship with a person of the same sex—fell outside of the scope of stereotypical understandings of masculinity and femininity. As the EEOC describes in the *Baldwin* decision, this robust application of protections from sex stereotyping discrimination reflects the understanding that sex stereotypes can involve not only expectations for masculine and feminine pender presentation, but also beliefs related to sexual orientation, such as the stereotype that men must date and marry women, and women must date and marry men.

In Veretto v. United States Postal Service, for example, the EEOC determined that the complainant's allegation of sexual orientation discrimination was a sufficient sex discrimination claim because the discrimination was based on the sex stereotype that "marrying a woman is an essential part of being a man" and "motivated by...attitudes about stereotypical gender roles in marriage." EEOC Appeal No. 0120110873, 2011 WL 2663401, at *3 (Jul. 1, 2011). Similarly, the court in *Terveer v. Billington* rejected a motion to dismiss the plaintiff's claim of sex discrimination on the basis of sexual orientation and sex stereotyping under Title VII. *Terveer v. Billington*, 34 F.Supp.3d 100 (2014). In this 2014 case, the court held that the plaintiff's "status as a homosexual male did not conform to [his supervisor's] gender stereotypes associated with men under his supervision and that his orientation as a homosexual had removed him from [his supervisor's] preconceived definition of male." *Id.* at 116. Similarly, the Ninth Circuit has held that an openly gay employee had a valid sex discrimination claim under Title VII for sexual harassment targeting his sexual orientation. *Rene v. MGM Grand Hotel, Inc.*, 305 F.3d 1061 (9th Cir. 2002).

²³ See, e.g., Smith v. City of Salem, 378 F.3d 566, 572-75 (6th Cir. 2004); Rosa v. Park West Bank & Trust Co., 214 F.3d 213, 215-16 (1st Cir. 2000) (Equal Credit Opportunity Act); Schwenk v. Hartford, 204 F.3d 1187 (9th Cir. 2000) (Gender Motivated Violence Act). See also Statement of Interest of the United States at 14, Jamal v. Saks, No. 4:14-cv-02782 (S.D. Tex. Jan. 26, 2015).

²⁴ Macy v. Holder, E.E.O.C. App. No. 0120120821, 2012 WL 1435995, *12 (Apr. 20, 2012).

²⁵ Attorney General Memorandum, Treatment of Transgender Employment Discrimination Claims Under Title VII of the Civil Rights Act of 1964 (Dec. 15, 2014).

Departments of Labor, Education, Justice, and Housing and Urban Development have adopted the same or similar positions in internal guidance and regulations.²⁶

To date, the only court to rule on the issue in the context of Section 1557 has reached the same conclusion: the ACA's sex discrimination prohibition "necessarily" encompasses bias based on gender identity or transgender status.²⁷ This is obviously the correct application of the law's plain words. By explicitly articulating Section 1557's application to discrimination based on gender identity and sex stereotypes, the proposed rule's definition of sex discrimination will provide needed clarity and address a widespread and urgent problem.

The proposed definition of gender identity also naturally and necessarily includes nonbinary people. However, given that gender has often been assumed to be binary, a definition without explicit reference to non-binary identities may leave room for doubt or misinterpretation as to whether a natural reading would include a group that has often been ignored or marginalized. We therefore recommend that the definition of gender identity in § 92.4 be revised as follows:

Gender identity is an individual's internal sense of gender, *which may be male, female, neither, or both, or a combination of male and female, and* which may be different from that individual's sex assigned at birth. The way an individual expresses gender identity is frequently called "gender expression," and may or may not conform to social stereotypes associated with a particular gender. A transgender individual is an individual whose gender identity is different from the sex assigned to that person at birth; an individual with a transgender identity is referred to in this part as a transgender individual.

Benefit Design

We strongly support HHS's recognition that Section 1557 prohibits discriminatory benefit designs and marketing practices. (See discussion on § 92.207 below). However, we urge HHS to define benefit design, as well as marketing practices and materials, to better clarify that Section 1557's non-discrimination protections apply to the full scope of health programs and activities.

We recommend HHS add the following definitions:

Benefit designs means the coverage and benefits offered in the provision and administration of health services in a covered program or entity, including, but not limited to: prescription drug formularies; tiering structures; wellness programs; cost sharing, including co-payments and co-insurance; utilization management; quantitative treatment limits; non-quantitative treatment limits including prior authorization and step therapy; provider networks, including access to specialists; and pharmacy access.

²⁶ Department of Labor, Discrimination on the Basis of Sex, Proposed Rule, 80 Fed. Reg. 5,246 (Jan. 30, 2015); Office of Federal Contract Compliance Programs (OFCCP) Dir. 2015-1, Handling individual and systemic sexual orientation and gender identity discrimination complaints (Apr. 16, 2015); OFCCP Dir. 2014-02, Gender Identity and Sex Discrimination (Aug. 19, 2014); See 5 C.F.R. §§ 300.102-300.103, 335.103, 410.302, 537.105; Statement of Interest of the United States at 5, G.G. *ex rel. Grimm v. Gloucester Cty. Sch. Bd.*, No. 4:15cv54 (E.D. Va. *filed June* 29, 2015); Statement of Interest of the United States at 12, *Tooley v. Van Buren Pub. Sch.*, No. 2:14-cv-13466 (E.D. Mich. *filed* Feb. 24, 215); Dep't of Educ., *Title IX Resource Guide*, 1 (Apr. 2015); Dep't of Educ., "Questions and Answers on Title IX and Sexual Violence," 5 (Apr. 29, 2014); See Dep't of Educ., "7-8 (Oct. 26, 2010); *HUD v. Toone*, Charge of Discrimination, FHEO Nos. 06-12-1130-8; 06-121363-8 (Ofc. Hear. & App. Aug. 15, 2013); Memorandum from John Trasviña to FHEO Regional Directors, Assessing Complaints that Involve Sexual Orientation, Gender Identity, and Gender Expression (June 2010).

²⁷ Rumble v. Fairview Health Services, No. 14-cv-2037, 2015 WL 1197415, *2 (D. Minn. Mar. 16, 2015).

Marketing practices means the activities of any covered entity or program designed to encourage individuals to enroll in or seek services from a covered entity.

Marketing materials means any written or oral communication undertaken by the covered entity with the intent of having individuals enroll in or seek services from a covered entity. Marketing materials includes at least the following materials:

- (1) General audience materials, such as general circulation brochures, direct mail, newspapers, magazines, television, radio, billboards, yellow pages, or the Internet
- (2) Marketing representative materials, such as scripts or outlines for telemarketing or other presentations
- (3) Presentation materials, such as slides and charts
- (4) Promotional materials, such as brochures or leaflets, including materials circulated by physicians, other providers, or third-party entities
- (5) Membership communications and communication materials including membership rules, subscriber agreements, enrollee handbooks and wallet card instructions to enrollees (e.g., Annual Notice of Change (ANOC), Evidence of Coverage (EOC), Provider/Pharmacy Directory)
- (6) Communications to enrollees about contractual changes, and changes in providers, premiums, benefits, plan procedures
- (7) Membership activities (e.g., materials on rules involving non-payment of premiums, confirmation of enrollment or disenrollment, or non-claim specific notification information).

Employee Health Benefit Program

There are multiple types of programs, activities and benefits that employers offer to employees that are health benefit programs. The final rule should clearly state that benefits that are considered excepted benefits under the Health Insurance Portability and Accountability Act, as defined in 45 C.F.R. §148.220, may still constitute an employee health benefit program under Section 1557. While the proposed definition expressly and appropriately includes long-term care coverage, other critical forms of health coverage are not expressly included. Employers offer various types of health benefits, including, but not limited to, vision insurance, dental insurance, disease-specific insurance, and fixed indemnity plans. These types of plans provide benefits to employees for health services and are thus clearly health programs. We recommend that the definition of "employee health benefit program" expressly includes these types of benefits. In addition, the definition should be clear that for purposes of Section 1557, "employee health benefit program" includes voluntary employer-provided individual or group insurance that is health-related, even if the employee pays the entire cost. As long as the employer is making payroll deductions and forwarding such deductions to the insurer, the employer is taking administrative steps to make the plan available to the employees and such a program constitutes an "employee health benefit program."

We commend the Department for including employer-provided or -sponsored wellness programs in the definition of "employee health benefit program." Wellness programs present various opportunities for discrimination, especially when they include financial incentives or penalties. To ensure Section 1557's protections apply to all employer-provided or -sponsored wellness programs, we recommend that the final rule clarify that wellness programs separate from the employee health benefit plans are still an "employee health benefit program" under Section 1557. An example of a wellness program that is not a part of the health benefit plan would be an employer providing an incentive, such as a gift card, to each employee that receives a flu shot or participates in an exercise initiative.

Finally, we also recommend that the final regulations add language to the "employee health benefit program" definition that explicitly includes any other program an employer uses to reimburse employee health costs, including programs that are funded through employee payroll deductions without any employer contribution. The addition of this language will ensure that flexible spending accounts, health spending accounts, health reimbursement accounts and any other system an employer uses to pay for health-related costs is considered an employee health benefit program.

Thus, we recommend clarifying in the preamble to the final regulations that an employee health benefit program includes voluntary health-related programs in which the employee pays the entire cost through a payroll deduction. In addition, we recommend § 92.4 be rewritten as follows:

Employee health benefit program. The term "employee health benefit program" means (1) health benefits coverage or health insurance provided to employees and/or their dependents established, operated, sponsored or administered by, for, or on behalf of one or more employers, whether provided or administered by entities including but not limited to, a health insurance issuer, group health plan (as defined in the Employee Retirement Income Security Act of 1974 (ERISA, at 29 U.S.C. 1191(a)), a third party administrator, or an employer; (2) an employer-provided or sponsored wellness program, including programs that are not part of health benefits coverage or health insurance; (3) an employer-provided health clinic; or (4) long term care coverage or insurance provided or administered by an employer, group health plan, third party administrator, or health insurance issuer; (5) dental or vision coverage or insurance provided or administered by an employer, group health plan, third party administrator, or health insurance issuer; coverage or insurance for a specific disease or illness (as defined in 45 C.F.R. § 148.220(b)(3)) provided or administered by an employer, group health plan, third party administrator, or health insurance issuer; fixed indemnity coverage or insurance provided or administered by an employer, group health plan, third party administrator, or health insurance issuer; or (6) any other program an employer uses to reimburse employees or employees' dependents for health-related costs including, but not limited to, flexible spending accounts, health savings accounts and health reimbursement accounts.

Health Program or Activity

We strongly support the proposed regulation's reliance on the Civil Rights Restoration Act in defining "health program or activity".

Because Section 1557 is structured similarly to Title IX, the Civil Rights Restoration Act's application in the Title IX context is instructive for the interpretation of Section 1557. Like Title IX, Section 1557 is written with a term that modifies the phrase "program or activity" ("education" in Title IX, "health" in Section 1557). Under Title IX and the Civil Rights

Restoration Act, if any part of an entity that has education as its primary purpose receives federal financial assistance, it may not discriminate in any of its activities. If any part of an entity that does not have education as its primary purpose receives federal financial assistance for any purpose, it may not discriminate in its education programs or activities.²⁸ Similarly, under Section 1557 and the Civil Rights Restoration Act, if any part of an entity that has health care or health insurance as its primary purpose receives federal financial assistance, it may not discriminate in any of its activities. For a covered entity that does not have health as its primary purpose, Section 1557 prohibits discrimination in that entity's health programs or activities, as long as any part of the entity itself receives federal financial financial assistance. In order to make clear the scope of "health program or activity," we urge that the reference to the Civil Rights Restoration Act be included in the rule itself and not only the preamble.

In addition, as written, the proposed regulation relies on the term "health" to define "health program or activity" without providing a definition of "health." We recommend additional language be added to the definition to make the scope of the application of Section 1557 clear. To effectuate Section 1557's nondiscrimination principle, the determination of whether a program is a "health" program or activity should be consistent with existing interpretations of the meaning of the term "health" offered by the World Health Organization (WHO). WHO defines health to include not just the absence of disease but also "physical, mental, and social well-being."²⁹ Based on this widely accepted definition of health, a health program or activity includes any program or activity that is designed to promote, maintain, or prevent the decline of an individual's or a population's physical, mental, or social well-being.

The definition also should clarify that Medicaid is not the only state or local government program that may be a health program or activity. Additional services or programs operated by state and local governments, such as the Children's Health Insurance Program (CHIP), public health activities, and health programs at state based universities, are health programs or activities, and the definition should not suggest otherwise. We therefore recommend additional language that clarifies that additional state or local government programs may be health programs or activities.

We support the Department's interpretation of "health programs and activities" to include health research. While progress has been made, the discriminatory exclusion of women from medical research continues to harm women's health. Intentional exclusion and underinclusion of women in clinical trials, including the failure to adequately recruit women to participate in medical research, is a long-standing and well-documented problem.³⁰ For

²⁸ See, e.g., Jeldness v. Pearce, 30 F.3d 1220, 1226 (9th Cir. 1994) (recognizing that the recipient of federal financial assistance need not be educational in nature for an education program or activity operated by the non-educational entity to be covered by Title IX); Dep't of Justice, *Title IX Legal Manual* (2001), *available at* http://www.justice.gov/crt/about/cor/coord/ixlegal.php. As the Senate Report for the CRRA explains:

If a private hospital corporation is extended federal assistance for its emergency room, all the operations of the hospital, including for example, the operating rooms, the pediatrics department, admissions, discharge offices, etc., are covered under Title VI, section 504, and the Age Discrimination Act. Since Title IX is limited to education programs or activities, it would apply only to the students and employees of educational programs operated by the hospital, if any.

S. Rep. 100-64, at 18 (1987). The Senate Report provides another example: "If corporation X is a chain of five nursing homes, federal financial assistance to one of the nursing homes will require compliance with the civil rights laws in all of the operations of all five of the nursing homes, subject to the education limitation in Title IX described in the preceding example." *Id.*

²⁹ Constitution of the World Health Organization, June 22, 1946, 14 U.N.T.S. 185.

³⁰ See Barriers to Women's Participation in Clinical Trials and SWHR Proposed Solutions, SOC'Y FOR WOMEN'S HEALTH RES., available at http://swhr.org/barriers-to-womenspartipication-in-clinical-trials-and-swhr-proposed-solutions/. In 1993, Congress enacted the National Institutes of Health Revitalization Act of 1993 which requires, among other things, that women and minorities be appropriately included in NIH clinical trials. 42 U.S.C. §§ 283-300 (2012). The next year, Congress created the Office of Women's Health in the Food and Drug Administration (FDA) which has a mission of protecting and advancing the health of women through policy, science and outreach, and advocacy for the inclusion of women in clinical trials as well as sex/gender and subpopulation analyses. See U.S. GEN. ACCOUNTING OFFICE, Women's Health: Women Sufficiently Represented in New Drug Testing, but FDA Oversight Needs Improvement (2001) (describing inclusion of women in FDA activities); Paula Johnson et al., Mary Horrigon Connors Ctr. for

example, although heart disease is the leading cause of death for women in the United States,³¹ women are inadequately represented in heart disease trials and have been for some time.³² One study found that male participants outnumbered female participants by a ratio of 3.66 to 1³³ and another found that only one-third of studies report sex-specific results.³⁴

Failure to include sufficient numbers of women in medical research to determine whether sex differences in risk factors and responses to treatments exist results in women receiving inadequate care compared to their male counterparts.³⁵ Research that uses an exclusively male model to evaluate and understand women's health needs means that women cannot receive medical care of the same quality provided to men.

We further appreciate the Department's recognition that research protocols may sometimes appropriately exclude or target particular populations based on compelling nondiscriminatory justifications related to health and safety, scientific study design, or legitimate research purposes. However, we urge the Department to monitor to ensure that federally funded sex-specific research designs are narrowly tailored to accomplish an essential health goal.

We recommend that the Department amend § 92.4 by inserting the following language to the definition for health program or activity:

Health program or activity means the provision or administration of health-related services or health-related insurance coverage and the provision of assistance to individuals in obtaining health-related services or health-related insurance coverage. Pursuant to the Civil Rights Restoration Act and consistent with analogous Title IX protections, for example, for an entity principally engaged in providing or administering health services or health insurance coverage, all of its operations are considered part of the health program or activity, except as specifically set forth otherwise in this part. Such entities include a hospital, health clinic, group health plan, health insurance issuer, physician's practice, community health center, nursing facility, residential or community-based treatment facility, or other similar entity. A health program or activity also includes all of the operations of *Medicare*, a State Medicaid program, the Children's Health Insurance Program, and all of the operations of other health programs, including public health programs, operated by state and local governments. "Health related" means designed to promote, maintain, or prevent the decline of an individual's or population's physical, mental, or social well-being.

Women's Health & Gender Biology, Sex-Specific Medical Research Why Women's Health Can't Wait (2014), available at

http://www.brighamandwomens.org/Departments_and_Services/womenshealth/ConnorsCenter/Policy/ConnorsReportFINAL.pdf (describing the impact of the NIH Revitalization Act on women's inclusion in clinical trials and where improvement is still needed).

³¹ Leading Causes of Death in Females United States, 2013, U.S. DEP'T OF HEALTH & HUMAN SERVS., CTRS. FOR DISEASE CONTROL & PREVENTION, available at http://www.cdc.gov/women/lcod/2013/index.htm (last updated July 10, 2015).

³² Paula Johnson et al., Mary Horrigon Connors Ctr. for Women's Health & Gender Biology, Sex-Specific Medical Research Why Women's Health Can't Wait 12 (2014), available at http://www.brighamandwomens.org/Departments_and_Services/womenshealth/ConnorsCenter/Policy/ConnorsReportFINAL.pdf ("Only 35 percent of clinical trial subjects in cardiovascular research are women, and just 31 percent of those studies report outcomes by sex."); see also Esther S.H. Kim & Venu Menon, Status of Women in Cardiovascular *Clinical Trials*, 29 ARTERIOSCLEROSIS, THROMBOSIS, AND VASCULAR BIOLOGY 279 (2009), http://atvb.ahajournals.org/content/29/3/279.long.

³³ Nahid Azad & Sania Nishtar, A Call for a Gender Specific Approach to Address the Worldwide Cardiovascular Burden, 1 PREVENTION & CONTROL 223, 225 (2005).

³⁴ Chiara Melloni et al., *Representation of Women in Randomized Clinical Trials of Cardiovascular Disease Prevention*, 3 CIRCULATION: CARDIOVASCULAR QUALITIES AND OUTCOMES 110 (2010), *available at* http://circoutcomes.ahajournals.org/content/early/2010/02/16/CIRCOUTCOMES.110.868307.full.pdf (finding that sex-specific results were included in only 31 percent of primary trial publications).

³⁵ Paula Johnson et al., Mary Horrigon Connors Ctr. for Women's Health & Gender Biology, Sex-Specific Medical Research Why Women's Health Can't Wait 8 (2014), available at http://www.brighamandwomens.org/Departments and Services/womenshealth/ConnorsCenter/Policy/ConnorsReportFINAL.pdf.

On the Basis of Sex

We strongly support the proposed regulation's definition of "on the basis of sex" to include discrimination on the basis of "pregnancy, false pregnancy, termination of pregnancy, or recovery therefrom, childbirth or related medical conditions." Section 1557's prohibition of sex discrimination necessarily includes discrimination based on pregnancy—as the preamble rightly notes.³⁶ Pregnancy discrimination constitutes sex discrimination under Title IX³⁷ and other civil rights statutes such as Title VII,³⁸ and also necessarily constitutes sex discrimination under Section 1557. These laws prohibit discrimination based on pregnancy itself, as well as pregnancy-related conditions.³⁹

We appreciate the explicit recognition that gender identity and sex stereotypes fall within the definition of sex in Section 1557. Including these clear protections in the regulations will be a powerful tool in combating discrimination against transgender and gendernonconforming people. To effectively address the full scope of discrimination against LGBT individuals, we very strongly urge HHS to also clarify that the protections against sex discrimination in Section 1557 include discrimination on the basis of sexual orientation.

The absence of explicit protections from discrimination on the basis of sexual orientation in the proposed regulation not only ignores the health crisis facing lesbian, gay, and bisexual (LGB) people, but also fails to reflect and reinforce important steps that HHS has already taken under the ACA to explicitly protect LGB people from discrimination on the basis of their sexual orientation. Moreover, the exclusion of sexual orientation from the definition of sex in the proposed rule is out of step with current legal doctrine concerning sexual orientation that has been adopted by other federal agencies and federal courts.

HHS has already used its regulatory authority under the ACA to take some steps to address these issues by clarifying that the ACA prohibits insurance carrier practices that discriminate on the basis of sexual orientation.⁴⁰ In 2014, for example, the Centers for Medicare and Medicaid Services (CMS) issued guidance under regulations interpreting Section 2702 of the Public Health Service Act (PHSA), as amended by the ACA, to require health insurance carriers offering non-grandfathered group or individual health coverage in all states to offer legally married same-sex couples the same spousal or family benefits available to different-sex couples.⁴¹ The plain language of PHSA § 2702 simply requires insurance carriers to guarantee the availability of coverage unless certain exceptions (e.g., open enrollment periods) apply. The regulations promulgated under this section, at 45 C.F.R. 147.104(e), clarify that this requirement means carriers cannot employ marketing

https://www.americanprogress.org/issues/lgbt/report/2015/04/30/112169/open-doors-for-all/.

⁴¹ Center for Consumer Information and Insurance Oversight, *Frequently Asked Questions on Coverage of Same-Sex Spouses* (2014), *available at* https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/frequently-asked-questions-on-coverage-of-same-sex-spouses.pdf.

³⁶ Nondiscrimination in Health Programs and Activities, 80 Fed. Reg. at 54,177.

³⁷ 34 C.F.R. § 106.40(b)(1) (2012). See also Pfeiffer v. Marion Ctr. Area Sch. Dist., 917 F.2d 779, 784 (3d Cir. 1990); Hogan v. Ogden, No. CV-06-5078-EFS, 2008 U.S. Dist. LEXIS 58359, at *26 (E.D. Wash. July 30, 2008); Chipman v. Grant County Sch. Dist., 30 F. Supp. 2d 975, 977-78 (E.D. Ky. 1998); Hall v. Lee Coll., 932 F. Supp. 1027, 1033 n.1 (E.D. Tenn. 1996); Cazares v. Barber, Case No. CIV-90-0128-TUC-ACM, slip op. (D. Ariz. May 31, 1990); Wort v. Vierling, Case No. 82-3169, slip op. (C.D. Ill. Sept. 4, 1984), aff d, 778 F.2d 1233 (7th Cir. 1985).

³⁷ 34 C.F.R. § 106.40(b)(1) (2012). See also Pfeiffer v. Marion Ctr. Area Sch. Dist., 917 F.2d 779, 784 (3d Cir. 1990); Hogan v. Ogden, No. CV-06-5078-EFS, 2008 U.S. Dist. LEXIS 58359, at *26 (E.D. Wash. July 30, 2008); Chipman v. Grant County Sch. Dist., 30 F. Supp. 2d 975, 977-78 (E.D. Ky. 1998); Hall v. Lee Coll., 932 F. Supp. 1027, 1033 n.1 (E.D. Tenn. 1996); Cazares v. Barber, Case No. CIV-90-0128-TUC-ACM, slip op. (D. Ariz. May 31, 1990); Wort v. Vierling, Case No. 82-3169, slip op. (C.D. Ill. Sept. 4, 1984), aff d, 778 F.2d 1233 (7th Cir. 1985).

^{38 42} U.S.C. § 2000e(k) (2012).

³⁹ See, e.g., 42 U.S.C. § 2000e(k) (2012); see also 29 C.F.R. pt. 1604 app.; Newport News Shipbuilding & Dry Dock v. EEOC, 462 U.S. 669 (1983).
⁴⁰ Kellan Baker, Open Doors for All: Sexual Orientation and Gender Identity Protections in Health Care (Apr. 2015), available at

practices or benefit designs that discriminate on the basis of factors that include sexual orientation. To ensure that the protections of Section 1557 reinforce and harmonize with existing nondiscrimination protections under the ACA—and to protect LGB people not only in gaining access to health insurance coverage but also in successfully accessing health care—the final rule should include explicit protection from discrimination on the basis of sexual orientation.

We therefore recommend that the definition of "on the basis of sex" in § 92.4 be revised as follows:

On the basis of sex includes, but is not limited to, on the basis of pregnancy, false pregnancy, termination of pregnancy, or recovery therefrom, childbirth or related medical conditions, sex stereotyping, *sexual orientation*, or gender identity.

Similarly, we recommend that language be added to § 92.4 defining sexual orientation as follows, adapted from the Equality Act⁴²:

Sexual orientation means homosexuality, heterosexuality, or bisexuality.

Electronic and Information Technology

The proposed regulations' substantive provisions on electronic and information technology focus on nondiscrimination and accessibility for individuals with disabilities.⁴³ Similarly, the proposed definition of "electronic and information technology" is based on regulations implementing Section 508 of the Rehabilitation Act of 1973, namely 36 C.F.R. § 1194.4, promulgated in 2000.⁴⁴

Section 1557 prohibits discrimination on the basis of all of the grounds it incorporates, and the definition of electronic health information technology must have equally broad scope and application. As we explain below, Section 1557 is not limited to discrimination on the basis of disability alone in its application to electronic health information technology or any other covered program or activity.

Because the proposed definition is based on regulations implementing Section 508, it does not reflect current, broader definitions of electronic health information technology. We refer HHS to the broader definition of "health information technology" in the Health Information Technology Economic and Clinical Health (HITECH) Act of 2009⁴⁵ governing adoption and use of electronic health records and information exchange nationwide:

We therefore recommend amending the definition of "electronic and information technology" to read as follows:

⁴⁴ *Id.* at 54,174.

⁴² H.R. 3185, 114th Cong. § 1101 (2015).

⁴³ Nondiscrimination in Health Programs and Activities, 80 Fed. Reg. at 54,219 (proposed § 92.204); *Id.* at 54,187-88.

⁴⁵ Health Information Technology for Economic and Clinical Health (HITECH) Act of 2009, Title XIII of Division A and Title IV of Division B of the American Recovery and Reinvestment Act of 2009, Pub. L. No. 111-5, §§ 13001-13424 (February 17, 2009) (codified at 42 U.S.C. §§ 201 note, 300jj - 300jj - 300jj - 1, 17901-17953).

Electronic and information technology includes hardware, software, integrated technologies or related licenses, intellectual property, upgrades, or packaged solutions sold as services that are designed for or support the use by health care entities or patients for the electronic creation, maintenance, access, or exchange of health information.⁴⁶information technology and any equipment or interconnected system or subsystem of equipment that is used in the creation, conversion, or duplication of data or information.

(1) The term

§ 92.5 Assurances Required

We strongly support having assurances required for compliance with Section 1557 for those receiving federal funds. In addition, we recommend requiring data collection to demonstrate compliance with Section 1557.

Data collection assists in ensuring compliance with nondiscrimination requirements. We urge HHS to add specific demographic data collection requirements to the rule for all covered entities. Covered entities should be required to collect data on race, ethnicity, language, sex, gender identity, sexual orientation, disability status, and age. Further, covered entities should be required to assess (and update their assessments of) the populations they serve so that they can appropriately plan how to meet the needs of their clients/patients.

We recommend that HHS prioritize data collection requirements, for the purposes of nondiscrimination compliance and enforcement, in two key areas that will result in the greatest impact: (1) federally-supported health care providers (at the point of care); and (2) publicly administered health programs (at enrollment). Data collection by federallysupported health care providers as well as health care programs like Medicare, Medicaid, CHIP and the health insurance marketplaces will also be critical to ensuring entities comply with all civil rights laws, including Section 1557. Requiring data collection enables the enforcement of the civil rights laws that prohibit discriminatory actions by health programs or activities.

HHS should provide guidelines as to how to conduct an assessment and what data may be readily available to covered entities. As part of data collection provisions and guidelines, HHS should address the following issues:

- Training staff in collecting demographic data, including explaining why this data is being collected;
- Adopting clear privacy and nondiscrimination protections;
- Safeguarding that patient/enrollee reporting of demographic data be voluntary; and
- Supporting analyses based on multiple demographic variables.

While some providers may raise concerns about the practicability of collecting demographic data collection at the point of care, we believe collecting this data is a reasonable requirement. Indeed, many practitioners are already collecting several key forms of data,

^{46 42} U.S.C. § 300jj.

either voluntarily or because of existing laws and regulations at both the state and federal level. $^{47}\,$

In addition, the federal government has recently taken steps to ensure more uniform demographic data collection requirements at the point of care. The Medicare and Medicaid Electronic Health Record (EHR) Incentive Program requires participating Medicare and Medicaid providers and hospitals to record patient demographic data, including race, ethnicity, preferred language, and gender.⁴⁸ Recent data on the Medicare and Medicaid EHR Incentive Program show that 95.1 percent of eligible physicians and 97.3 percent of eligible hospitals met the requirements for recording these patient demographic data in 2014,⁴⁹ demonstrating that providers are already collecting standardized demographic data. Furthermore, the data collection requirements have just become more comprehensive. For Stage 3 beginning in 2018 (optional in 2017) – which all eligible Medicare providers must comply with or face reimbursement reductions – providers will collect demographic data using improved and more granular standards for race, ethnicity, gender, language, sexual orientation, and gender identity.⁵⁰

We also believe that requiring data collection at enrollment in publicly administered health programs – including Medicare, Medicaid, CHIP and the marketplaces – is not only practicable but critical to ensuring equal care is provided to all participants and discrimination does not impact access to care.

As an overarching recommendation, we recommend HHS include a specific data collection requirement in § 92.5. In addition, we suggest HHS provide detailed information for recipients about how to appropriately collect this data. For detailed recommendations on how HHS should instruct covered entities to collect data, we refer the Department to comments submitted by the Leadership Conference for Civil and Human Rights.

§ 92.8 Notice Requirements

§ 92.8(1)

To ensure that covered entities are adequately aware of their responsibility to notify the individuals they serve and the public at large of the full scope of applicable nondiscrimination protections under Section 1557, the language in § 92.8(a)(1) and the proposed Appendix to Part 92 ("Sample Notice Informing Individuals about Nondiscrimination and Accessibility Requirements") must reflect the full scope of protected classes described in § 92.4.

§ 92.8(c) Translation of Sample Notices

⁴⁷ Nationally, 82 percent of hospitals already collect race and ethnicity data and 67 percent collect data on primary language. Hasnain-Wynia, R., Pierce, D., Haque, A., Hedges Greising, C., Prince, V., Reiter, J. (2007) *Health Research and Educational Trust Disparities Toolkit, available at* <u>http://www.hretdisparities.org</u>. Twenty-two states have passed regulations requiring hospitals to collect race, ethnicity, and language data. *Id*. Grantees of the Health Resources and Services Administration's (HRSA's) primary care programs, like community health centers, also are required to collect and report patient demographic data.

⁴⁸ 42 C.F.R. § 495.20(d)(7) (recording demographics – preferred language, gender, race, ethnicity, and date of birth – is required before 2015); Dep't of Health and Human Serv., Electronic Health Record Incentive Program—Stage 3 and Modifications to Meaningful Use in 2015 Through 2017, 80 Fed. Reg. 62,762, 62,784-85 (Oct. 16, 2015) (in Stage 3, demographic data are captured in more advanced functions through inclusion of electronic summaries of care provided in transitions of care and referrals).
⁴⁹ Dep't of Health and Human Services, *Medicare and Medicaid EHR Incentive Programs*, at 6, 8 (Oct. 6, 2015, *available at* <u>https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/Downloads/HITPC October2015 Fulldeck.pdf.</u>

⁵⁰ Dep't of Health and Human Serv., Electronic Health Record Incentive Program—Stage 3 and Modifications to Meaningful Use in 2015 Through 2017, 80 Fed. Reg. 62,762, 62,858 (Oct. 16, 2015) (under the 2015 Edition final rule, certified EHR technology captures even more granular demographic data which supports improved, patient-centered care and reducing health disparities – including more granular data on race and ethnicity and data extending beyond a more limited understanding of clinical care data, such as collection of social, psychological, and behavioral health information).

The proposed rule provides that the notice described in § 92.8(a) shall be translated for covered entities by the Director in the "top 15 languages spoken by individuals with limited English proficiency nationally." Using this national standard will leave out many languages spoken by large numbers of individuals with limited English proficiency and fails to accurately ensure meaningful access. As an alternative, we recommend that translated notices should be made available in the top 15 languages spoken by individuals with limited English proficiency in each state. Relying on state data would require translating the notice into additional languages and would include languages with significant representation in certain states. Adopting this standard will broaden the scope of covered languages and ensure that a much larger population of limited English proficient individuals in a covered entity's service area is reached.

§ 92.8(d) Tagline Languages

As with the translated notices, we recommend that the taglines be made available in the top 15 languages spoken by limited English proficient persons by state. This would not be overly burdensome, as it would require translation into approximately 10 to 15 additional languages.

§ 92.8(f)(1) Location of Required Notices

Consistent with Title VI, its implementing regulations and the HHS Limited English Proficiency (LEP) guidance, the proposed rule requires that covered entities post the English language notice and taglines in a conspicuously visible font size in a variety of publications. More specifically, the proposed rule requires that the English notice and taglines be included in "significant publications or significant communications targeted to beneficiaries, enrollees, applicants or members of the public" and provides examples of such documents. The proposed rule seeks comment on how to define the scope of significant publications and communications.

For example, at minimum, the following constitute vital or significant publications: Evidence of Coverage, Summary of Benefits and Coverage, Explanation of Benefits, internal claims appeals for Qualified Health Plans, Benefits of Coverage, provider lists, and other standard member materials and drug labels on prescription medicines. We urge the Department to include them in the proposed rule; however, we do not intend this list to be exhaustive. Taglines should be positioned toward the front of these vital and significant publications.

§ 92.101 Discrimination Prohibited

Employment Discrimination

As currently written, the proposed rule would not apply to discrimination by a covered entity against its own employees except for some employee health benefit programs.⁵¹ We strongly disagree with this statement. There is no basis in the text of Section 1557 that permits this exclusion. The final rule should eliminate this exclusion and make clear that

⁵¹ Nondiscrimination in Health Programs and Activities, 80 Fed. Reg. at 54,180.

Section 1557's prohibition against discrimination applies to employment discrimination by a covered entity.

Principles of statutory interpretation support the inclusion of employment discrimination under Section 1557. Indeed, the plain meaning of Section 1557 reaches employment discrimination.⁵² Section 1557 provides that an individual shall not "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)." There is no carve-out in the text for employment discrimination. Rather, the text of the statute prohibits all "discrimination" under "any health program or activity" receiving funds under the ACA. The statute uses broad terminology that extends Section 1557's protections to any "individual" (not limited to a participant or a beneficiary) "under" (not limited to those participating or enrolled in) "any health program or activity." To carve out employment discrimination, without any statutory language doing so, would go against the plain meaning of the statute.⁵³

Moreover, courts have found that related anti-discrimination statutes reach employment discrimination, and those findings are applicable here. Courts have interpreted similar statutory language in Title IX to include employment discrimination. In North Haven Bd. of Ed. v. Bell, 456 U.S. 512 (1982), the Supreme Court relied on both the statutory language and legislative history of Title IX to conclude that the statute prohibited employment discrimination. Just as the court found that the use of "person" in Title IX – as opposed to "student" or "beneficiary" – suggested a more inclusive Congressional purpose, so, too, does the use of "individual" instead of "participant" or "beneficiary" in 1557.54 In addition, the court in North Haven reasoned that it should not read an exception for employee coverage where one was not "expressly nor impliedly" provided, because Congress could have "easily" adopted narrower language if it chose to restrict Title IX's scope.⁵⁵

Indeed, even where employment exceptions have been carved into anti-discrimination statutes, they have not been interpreted as outright bans. Without justification, the proposed rule reads an employment discrimination exemption into Section 1557 that is broader than any found in the referenced statutes. Though the proposed rule aims for consistency with the statutes it encompasses, none of those statutes include an outright exemption for employment discrimination. Even Title VI, which limits the application of its anti-discrimination provisions in the employment context, prohibits employment discrimination where the "primary objective of the Federal financial assistance is to provide employment."⁵⁶ Further, the regulations provide that even when employment is not the primary objective of federal funding, Title VI will bar discriminatory practices that "tend... . on the grounds of race, color, or national origin, to exclude persons from participation in,

⁵² See Caminetti v. U.S., 242 U.S. 470, 485 (1917) ("It is elementary that the meaning of a statute must, in the first instance, be sought in the language in which the act is framed."); U.S. v. Ron Pair Enterprises 489 U.S. 235, 241 (quoting Caminetti: "where . . . the statute's language is plain, 'the sole function of the courts is to enforce it according to its terms.""); see also 2A Sutherland Statutory Construction § 46:1 (7th ed.).

⁵³ See Swarts v. Siegel, 117 F. 130 (8th Cir. 1902) ("There is no safer nor better settled canon of interpretation than that when language is clear and unambiguous it must be held

Mt. Hood Stages, Inc., 437 U.S. 322, 330 . . . Section 901(a)'s broad directive that "no person" may be discriminated against on the basis of gender appears, on its face, to include employees as well as students.").

North Haven Bd. of Ed. v. Bell, 456 U.S. at 521; see also Consolidated Rail Corp. v. Darrone, 465 U.S. 624, 635 (1984) (finding same with respect to Section 504 and noting that it would be "anomalous" to conclude that Section 504 "silently adopted a drastic limitation on the handicapped individual's right to sue federal grant recipients for employment discrimination."). 56 42 U.S.C. § 2000d-3.

to deny them the benefits of or to subject them to discrimination under the program receiving Federal financial assistance."⁵⁷ Given the extent to which Title VI reaches employment discrimination, a wholesale exemption in Section 1557 is not consistent with the statutes it invokes.

Finally, employment discrimination under Section 1557 could be enforced in conjunction with related anti-discrimination statutes. Executive Order (EO) 12250 provides a framework for coordinating the implementation of Section 1557 with other antidiscrimination laws. EO 12250 enables the "consistent and effective implementation of various laws prohibiting discriminatory practices."⁵⁸ Under EO 12250, the Attorney General is responsible for "coordinat[ing] the implementation and enforcement by Executive agencies of various nondiscrimination provisions" of, among other statutes, Title IX, Title VI, and Section 504 of the Rehabilitation Act – all of which have been invoked by Section 1557 for application in the health care context.⁵⁹ To harmonize agency implementation of these laws, the Federal Coordination and Compliance Section of DOJ is tasked with daily implementation of the EO.⁶⁰ The regulations guiding its work provide common definitions - for example, "covered employment" - and procedures for efficient cross-agency practices.⁶¹ Furthermore, the Section has issued directives and formed an interagency working group to ensure efficient collaboration among the "civil rights staff of the federal funding agencies."62 Given this robust mechanism for coordination across antidiscrimination statutes, incorporating Section 1557 into the EO's existing framework would provide a streamlined approach for enforcing its employment discrimination provisions.

Sex Discrimination

Section 1557 marks the first time that federal law contains a broad-based prohibition of sex discrimination in health programs or activities. Sex discrimination takes many forms and can occur at every step in the health care system—from obtaining insurance coverage to receiving proper diagnosis and treatment. This discrimination seriously harms women and threatens their health, causing them to pay more for health care and to risk receiving improper diagnoses and less effective treatments.

It is critical that regulations issued pursuant to this new statute reflect the longestablished jurisprudence of strong protections against sex discrimination in federal law. Regulations, guidance, and case law under Title VII of the Civil Rights Act of 1964 – including the Pregnancy Discrimination Act (PDA) and Title IX of the Education Amendments of 1972 – appropriately inform the interpretation of what constitutes sex discrimination under Section 1557, particularly to the extent that these sources address issues specifically relevant to health programs and activities. Moreover, many entities are directly bound by these antidiscrimination laws in addition to Section 1557, which strongly counsels toward interpreting Section 1557 to provide at least as much protection against

⁶¹ 28 C.F.R. § 42.401 et seq.

 ⁵⁷ 28 C.F.R. § 42.104(c)(2); see United States v. Jefferson County Board of Education, 372 F.2d 836, 883 (5th Cir. 1966) ("Faculty integration is essential to student desegregation.").
 ⁵⁸ Exec. Order No. 12,250, 3 C.F.R. 298 (1980).

⁵⁹ *Id.; see* 42 U.S.C. § 18116 (2012).

⁶⁰ See Dep't of Justice, Executive Order 12250 Coordination of Grant-Related Civil Rights Statutes (2005), available at http://www.justice.gov/crt/federal-coordination-and-compliance-section-212.

⁶² Memorandum from Jocelyn Samuels, Acting Assistant Attorney Gen., to Title VI Civil Rights Staff Across the Fed. Gov't (Jul. 24, 2014), available at http://www.justice.gov/sites/default/files/crt/legacy/2014/07/29/7_24_14_Coordination_Memo_50th_Anniv.pdf.

discrimination as these laws.⁶³ In addition, the statutory text of Section 1557 makes clear that the statute may not be interpreted to narrow existing interpretations of and protections against sex discrimination.⁶⁴

The proposed regulation sets out core antidiscrimination principles drawn from implementing regulations for Title VI, Section 504, the Age Act, and Title IX. However, the Title IX regulations that are cross-referenced to set out the specific discriminatory actions prohibited on the basis of sex reflect the different educational context for which they were created, and do not reach the full breadth of discriminatory actions that are prohibited by Section 1557. For example, the Title IX regulations prohibit "[s]ubject[ing] any person to separate or different rules of behavior, sanctions, or other treatment" and "[d]iscriminat[ing] against any person in the application of any rules of appearance" on the basis of sex⁶⁵—forms of discrimination far more likely to arise in educational institutions' treatment of students than in health care providers' treatment of patients, for example, or health insurance providers' treatment of beneficiaries. The referenced Title IX regulation also prohibits "[a]pply[ing] any rule concerning the domicile or residence of a student or applicant, including eligibility for in-state fees and tuition" on the basis of sex⁶⁶—another rule that has clear applicability to educational programs and activities and limited relevance for health programs and activities.

Due to the educational context of Title IX, in addition to the referenced Title IX provisions, the final regulation should also draw from the Title VI, Section 504, and Age Act prohibitions that are incorporated into Section 1557 to more fully address discrimination on the basis of sex in health programs and activities.

We therefore recommend that § 92.101(b)(3) be revised by adding the following language, drawn from the Title VI, Section 504, and Age Act regulations, and consistent with Title IX principles:

In addition, each covered entity must comply with the following provisions:

- (i) A covered entity may not, directly or through contractual or other arrangements, utilize criteria or methods of administration which have the effect of subjecting individuals to discrimination on the basis of their sex, or have the effect of defeating or substantially impairing accomplishment of the objectives of the program with respect to individuals on the basis of sex.
- (ii) In determining the site or location of a facility, a covered entity may not make selections with the effect of excluding individuals from, denying them the benefits of, or subjecting them to discrimination under any programs to which this regulation applies, on the basis of sex; or with the purpose or effect of defeating or substantially impairing the accomplishment of the objectives of the program or activity on the basis of sex.
- (iii) In the absence of a finding of discrimination, a covered entity in administering a program may take affirmative action to overcome the effects

⁶³ Title VII, for example, covers employers who have fifteen or more employees. 42 U.S.C. § 2000e(b) (2012). Title IX prohibits an education program or activity that receives federal financial assistance from discriminating against individuals on the basis of sex. 20 U.S.C. § 1681, et seq. ⁶⁴ Patient Protection and Affordable Care Act § 1557(b), 42 U.S.C. § 18116(b) (2012).

⁶⁵ Patient Protection and Affordable Care Act § 1557(b), 42 U.S.C. § 181
⁶⁵ See 45 C.F.R. § 86.31(b)(4), (5) (2015).

⁶⁶ See id. § 86.31(6).

See Id. 9 86.31(6)

of conditions which resulted in limiting participation by persons on the basis of sex.

In addition, we recommend that HHS interpret these standards to prohibit actions by covered entities that have the effect of denying or restricting women's timely access to providers specializing in women's health care. Restrictions on the participation of otherwise eligible women's health providers in federal health programs place serious obstacles on women seeking timely access to care. When trusted, well-qualified women's health programs, the many women who depend on such providers for their usual care may be forced to seek federally-supported services from geographically remote providers, settle for inferior care, or forgo care altogether. Women in need of services that reside in areas that lack adequate medical resources are likely to face significantly increased wait times and disproportionate increases in travel along with other associated costs, rendering access to a comparable alternative provider inconvenient if not prohibitively expensive. The costs and delays imposed by such restrictions harm the health and wellbeing of women as a class.

Specifically, we recommend inserting the following language in the preamble of the final rule discussing §§ 92.101(b)(3)(i)-(iii) to reinforce the rule's application in the context of protecting women's access to health care.

The standards we propose in 92.101(b)(3)(i)-(iii) are intended to reach a variety of circumstances in which the actions of covered entities undermine the ability of individuals to participate in and benefit from health programs and activities on the basis of sex. For example, a covered entity engages in unlawful sex discrimination when it employs criteria that have the effect of disfavoring or disqualifying otherwise eligible providers of women's health care for participation in federal health programs, resulting in reduced access to federally supported health care for women in a region.

Finally, we are concerned the rule does not explicitly provide that Section 1557 prohibits all forms of harassment based on a protected characteristic, including sexual harassment and other forms of sex-based harassment, which includes harassment based on gender identity and sexual orientation. Title IX has been interpreted to protect every student (and other individuals protected by Title IX) from sex-based harassment that limits their ability to participate in or benefit from the education program, or that creates a hostile or abusive educational environment.⁶⁷ Similarly, Title VII protects employees from sex-based harassment that limits an individual's ability to participate in or benefit from the education 1557 therefore prohibits harassment that limits an individual's ability to participate in or benefit from a health program or activity or creates a hostile or abusive health care environment.

Sexual harassment in health care can discourage people from seeking health care, thus undermining the ACA's broader goals of ensuring access to health care. A provider who uses derogatory language when talking to unmarried or sexually active or pregnant women

⁶⁷ See U.S. Dept. of Educ., Office for Civil Rights, Sexual Harassment Guidance (1997), available at http://www2.ed.gov/about/offices/list/ocr/docs/sexhar01.html.
⁶⁸ U.S. Equal Emp't Opportunity Comm'n., Harassment, available at <u>http://www.eeoc.gov/laws/types/harassment.cfm</u>; see also 29 C.F.R. § 1604.11(a) (Harassment on the basis of sex "has the purpose or effect of unreasonably interfering with an individual's work performance or creating an intimidating, hostile, or offensive working environment.").

may be creating a hostile environment⁶⁹ that could keep women from accessing needed health care.⁷⁰ A persistent and intentional refusal to use a patient's preferred name and pronoun rather than those corresponding to the patient's gender assigned at birth may constitute illegal gender identity-based harassment if it creates a hostile environment.⁷¹

We therefore recommend adding a new § 92.210:

§ 92.210 Harassment

Harassment that denies or limits an individual's ability to participate in or benefit from a health program or activity on the basis of an individual's race, color, national origin, age, disability, sex (including pregnancy, false pregnancy, termination of pregnancy or recovery therefrom, childbirth or related medical conditions, sex stereotypes, gender identity, and sexual orientation) is a form of discrimination prohibited by § 92.101.

§ 92.201 Meaningful Access for Individuals with Limited English Proficiency

Because of the nature and importance of health care, health-related insurance, and other health-related coverage to individuals and communities and the consequences that can result from language barriers, the proposed rule properly includes specific requirements to ensure that covered entities understand their obligations to ensure meaningful access and have clear instructions on how to comply with those obligations. We support this approach as it is consistent with Title VI and existing HHS LEP Guidance. Consistent with the proposed rule, discrimination on the basis of limited English proficiency (LEP) creates unequal access to health. LEP is often compounded with the "cumulative effects of race and ethnicity, citizenship status, low education, and poverty," resulting in more barriers to access.⁷² For detailed recommendations on how best to effectuate the text and intent of Section 1557 and to ensure meaningful access for LEP individuals, we refer the Department to comments submitted by the Leadership Conference for Civil and Human Rights.

We also note that the proposed rule requests comment on whether certain entities should have enhanced obligations regarding meaningful access for LEP individuals and, if so, what

⁷⁰ When patients do not feel comfortable as a result of harassment or because of a provider's perceived implicit or explicit bias, they are less likely to get comprehensive medical care. See e.g., Irene Blair et al., *Clinicians' Implicit Ethnic/Racial Bias and Perceptions of Care Among Black and Latino Patients*, 11 Annals of Family Med. 43 (2013) (finding that "clinicians' implicit bias may jeopardize their clinical relationships with black patients, which could have negative effects on other care processes"); Nat'l. Gay and Lesbian Task Force & Nat'l Ctr. for Transgender Equality, *Injustice at Every Turn: A Report of the National Transgender Discrimination Survey* 76 (2011), *available at*

http://www.thetaskforce.org/downloads/reports/ntds_full.pdf (showing nearly 30 percent of transgender individuals reported postponing or avoiding medical care when they were sick or injured due to discrimination and disrespect, and over 30 percent delayed or did not try to get preventive care); Texas Pol'y. Evaluation Project, Barriers to Family Planning Access in Texas (May 2015), *available at* http://www.utexas.edu/cola/txpep/_files/pdf/TxPEP-ResearchBrief_Barriers-to-Family-Planning-Access-in-

Texas May2015.pdf (showing that 30 percent of respondents reported that being unable to "find a place where they feel comfortable with health care providers" was a barrier to accessing reproductive health care); Valerie Ulene, Doctors and Nurses' Weight Biases Harm Overweight Patients, L.A. TIMES (Dec. 13, 2010), available at

⁶⁹ Factors to "evaluate hostile environment" include the severity of the effect on the individual, the type, frequency and duration of the conduct, the age and sex of the people involved, whether the harasser is in a position of authority over the individual, and other context such as location and non-sexual threats or intimidation. Even one act of harassment can create a hostile environment. U.S. Dep't of Educ., Office for Civil Rights, Revised Sexual Harassment Guidance: Harassment of Students by School Employees, Other Students, or Third Parties 5-7 (2001), available at http://www2.ed.gov/about/offices/list/ocr/docs/shguide.pdf.

http://articles.latimes.com/2010/dec/13/health/la-he-the-md-weight-bias-20101213 (discussing negative health implications of providers' weight bias on overweight patients). ⁷¹ See Lusardi v. McHugh, E.E.O.C. App. No. 0120133395, 15 (Apr. 1, 2015) ("Persistent failure to use [a transgender] employee's correct name and pronoun may constitute unlawful, sex-based harassment..."); Jameson v. U.S. Postal Service, E.E.O.C. Appeal No. 0120130992, 2 (May 21, 2013) ("[Slupervisors and coworkers should use the name and pronoun of the gender that the employee identifies with.... Intentional misuse of the employee's new name and pronoun may cause harm to the employee, and may constitute sex based discrimination and/or harassment..."); See also Office of Personnel Management, Guidance Regarding the Employment of Transgender Individuals in the Federal Workplace, available at www.opm.gov/policy-data-oversight/diversity-and-inclusion/reference-materials/gender-identity-guidance ("Continued misuse [of a transitioning employee's] new name and pronouns, and reference to the employee's former gender by managers, supervisors, or coworkers is contrary to the goal of treating transitioning employees with dionity and respect. and creates an unwelcoming work environment.").

employees with dignity and respect, and creates an unwelcoming work environment."). ⁷² Kaiser Family Foundation, Overview of Health Coverage for Individuals with Limited English Proficiency, at 3.

those obligations should be. We echo the comments submitted by the Leadership Conference for Civil and Human Rights and likewise recommend that entities that should be required to meet enhanced obligations include the U.S. Department of Health and Human Services; State agencies administering Medicaid or CHIP; Federal, State and Partnership Health Insurance Marketplaces; and Qualified Health Plans.

§ 92.204 Accessibility of Electronic and Information Technology

As proposed, § 92.204 on electronic and information technology would focus on nondiscrimination and accessibility for individuals with disabilities only.⁷³ Section 1557 is not limited to discrimination on the basis of disability alone; accordingly, § 92.204 should cover and prohibit discrimination on the basis of *all* enumerated grounds, including discrimination based on race, color, national origin, sex, and age as well as disability.

The point has considerable urgency because the Health Information Technology for Clinical and Economic Health (HITECH) Act of 2009^{74} currently provides extensive federal financial assistance through a panoply of federal health programs to build a nationwide health information network. Section 1557 requires that individuals not be excluded from participation, denied benefits, nor suffer discrimination in these critical new programs on *all* enumerated grounds, not just disability.

Federal Financial Assistance and Federal Health Programs

First, the HITECH Act provides substantial federal financial assistance, totaling more than \$30 billion, to private and public health programs and activities across the nation. The majority of this federal financial assistance takes the form of incentive payments to eligible professionals and eligible hospitals serving Medicare and Medicaid beneficiaries, to encourage them to adopt certified EHR technology and use it meaningfully to improve patient and population health and health care.⁷⁵ As of August 2015, more than 476,000 eligible professionals and eligible hospitals in all 50 states had received more than \$31 billion in federal financial assistance.⁷⁶

Under Section 13301 of the HITECH Act, federal financial assistance also includes approximately \$2 billion more for health information technology architecture, such as programs and activities under planning and implementation grants to states to promote health information exchange; grants for regional extension centers to provide technical assistance and disseminate best practices; grants to integrate health information technology into clinical education; and grants to support medical health informatics programs and information technology professionals in health care.⁷⁷ Overall, "the Secretary [of Health and Human Services] shall . . . invest in the infrastructure necessary to allow for and promote the electronic exchange and use of health information for *each individual in the United States* consistent with the goals outlined in the strategic plan developed by the National Coordinator".⁷⁸

⁷³ Nondiscrimination in Health Programs and Activities, 80 Fed. Reg. at 54,219 (proposed § 92.204); id. at 54,187-88.

⁷⁴ Health Information Technology for Economic and Clinical Health (HITECH) Act of 2009, Title XIII of Division A and Title IV of Division B of the American Recovery and Reinvestment Act of 2009, Pub. L. No. 111-5, §§ 13001-13424 (February 17, 2009) (codified at 42 U.S.C. §§ 201 note, 300jj - 300jj-51, 17901-17953).

^{75 42} U.S.C. § 1395ww(n) (Medicare, eligible hospitals); id. § 1396b(t) (Medicaid, States for eligible professional and hospitals); id. § 1848(o) (Medicare, eligible professionals).

⁷⁶ Centers for Medicare & Medicaid Services, Medicare and Medicaid EHR Incentive Program, HIT Policy and Standards Committees (Oct. 6, 2015).

⁷⁷ 42 U.S.C. §§ 300jj-31 - 300jj-38.

⁷⁸ Id. § 300jj-31(a) (italics added).

Most recently, the Medicare Access and CHIP Reauthorization Act (MACRA) of 2015 incorporated federal Medicare payment adjustments for meaningful use of certified EHR technology into its new Merit-Based Incentive Payment System (MIPS) and Alternative Payment Models (APMs).⁷⁹

Separately, HHS administers programs with nationwide scope for "electronic exchange and use of health information and the enterprise integration of such information." "utilization of an electronic health record for each person in the United States by 2014," "a framework of coordination and flow of recommendations and policies under this subtitle," and "a governance mechanism for the nationwide health information network."⁸⁰ The Office of the National Coordinator for Health Information Technology⁸¹ and CMS actively administer such programs. For example, the National Coordinator is responsible for a strategic plan with specific objectives and milestones for "electronic exchange and use of health information and the enterprise integration of such information," "utilization of an electronic health record for each person in the United States by 2014," "a framework of coordination and flow of recommendations and policies under this subtitle," and for "a governance mechanism for the nationwide health information network."82

Section 1557 governs all of this federal financial assistance and these programs and activities administered by the Department.

The Need for Relief and Enforcement

A few examples regarding electronic health information technology will illustrate the importance of applying and enforcing Section 1557 and § 92.204 for all individuals covered by Section 1557, not just individuals with disabilities.

According to the 2010 Census, approximately 60.5 million people ages five and older speak a language other than English at home.⁸³ The proposed rule acknowledges elsewhere the importance of providing translated materials in the top 15 languages nationally.⁸⁴ But regulations just promulgated for the third and final stage of the Meaningful Use program would not require providers to have certified EHR technology that makes online access and health information available to patients in languages other than English.⁸⁵ The 25 million individuals identified in the proposed rule with limited English proficiency⁸⁶ are effectively excluded from participation in, denied the benefits of, or subject to discrimination under this health program or activity. For example, a Spanish speaker and reader who receives her hospital discharge instructions electronically, but in English only, cannot use that information. A Chinese reader who receives his medication instructions electronically, but in English only, cannot read and follow the instructions for dosage and precautions.

⁹ Medicare Access and CHIP Reauthorization Act (MACRA) of 2015, Pub. L. No. 114-10, § 101(b) (Apr. 16, 2015).

⁰ 42 U.S.C. § 300jj-11(c)(3)(A), (c)(8).

⁸¹ E.g., id. § 300jj-11.

⁸² Id. § 300jj-11(c)(3)(A), (c)(8).

⁸³ U.S. Census Bureau, Language Use in the United States: 2011, at 3 (Aug. 2013), available at http://www.census.gov/prod/2013pubs/acs-22.pdf

Nondiscrimination in Health Programs and Activities, 80 Fed. Reg. at 54,179; see also id. at 54,182-86.

⁸⁵ E.g., Dep't of Health and Human Services, 2015 Edition Health Information Technology (Health IT) Certification Criteria, 80 Fed. Reg. 62,602, 62,625 (Oct. 16, 2015) (codified at 45 C.F.R. pt. 170) (language access optional, not required, for patient-specific education materials); id. at 62,661 (language access not included for patients' secure messaging with providers); Dep't of Health and Human Services, Electronic Health Record Incentive Program-Stage 3 and Modifications to Meaningful Use in 2015 Through 2017, 80 Fed. Reg. 62,762 (Oct. 16, 2015) (codified at 42 C.F.R. pts. 412, 495) (nowhere requiring <u>use</u> of certified EHR technology to provide access in languages other than English). ⁸⁶ Nondiscrimination in Health Programs and Activities, 80 Fed. Reg. at 54,182.

Proposed § 92.204 requires accessibility for individuals with a disability. According to the 2010 census, 56.6 million people had a disability in America, or 18.7 percent of the population. Over 14.9 million people (29.0 percent of people with a disability aged 15 years and older) had a seeing, hearing, or speaking disability. Approximately 15.1 million (29.4 percent) had a mental disability. Nearly 15.8 million people (30.7 percent) had disabilities in two domains, not just one.⁸⁷ But regulations just promulgated for the third and final stage of the Meaningful Use program would *not* require providers to record disability status in certified EHR technology, nor use certified EHR technology to help accommodate those disabilities in the ways that the EHR shares personal health information with the individual, nor require an EHR developer to meet *any* accessibility laws or accessibility-centered design standards.⁸⁸

If well designed and built for the diversity of America, electronic health information technology can instead help to identify and reduce health disparities across the nation. Significant disparities exist by race and ethnicity; by language (national origin); by gender, gender identity, and sexual orientation; and by socio-economic status.⁸⁹ The Hispanic population reached 50.5 million, and over 57 million people identifying solely as Black or African-American, American Indian or Native Alaskan, Asian, or Native Hawaiian and Other Pacific Islander.⁹⁰ Women account for 50.8 percent of the population.⁹¹ New, more accurate data have begun to emerge as social acceptance has grown and legal systems have become more affirming of the LGBT populations. While recent studies estimate that overall LGBT individuals comprise 3.8 percent of the national population (or roughly 9 million people), some states report significantly larger populations of people who identify as LGBT.⁹²

Health disparities illustrate the problem, and they illustrate why OCR should revise proposed § 92.204 to implement Section 1557 and use health information technology now to reduce health disparities and discrimination. The Consumer Partnership for eHealth, led by the National Partnership for Women & Families, developed a Disparities Action Plan setting forth changes that HHS should make to certified EHR technology and meaningful use of EHR technology in three areas: 1) data collection and use to identify disparities; 2) barriers regarding language, literacy, and communication that exclude protected classes from participation, deny them the benefits of, or discriminate against them in health IT programs or activities receiving federal financial assistance; and 3) barriers in care coordination and planning which do the same.⁹³ These changes are essential to meet the requirements of Section 1557 and ensure that covered individuals are not excluded from participation, denied benefits, or suffer discrimination.

⁸⁹ See generally California Pan-Ethnic Health Network et al., Equity in the Digital Age: How Health Information Technology Can Reduce Disparities (2013), available at http://www.cpehnorg/pdfs/EquityInTheDigitalAge2013.pdf; Nat'l Opinion Research Ctr., Understanding the Impact of Health IT in Underserved Communities and Those with Health Disparities (2013) (under contract with Office of the National Coordinator for Health Information Technology and Health Resources and Services Administration), available at http://www.healthit.gov/sites/default/files/hit_disparities report 050713.pdf; White House Summit on Achieving eHealth Equity (Apr. 2013), available at http://www.healthit.gov/sites/default/files/ehealthequitysummary-layout_2013-04-25b-508.pdf; Joint Ctr. for Pol. and Econ. Studies, The Economic Burden of Health Inequalities in the

⁸⁷ U.S. Census Bureau, Americans With Disabilities: 2010, at 4, 8-9, 17-19 (July 2012), available at http://www.census.gov/prod/2012pubs/p70-131.pdf.

⁸⁸ Electronic Health Record Incentive Program—Stage 3 and Modifications to Meaningful Use in 2015 Through 2017, 80 Fed. Reg. at 62,812; 2015 Edition Health Information Technology (Health IT) Certification Criteria, 80 Fed. Reg. at, 62,673.

United States (Sept. 2009), available at http://www.jointcenter.org/sites/default/files/upload/research/files/The%20Economic%20Burden%20of%20Health%20Inequalities%20in%20the%20United%20States.pdf; Agency for Healthcare Research and Quality, Dep't of Health and Human Serv., National Healthcare Disparities Report 2012, at H-1 to H-16 (May 2013), available at http://www.ahr.gov/research/files/The%20Economic%20Burden%20of%20Health%20Inequalities%20in%20the%20United%20States.pdf; Agency for Health and Human Serv., National Healthcare Disparities Report 2012, at H-1 to H-16 (May 2013), available at http://www.ahr.gov/research/files/The%20Economic%20Burden%20of%20Health%20Inequalities%20in%20the%20United%20States.pdf; Agency for Health and Human Serv., National Healthcare Disparities Report 2012, at H-1 to H-16 (May 2013), available at http://www.ahr.gov/research/files/The%20Economic%20Burden%20of%20Health%20Inequalities%20in%20the%20United%20States.pdf; Agency for <a href="http://www.ahr.gov/research/files/The%20Economic%20Burden%20of%20Health%20Inequalities%20in%20Health%20Inequalities%20In%20Health%20Inequalities%20In%20Health%20Inequalities%20In%20Health%20Inequalities%20In%20Health%20Inequalities%20In%20Health%20Inequalities%20In%20Health%20Inequalities%20In%20Health%20Inequalities%20In%20Health%20Inequalities%20Health%20Inequalities%20Health%20Health%20Health%20Health%20Health%20Health%20Health%20Health%20Health%20Health%20Health%20Health%20Health%

⁹⁰ U.S. Census Bureau, Overview of Race and Hispanic Origin: 2010, at 4 (2011), available at http://www.census.gov/prod/cen2010/briefs/c2010br-02.pdf.

⁹¹ U.S. Census Bureau, Age and Sex Composition: 2010, at 2 (2011), available at http://www.census.gov/prod/cen2010/briefs/c2010br-03.pdf.

⁹² Gary Gates & Frank Newport, *Gallup Special Report: New Estimates of the LGBT Population in the United States* (2013), *available at* http://williamsinstitute.law.ucla.edu/research/census-lgbt-demographics-studies/gallup-lgbt-pop-feb-2013/.

⁹³ Consumer Partnership for eHealth, Leveraging Meaningful Use to Reduce Health Disparities: An Action Plan (2013), available at http://www.nationalpartnership.org/research-library/health-care/HIT/leveraging-meaningful-use-to.pdf.

In summary, proposed § 92.204 regarding electronic health information technology should be applicable not just to individuals with disabilities but to all individuals covered by Section 1557. The OCR should consider the benefits and barriers all protected classes might encounter in accessing electronic information technology in health programs and activities. If designed, built, and used correctly, health information technology introduces important new solutions and can reduce the disparities in access and outcomes covered by Section 1557; but if these programs and activities fail to anticipate and accommodate such needs, then millions of people will continue to be denied the benefits of – or even be excluded from participation in – these programs and activities.

Accordingly, the OCR should not limit proposed § 92.204 to individuals with disabilities, but should broaden it so that it covers all grounds. This can be accomplished by amending the heading and inserting the broad provision:

§ 92.204 Accessibility of eElectronic and information technology.

(a) Covered entities shall ensure that electronic and information technology in their health programs or activities does not exclude individuals from participation in, deny them the benefits of, or subject them to discrimination under any health program or activity on the basis of race, color, national origin, sex, age or disability.

(b) Covered entities shall ensure that their health programs or activities provided through electronic and information technology are accessible to individuals with disabilities,

§ 92.206 Equal Program Access on the Basis of Sex

We support the requirement that covered entities provide equal access to health programs or activities without discrimination on the basis of sex, including treating individuals consistently with their gender identity. In addition, the final rule should state that equal access without discrimination on the basis of sex includes equal access for pregnant women. Pregnant women have experienced considerable discrimination in accessing certain health care services such as mental health care and drug treatment services.⁹⁴

In addition, the Department should clarify that the circumstances under which sex-specific programs and activities are nondiscriminatory and thus permissible under Section 1557 are narrow. Consistent with Section 1557's broad nondiscrimination purpose, sex-specific programs may be permissible only when they are narrowly tailored and *necessary to accomplish an essential health purpose*. Sex-specific programs may be clinically necessary in some instances: for instance, clinical trials that aim to determine whether sex differences exist in certain diseases or responses to treatment do not violate Section 1557 when they

⁹⁴ See e.g., J. Marsh et al., Increasing Access and Providing Social Services to Improve Drug Abuse Treatment for Women with Children, 95 ADDICTION 237 (2000). In 2011, only 12.7 percent of substance abuse treatment facilities in the U.S. included programs for pregnant or postpartum women. U.S. DEPT. OF HEALTH AND HUMAN SERV., 2011 NATIONAL SURVEY OF SUBSTANCE ABUSE TREATMENT SERVICES 4 (2011), available at http://www.uditaces.agov/webt/state_data/US11.pdf. In addition, only 19 states have drug treatment programs specifically targeted to women. State Policies in Brief: Substance Abuse During Pregnancy, GUTTMACHER INST. (OCT. 1, 2015), available at http://www.uditaces.agov/ubit/statecenter/spibs/spibs/sb3DP.pdf. SabP.pdf, See also Andrew Solomon, The Secret Sadess of Pregnancy with Depression, N.Y. TIMES (May 28, 2015), available at http://www.uditaces.agov/ubits/statecenter/spibs/spibs/sb3DP.pdf. The Secret Sadess of Pregnancy with Depression, N.Y. TIMES (May 28, 2015), available at http://www.uditaces.agov/ubits/statecenter/spibs/spibs/sb3DP.pdf. The Secret Sadess of Pregnancy with Depression, N.Y. TIMES (May 28, 2015), available at http://www.uditaces.agov/ubits/statecenter/spibs/spibs/sb154. (adores: a data are also and are spices. (adores: a data are also and are spices.) (adores: a data are also are also and are spices.) (adores: a data are also are also and are also are also and are also are also

http://www.guttmacher.org/statecenter/spibs/spib_SADP.pdf. See also Andrew Solomon, The Secret Sadness of Pregnancy with Depression, N.Y. IIMES (May 28, 2015), available at http://www.nytimes.com/2015/05/31/magazine/the-secret-sadness-of-pregnancy-with-depression.html? r=0 (discussing doctors' reluctance to treat pregnant women suffering from depression).

establish sex-specific studies, because the very purpose of the study is to examine sex difference and its impact on medical treatments.

We therefore recommend revising § 92.206 as follows:

A covered entity shall provide individuals equal access to its health programs or activities without discrimination on the basis of sex, and shall treat individuals consistent with their gender identity, except that any health services that are ordinarily or exclusively available to individuals of one gender may not be denied or limited based on the fact that an individual's sex assigned at birth, gender identity, or gender otherwise recorded in a medical record is different from the one to which such health services are ordinarily or exclusively available. *Sex-specific health programs and activities are permissible when necessary to accomplish an essential health purpose.*

Further, we strongly support the recognition in § 92.206 that Section 1557 requires covered entities to treat individuals consistent with their gender identity and to provide them with equal access to health programs and activities. This interpretation of Section 1557 as protecting the rights of transgender people to access facilities and programs consistent with their gender identity rests on strong legal footing. Discrimination in access to gender-specific facilities remains one of the most common, and most harmful, forms of sex-based discrimination against transgender people.⁹⁵ Denying access to gender-appropriate facilities singles out transgender individuals, invites others to harass them, and places them in the untenable position of either enduring this humiliation or avoiding the use of such facilities and the associated medical care.⁹⁶ The Occupational Safety and Health Administration cautions that denying access to appropriate restrooms "can lead to potentially serious physical injury or illness" caused when individuals delay or avoid restroom use altogether.⁹⁷ Obstacles to living one's life in a manner consistent with one's gender identity can also increase risk for depression, anxiety, and suicidality.

The proposed rule rightly recognizes that, to meet their obligations under § 92.206, health care providers must treat individuals according to their self-identified gender. This principle applies not only to transgender women and men, but also to workers whose gender identity is not male or female. We strongly encourage HHS to strengthen § 92.206 with explicit protections for non-binary people who need access to gender-specific programs and facilities, and to affirm that non-binary individuals, like all individuals, should be permitted to determine which facilities are appropriate for them.

We also strongly support the recognition in § 92.206 that health services ordinarily associated with one gender may not be denied or limited based on the fact that an individual's sex assigned at birth, gender identity, or gender otherwise recorded in a medical record is different from that gender. As the preamble to the proposed rule notes: while individuals generally have the right to be treated according to their gender identity, in the context of health care individuals sometimes need clinical services typically

⁹⁵ For example, 22 percent of respondents in the 2011 National Transgender Discrimination Survey indicated that they were denied access to gender-appropriate restrooms in the workplace. Nat'l. Gay and Lesbian Task Force & Nat'l Ctr. for Transgender Equality, *Injustice at Every Turn: A Report of the National Transgender Discrimination Survey* 56 (2011), *available at* http://www.thetaskforce.org/downloads/reports/reports/ntds_full.pdf.

⁹⁶ The 2011 National Transgender Discrimination Survey found that fear of discrimination, such as the denial of access to appropriate gender-specific facilities, led 28 percent of respondents to postpone or avoid seeking preventive care. *Id.* at 76.

⁹⁷ Occupational Safety and Health Administration, A Guide to Restroom Access for Transgender Workers 1 (2015), available at www.osha.gov/publications/OSHA3795.pdf.

associated with another gender, such as a mammogram, a cervical Pap test, or a prostate exam.⁹⁸ Providing such services, where clinically appropriate, recognizes the patient's individual medical needs rather than inaccurately—and in an inherently discriminatory manner—basing the availability of medically necessary health care services solely on gender. We therefore recommend that § 92.206 be clarified to address this issue, and we refer the Department to comments submitted by the Leadership Conference for Civil and Human Rights.

§ 92.207 Nondiscrimination in Health-Related Insurance and Other Health-Related Coverage

Benefit Design Generally

We welcome HHS's recognition that health insurers may seek to circumvent nondiscrimination protections in the ACA by employing discriminatory benefit designs or marketing practices when "providing or administering" health insurance or coverage. However, we urge HHS to further explain and clarify discrimination through benefit design and marketing, as well as how HHS (and OCR) will coordinate with other federal and state agencies to monitor compliance and enforce Section 1557 protections.

The ACA prohibits many long-standing discriminatory practices by health insurers, including requiring guaranteed issue of coverage in the individual and small group health insurance markets so that no one can be denied health insurance due to a preexisting condition.⁹⁹ The ACA also prohibits discrimination against individual participants and beneficiaries based on health status or medical condition, and it prevents insurers from imposing annual or lifetime limits on benefits.¹⁰⁰

Section 1311 of the ACA requires HHS to establish certification standards so that a QHP may "not employ marketing practices or benefit designs that have the effect of discouraging the enrollment in such plan by individuals with significant health needs."¹⁰¹ However, the § 1311 certification requirements can be waived beginning in 2017 under a § 1332 waiver. Therefore, the protections from discriminatory benefit designs and marketing under Section 1557 become even more important to protect consumers from insurance company abuses.

Healthcare advocates and researchers have identified several areas where issuers have employed discriminatory practices or benefit design, including:

- Adverse tiering in prescription drug formularies;
- Narrow provider networks that exclude certain types of specialists;
- Arbitrary or unreasonable utilization management (e.g., prior authorization, step therapy, age or quantity limits on treatment); and
- Coercive wellness programs that prevent participation by persons with disabilities.

³⁹ 42 U.S.C. § 300gg ¹⁰⁰ Id. § 300gg-11.

⁹⁸ See, e.g., World Prof. Ass'n for Transgender Health, Standards of Care for the Health of Transsexual, Transgender and Gender-Nonconforming People 65-66 (2012); Am. College of Obstetricians and Gynecologists, Committee Opinion No. 512: Health Care for Transgender Individuals, Obstetrics & Gynecology 118(6): 1454 (2011).
⁹⁹ 42 U.S.C. § 300qq-1.

¹⁰¹ 42 U.S.C. § 18031(c)(1)(a); see also 45 C.F.R. § 156.225(b).

Adverse Tiering

Adverse tiering can have serious consequences by impeding access to potentially life-saving medications. Adverse tiering works for insurers by steering persons with significant health needs, such as HIV/AIDS, away from their plans. As a result, plans with more balanced tiering structures become more likely to enroll high-need patients. At this point, the health plan's enrollment could become imbalanced, placing pressure on the health plan to change its coverage policies or raise premiums and/or deductibles. This can lead to a "race to the bottom" effect where the plans in the marketplace all start putting these medications in the highest-cost tiers. Meanwhile, people who most need coverage are left with few options.

Although OCR has not yet issued a decision in a 2014 discrimination complaint filed by NHeLP and The AIDS Institute,¹⁰² HHS has recognized that health plans that place most or all drugs used in the treatment for certain conditions into the highest cost sharing tier may violate the ACA's non-discrimination requirements.¹⁰³

Narrow Provider Networks

Inadequate provider networks provide another opportunity for health insurers seeking to discriminate or otherwise discourage enrollment of persons from protected populations. For example, plans can limit or restrict access to certain types of healthcare professionals relied upon by persons with disabilities or limit the participation of safety-net and providers who serve in underserved areas. Such limited or restricted access would be a violation of Section 1557.

Unreasonable Utilization Management

Plan benefit design includes medical necessity criteria and other utilization management tools which may limit access to needed services and treatment. Data on treatment limitations is important to fully understand a plan's benefit coverage. However, information about treatment limitations can be difficult to find, even in a plan's Evidence of Coverage.

HHS should require health insurers and other covered entities to make information on utilization management, including quantitative and non-quantitative treatment limits publicly available. HHS should collect and evaluate the data and identify any treatment limitations that might be discriminatory. Given the Secretary's obligations under the ACA, this data should be used to ensure that arbitrary and unreasonable limits that restrict access to needed care fall within Section 1557 protections and enforcement actions.

Benefit Design Monitoring and Enforcement

We appreciate that monitoring and enforcement of Section 1557 and other nondiscrimination protections necessarily involved many activities and multiple agencies within HHS, including OCR, the Center for Consumer Information and Insurance

¹⁰² The AIDS Institute v. Coventry Health Care Clinic (Dep't of Health & Human Serv., Office for Civil Rights May 29, 2014) available at

http://www.healthlaw.org/publications/browse-all-publications/HHS-HIV-Complaint#.VjaWKCuqIVc. ¹⁰³ Preamble to the HHS Notice of Benefit and Payment Parameters for 2016 Final Rule, 80 Fed. Reg. 10,750 (Feb. 27, 2015); Center for Consumer Information & Insurance Oversight, Final 2016 Letter to Issuers in the Federally-facilitated Marketplaces (Feb. 2015), *available at* <u>https://www.cms.gov/CCIIO/Resources/Regulations-and-</u> <u>Guidance/Downloads/2016-Letter-to-Issuers-2-20-2015-R.pdf</u> (hereinafter 2016 Letter to Insurers).

Oversight (CCIIO), and CMS. Compliance monitoring of federal non-discrimination provisions should be ongoing, not just one of many issues considered during the annual plan certification process.

In the 2016 Letter to Issuers, CCIIO describes a number of monitoring activities to help determine whether plan benefit designs comply with the ACA requirements, including the non-discrimination provisions. Generally, we welcome these proposals and urge HHS to employ a broad, multi-pronged approach to non-discrimination compliance monitoring and enforcement. However, we remain concerned by a proposal in the 2016 Letter to Issuers for CCIIO to conduct outlier analyses for specific conditions examining estimated out-of-pocket costs under recognized treatment guidelines for five conditions – bipolar disorder, diabetes, HIV, rheumatoid arthritis, and schizophrenia. We are concerned that identifying the conditions to be reviewed in advance may incent plans to adjust their cost sharing structures for these conditions while discriminating in other ways. It would prove more effective to conduct an outlier analysis of additional medical conditions without providing advance notice to issuers.

Additionally, continual monitoring and enforcement of plan benefit design and marketing are as important as review during the initial certification period. For example, because provider contracts can be added, amended, or dropped throughout the plan year, there is the strong possibility that issuers could submit robust network plans without maintaining networks throughout the year. This could cause serious access gaps and continuity of care issues for enrollees, who may be unable to change plans outside of open enrollment periods. We urge HHS to require covered entities to comply with monitoring and enforcement policies that ensure adequate oversight compliance with non-discrimination requirements in plan benefit design throughout the coverage year. While the recertification process will give the marketplaces an opportunity to review QHP compliance with its network adequacy criteria, we urge HHS to require marketplaces to work with their QHPs to monitor compliance more frequently.

HHS further states that it will conduct compliance review of plans including examining appeals and complaints.¹⁰⁴ We strongly support this approach. Consumer complaints and appeals provide on-the-ground perspective of the challenges faced by individuals accessing health care. Complaints and appeals also provide information on plan design and performance in real time.

We note that neither the 2016 Letter to Issuers, the 2016 Payment Parameters Final Rule, nor the proposed Section 1557 regulations indicate how HHS will effectively process and monitor complaints concerning non-discrimination and civil rights protections. There are currently multiple entities with overlapping responsibilities to investigate consumer complaints and initiate enforcement actions, including the HHS OCR, CCIIO, the HHS Office of the Inspector General, CMS, DOJ, as well state insurance regulators and ombuds programs. Accordingly, we urge HHS to clarify its reporting and monitoring process for consumer complaints and appeals, with the HHS OCR as the lead agency.

¹⁰⁴ 2016 Letter to Issuers, at 35.

Federal and State Coordination

In the Preamble to the 2016 Payment Parameters rule, HHS states that "enforcement of this [ACA EHB non-discrimination] standard is largely conducted by states."¹⁰⁵ We disagree with this approach. HHS should be primarily responsible for monitoring and enforcing federal non-discrimination protections. We recognize that the ACA provides ample opportunities for state flexibility in some implementation areas. However, that flexibility should not apply to monitoring and enforcing the ACA's non-discrimination provisions designed to protect health care consumers, particularly highly vulnerable individuals living with chronic or disabling medical conditions. The HHS OCR must remain the primary monitoring and enforcement agency for Section 1557 protections against discriminatory plan benefit design and marketing.

Transgender Individuals

We strongly support § 92.207(b) in enumerating and prohibiting a range of insurance carrier and coverage program practices that discriminate against transgender individuals by arbitrarily singling them out for categorical denials of coverage for benefits provided to non-transgender people.

Like anyone, transgender individuals need preventive care to stay healthy and acute care when they become sick. Some may also seek medical treatment to physically transition from their assigned birth sex to the sex that reflects their gender identity. Expert medical organizations such as the American Medical Association, the American Psychological Association, the American Psychiatric Association, the American Academy of Family Physicians, the Endocrine Society, the American College of Obstetricians and Gynecologists, and the World Professional Association for Transgender Health agree that transition-related care is medically necessary for transgender people who experience clinically significant distress related to a profound misalignment between their gender identity and their assigned birth sex.¹⁰⁶

The procedures that may be medically necessary for a transgender individual as part of care related to gender transition are regularly prescribed for other medical indications for non-transgender individuals. The hormone therapy involved in gender transition, for example, is the same as that prescribed for endocrine disorders, such as hypogonadism, or women with menopausal symptoms.¹⁰⁷ The reconstructive surgical procedures that may be used in gender transition are regularly covered by insurance companies for non-transgender individuals for purposes such as treating injuries, or for cancer treatment or prevention.¹⁰⁸

Despite the fact that the services used in care related to gender transition, including hormone therapy, mental health services, and surgeries, as well as anatomically appropriate preventive screenings, are regularly covered for non-transgender individuals, many insurance carriers categorically deny coverage of the same—and equally medically

^{105 80} Fed. Reg. 10,823

¹⁰⁶ See Lambda Legal, Professional Organization Statements Supporting Transgender People in Health Care (2013), available at

http://www.lambdalegal.org/sites/default/files/publications/downloads/fs_professional-org-statements-supporting-trans-health_4.pdf

¹⁰⁷ Wylie C. Hembree et al., *Endocrine Treatment of Transsexual Persons: An Endocrine Society Clinical Practice Guideline*. J. Clinical Endocrinology & Metabolism, 3132 (2009). ¹⁰⁸ Dep't of Health and Human Serv., NCD 140.3, Transsexual Surgery, 12 (2014).

necessary—services for transgender people. The ACA has ameliorated several longstanding barriers to coverage for transgender people, such as unaffordable premiums and the insurer practice of limiting coverage by designating a transgender identity as a "pre-existing condition." However, many plans, as well as many state Medicaid programs, continue to discriminate against transgender individuals by using categorical exclusions that target them for denials of coverage for medically necessary health care services that are routinely covered for non-transgender individuals. As a result of these insurer practices in conjunction with other drivers of uninsurance such as poverty, in 2013 the uninsured rate among low- and middle-income transgender people was a staggering 59 percent.¹⁰⁹ Because they block access to vital health care services, transgender-specific insurance exclusions are also significant contributors to health disparities such as high rates of mental and behavioral health concerns, suicide attempts, experiences of abuse and violence, and HIV infection.¹¹⁰

The multifaceted nature of insurance discrimination against transgender individuals means that the provisions at § 92.207(b)(3), (4), and (5) are <u>all</u> vital to ensuring that transgender people are able to access the health coverage and care they need. We very strongly urge HHS to preserve all three of these provisions in the final rule, with the modifications suggested below.

We therefore urge the Department to maintain § 92.207(b)(3) without any changes and amend the proposed provisions at § 92.207(b)(4) and (5) as follows:

(4) Categorically or automatically exclude from coverage, or limit coverage for, all health services related to gender transition, *including gender reassignment surgeries* and other services or procedures described in the most current version of the recognized professional standard of medical care for transgender individuals; or

(5) Otherwise deny or limit coverage, or deny a claim, for specific health services related to gender transition if such denial or limitation results in discrimination against a transgender individual by denying the individual access to medically necessary health services in accordance with the most current version of the recognized professional standard of medical care for transgender individuals.

Enforcement

We further urge HHS to include a more detailed guide for plans of their responsibilities under this section in the final rule. In enforcing Section 1557, we urge OCR to work closely with CMS – including Medicare, Medicaid, and CCIIO – to coordinate a robust enforcement scheme that incorporates the Qualified Health Plan certification process, guidance related to the Essential Health Benefits, and analysis of federal and state data on insurance appeals and complaints filed under Section 1557 and other relevant laws, such as state laws prohibiting transgender exclusions under the rubric of unfair trade practices.

¹⁰⁹ Kellan E. Baker, Laura E. Durso & Andrew S. Cray, Moving the Needle: The Impact of the Affordable Care Act on LGBT Communities (2014), available at <u>https://cdn.americanprogress.org/wp-content/uploads/2014/11/LGBTandACA-report.pdf</u>.
¹¹⁰ See, e.g., Institute of Medicine, The Health of Lesbian, Gay, Bisexual, and Transgender People (2011) available at

²⁴⁷ See, e.g., Institute of Medicine, The Health of Lesbian, Gay, Bisexual, and Transgender People (2011) available at https://iom.nationalacademies.org/~/media/Files/Report%20Files/2011/The-Health-of-Lesbian-Gay-Bisexual-and-Transgender-People/L6BT%20Health%202011%20Report%20Brief.pdf.

§ 92.207(a) Third Party Administrators

The proposed regulations should be strengthened to clarify that Section 1557 protections apply broadly to activities taken by covered entities in their role as third party administrators. All covered entities are barred from providing assistance to an entity, program or activity that discriminates on the basis of race, color, national origin, sex, age or disability. Title IX's regulations provide, for example, that an educational institution may not, "[a]id or perpetuate discrimination against any person by providing aid or assistance to any agency, organization or person which discriminates on the basis of sex in providing any aid, benefit, or service to students or employees."¹¹¹

An institution that provides aid or assistance to an independent, but discriminatory, entity essentially adopts the discriminatory policies as its own. In *Iron Arrow Honor Society v. Heckler*, the Fifth Circuit upheld this provision of the Title IX regulations, finding that the Department of Health, Education and Welfare could terminate federal funding to the University of Miami because the University allowed an all-male honor society, to hold a "tapping" ceremony at a monument to the society on University property, in which "tapees" were removed from class before participating in the ceremony.¹¹² As is demonstrated by the *Iron Arrow* case, the assistance does not have to be monetary for Title IX to be implicated. We therefore recommend that the final regulations include language clarifying that a covered entity may not provide any aid or assistance to discriminatory health-related insurance or coverage.

In addition, we recommend the final regulation delineate various activities that a covered entity may perform that are considered "administering health-related insurance or other health-related coverage." Including a non-exhaustive list of administrative activities in the regulation will provide clarity to covered entities acting as third party administrators. The list of activities should include a variety of services covered entities may provide as third party administrators. We also support recognizing that a third party administrator that is legally separate from the issuer may still be a covered entity. We recommend language below that will prevent covered entities from creating separate legal entities in order to circumvent the Section 1557 protections against discrimination.

Specifically, we recommend amending § 92.207(a) as follows:

General. A covered entity shall not in providing or administering health-related insurance or other health-related coverage, discriminate on the basis of race, color, national origin, sex, age, or disability and shall not provide aid or assistance to any health-related insurance or other health-related coverage that discriminates on the basis of race, color, national origin, sex, age, or disability.

(1) Administering health-related insurance or other health-related coverage may include, but is not limited to, any of the following activities: claims processing, rental of a provider network, designing plan benefits or policies, drafting plan documents, processing or adjudicating appeals, administering disease management services, pharmacy benefit management, acting as a plan fiduciary as defined in the Employee Retirement Income Security Act of 1974

¹¹¹ See, e.g., 34 C.F.R. § 106.31(b)(6) (2015).

¹¹² 702 F.2d 549, 561 (5th Cir.), vacated on other grounds, 464 U.S. 67 (1983).

(ERISA, at 29 U.S.C. 1002), or acting as a plan administrator as defined in the Employee Retirement Income Security Act of 1974 (ERISA, at 29 U.S.C. 1002).

(2) A separate legal entity associated with a covered entity that provides or administers health-related insurance or other health-related coverage will be considered a covered entity if the legal separation exists for the purpose of permitting the entity to continue to administer discriminatory health-related insurance or other health-related coverage or as a subterfuge for discrimination.

92.207(b) Discriminatory Actions Prohibited

We support the Department's effort to make clear through the proposed regulation that Section 1557 applies to various aspects of health-related insurance coverage and other health-related coverage. While the proposed language will provide important protections related to the issuance and renewal of insurance or other health-related coverage as well as many aspects of insurance design and administration that affect how much an enrollee must pay for health related services, it falls short in some areas.

Waiting Periods

Subparagraph § 92.207(b)(1) should be strengthened by identifying waiting periods as one of the forms of denial or limitation of coverage that is prohibited if discriminatory. Waiting periods, in effect, deny coverage of services. Health insurance plans historically have discriminated against women by, for example, applying waiting periods for pregnancy related services.¹¹³ While the ACA ended this particular practice by requiring all plans to cover maternity care and ending pre-existing condition exclusions, we remain concerned that other waiting periods may be used in a discriminatory manner. For example, waiting periods have been imposed for transplant related services, which the Department has recognized may discriminate against people with present or predicted disability.¹¹⁴ While the Department has stated through guidance plans required to offer essential health benefits may not impose waiting periods for these benefits, there may be plans with waiting periods for non-essential health benefits or plans not required to cover the essential health benefits that impose waiting periods that have a similarly discriminatory result. Given that waiting periods effectively deny coverage for a period of time, a discriminatory waiting period would violate Section 1557 and § 92.207(b)(1) should make this clear.

Harm Because of a Protected Status

We also recommend strengthening subparagraph (1) by clarifying that, in addition to actions being disallowed when they are on the basis of an enrollee's or prospective enrollee's race, color, national origin, sex, age, or disability, the actions are also prohibited if they harm individuals because of an enrollee's or prospective enrollee's race, color, national origin, sex, age, or disability. For example, a plan design would be discriminatory if it had the effect of imposing higher cost sharing for diseases, such as lupus, that affect mostly

¹¹³ Lisa Codispoti et al., Nat'l Women's Law Ctr., Nowhere to Turn: How the Individual Health Insurance Market Fails Women 11 (2008), available at http://www.nwlc.org/sites/default/files/pdfs/NWLCReport-NowhereToTurn-81309w.pdf.

¹¹⁴ Dep't. of Health and Human Serv., Ctr. for Medicare & Medicaid Serv. and Ctr. for Consumer Info. & Ins. Oversight, *Frequently Asked Questions on Health Insurance Market Reforms and Marketplace Standards* (2014), available at https://www.cms.gov/cciio/resources/fact-sheets-and-faqs/downloads/final-master-faqs-5-16-14pdf.

women¹¹⁵ than for diseases, such as amyotrophic lateral sclerosis, commonly known as ALS, that affect mostly men.¹¹⁶

We therefore recommend amending § 92.207(b)(1) as follows:

- (b) Discriminatory actions prohibited. A covered entity shall not, in providing or administering health-related insurance or other health-related coverage:
 - (1) Deny, cancel, limit, or refuse to issue or renew a health insurance plan or policy, or other health coverage, or deny or limit coverage of a claim, or impose a waiting period or additional cost sharing or other limitations or restrictions, on the basis of an enrollee's or prospective enrollee's race, color, national origin, sex, age, or disability, or in a manner that deprives or tends to deprive an enrollee or perspective enrollee of coverage or otherwise adversely affects an enrollee or prospective enrollee because of the enrollee's or prospective enrollee's race, color, national origin, sex, age, or disability.

Categorical Exclusions for Maternity Coverage

Section 92.207(b) identifies certain coverage exclusions that constitute discrimination, but fails to make clear that a categorical exclusion of maternity coverage or a denial or limitation of coverage that results in discrimination against an individual affected by pregnancy or childbirth constitutes discrimination. Such clear statements are necessary to counter ongoing discrimination in insurance plans. For example, it remains a common practice for group health plans to exclude enrolled dependent children from maternity coverage.¹¹⁷ Through the Pregnancy Discrimination Act, Title VII ensures that most employers providing health insurance include maternity coverage for employees and enrolled dependent spouses, but the EEOC has concluded that denying such coverage to dependent children does not violate Title VII, because it represents sex discrimination against the dependent child, who is not protected by Title VII, rather than sex discrimination against the employee, who is.¹¹⁸ In contrast, as beneficiaries, child dependents are protected by Section 1557 when enrolled in a covered plan. And it is well established under civil rights laws such as Title IX and Title VII that a health insurance plan that fails to provide coverage for gynecological and maternity care is discriminating on the basis of sex.¹¹⁹ Likewise, under Section 1557, treating pregnancy differently, including by excluding maternity care from an otherwise comprehensive insurance plan, is sex discrimination.

A plan that categorically excludes maternity coverage for any beneficiary will need to eliminate the exclusion and offer maternity coverage to all enrollees, including child dependents, to comply with Section 1557. We provide recommended language below to

¹¹⁵ See Dep't of Health and Human Serv., Office on Women's Health, Lupus Fact Sheet (2012), available at https://www.womenshealth.gov/publications/our-publications/factneet/lupus.html

¹¹⁶ See Dep't of Health and Human Serv., Ctr. for Disease Control and Prevention, Prevalence of Amyotrophic Lateral Sclerosis – United States, 2010–2011 (2014), available at http://www.cdc.gov/mmwr/preview/mmwrhtml/ss6307a1.htm. 117 See Section 1557 Complaints: Sex Discrimination Complaints Against Five Institutions, Nat'l Women's Law Ctr. (June 3, 2013), available at http://www.nwlc.org/resource/nwlc-

section-1557-complaint-sex-discrimination-complaints-against-five-institutions. See also South Carolina EHB Benchmark Plan, Dep't of Health and Human Serv., Ctr. for Consumer Info. and Ins. Oversight available at https://www.cms.gov/cciio/resources/data-resources/ehb.html#South%20Carolina/

¹¹⁸ 29 C.F.R. § 1604.10(b); 29 C.F.R. § 1604, App., at Q. and A. 22 (2015).

¹¹⁹ See, e.g., 34 C.F.R. §§ 106.39, 106.40 (2015) (stating that Title IX requires comprehensive gynecological care when a recipient provides full coverage for health services and that a recipient must treat pregnancy in the same manner it treats other conditions); 29 C.F.R. pt. 1604 app. (2015) (stating that Title VII, amended by the Pregnancy Discrimination Act, requires that any employer-provided health insurance must cover expenses for pregnancy related conditions on the same basis as expenses for other medical conditions); Newport News Shipbuilding & Dry Dock v. EEOC, 462 U.S. 669 (1983) (holding that Pregnancy Discrimination Act, which amended Title VII, required employer health plan to cover pregnancy-related conditions for employees' spousal dependents on the same basis as other conditions covered for dependent spouses).

include in the final regulations to make clear that covered entities must provide maternity coverage to all enrollees, including all dependents. In addition, limitations in maternity coverage that result in discrimination against an individual affected by pregnancy or childbirth should be explicitly prohibited. Finally, we note that the preamble to the proposed regulation states that "[t]he proposed rule does not require plans to cover any particular benefit or service."¹²⁰ However, the preamble to the final regulation should clarify that the solution to a discriminatory benefit design, such as the ones discussed here, could be the addition of coverage for a benefit or service.

To address these concerns, we recommend that the preamble state that "The remedy for a discriminatory benefit design could be the addition of coverage for a benefit or service." We also recommend adding two new subparagraphs to § 92.207(b):

(b) Discriminatory actions prohibited. A covered entity shall not, in providing or administering health-related insurance or other health-related coverage:

(6) Categorically or automatically exclude from coverage, or limit coverage, for maternity services to any enrollee, including enrolled dependents.

(7) Otherwise deny or limit coverage, or deny a claim, for specific health services if such denial or limitation results in discrimination against an individual affected by pregnancy, false pregnancy, termination of pregnancy or recovery therefrom, childbirth or related medical conditions.

Medical Management Techniques

Medical management techniques are used by insurance plans and other health coverage to control access to covered services. There are reasonable uses of medical management, such as attempting to reduce duplication of services. However, medical management can also be used in a discriminatory manner. For example, HHS has previously noted that, if a plan places most or all drugs needed to treat specific conditions on the highest drug tier on the formulary that such plans discriminate against people with chronic conditions.¹²¹ Similarly, a formulary could discriminate in violation of Section 1557 if the placement in the formulary resulted in women being forced to pay more for drugs than men; if the formulary was more restrictive for drugs that mostly women use, or if drugs that are used to treat conditions that primarily affect men were. Other medical management techniques may be used in a discriminatory manner, such as placing prior authorization requirements on benefits used only by particular protected classes. Given the barrier medical management techniques that specifically prohibits discriminatory medical management techniques.

We recommend adding the following language to a new subparagraph under § 92.207(b):

(b) Discriminatory actions prohibited. A covered entity shall not, in providing or administering a health-related insurance or other health-related coverage:

¹²⁰ Nondiscrimination in Health Programs and Activities, 80 Fed. Reg. at 54,189.

¹²¹ HHS Notice of Benefit and Payment Parameters for 2016, 79 Fed. Reg. 70,674, 70,723 (Nov. 26, 2014) (to be codified at 45 C.F.R. pt. 144-48, 153-56, 158).

- - (8) Utilize medical management techniques including, but not limited to, prior authorizations, formulary design, step therapy, or use of case management or disease management in a way that limits or restricts coverage on the basis of an enrollee's or prospective enrollee's race, color, national origin, sex, age, or disability, or that otherwise adversely affects an enrollee or prospective enrollee because of the enrollee's or prospective enrollee's race, color, national origin, sex, age, or disability.

§ 92.207(d) Determining Whether a Particular Health Service is Covered

We are concerned about the inclusion of \S 92.207(d), stating that nothing in the section is intended to restrict a covered entity from determining whether a service is medically necessary or meets coverage requirements in an individual case. There may be instances in which the process the covered entity uses to determine whether a service is medically necessary or otherwise covered is discriminatory and, in such cases, the regulations should prevent the covered entity's use of such process. For example, women often experience different symptoms of heart disease than men. If a health insurance plan relied on guidelines based on typical male symptoms of heart disease to determine whether a test to diagnose a heart condition is medically necessary, such a determination could discriminate against women.¹²² Similarly, if a plan were to rely on age to determine if services were necessary rather than an individual's medical need, such as only approving treatment of menopause treatment for women above age 55, such a reliance would likely be discriminatory against people that need the service but do not meet the age restriction. We therefore recommend the final recommendations clarify that subparagraph (d) addresses determinations that are not discriminatory.

§ 92.207(d) should be amended as follows:

(d) Nothing in this section is intended to determine, or restrict a covered entity from determining, whether a particular health services is medically necessary or otherwise meets applicable coverage requirements in any individual case, if the determination of medical necessity or meeting applicable coverage requirements is not itself discriminatory and does not result in discrimination.

§ 92.209 Nondiscrimination on the Basis of Association

We applaud the inclusion of the explicit prohibition against nondiscrimination on the basis of association. The proposed regulation's language mirrors that of Title I and Title III of the Americans with Disabilities Act (ADA), which have been understood to protect against discrimination based on association or relationship with a disabled person.¹²³ Section 1557 should, therefore, be interpreted to provide at least the same protections for patients and provider entities. In accord with the ADA, this regulation should extend this protection to providers and caregivers, who are at risk of associational discrimination due to their professional relationships with patients, including those patient classes protected under

¹²² U.S. Dep't of Health and Human Serv., Nat'l Inst. of Health, What Are the Signs and Symptoms of Heart Disease? (2014), available at http://www.nhlbi.nih.gov/health/healthtopics/topics/hdw/signs. ¹²³ 42 U.S.C. §§ 12112, 12182 (2012).

Section 1557.¹²⁴ For these purposes, the rule should state that unlawful discrimination based on association occurs when a provider is subject to adverse treatment because it is known or believed to furnish services that are medically appropriate for, ordinarily available to, or otherwise associated with a patient population protected by Section 1557. This interpretation would, for instance, prohibit covered entities from using the provision of sex-specific services, such as abortion, as a disqualifying factor in recruiting otherwise eligible and qualified providers for participation in health programs supported by HHS. Providers should not be discriminated against for offering to competently care for a class of individuals with particular medical needs.

We specifically recommend amending § 92.209 to include the following additional language consistent with the ADA's prohibition on associational discrimination and the broad, remedial purposes of Section 1557.

- (a) General. A covered entity shall not exclude from participation in, deny the benefits of, or otherwise discriminate against an individual or entity in its health programs or activities on the basis of the race, color, national origin, age, disability, or sex of an individual with whom the individual or entity is known or believed to have a relationship or association.
- (b) Providers of health care or other related professional services. For the purposes of this section, the term "individual or entity" shall include individuals or entities that provide health care and other related professional services to individuals. Discrimination on the basis of association shall include any action by a covered entity to exclude from participation in, deny the benefits of, or otherwise discriminate against a provider in its health programs or activities based on the services the provider is known or believed to provide that are medically appropriate for, ordinarily available to, or otherwise associated with individuals of a certain race, color, national origin, age, disability, or sex.

§§ 92.301-92.303 Enforcement Mechanisms

It is critical that OCR create and administer a strong enforcement system for this new statute. Section 1557 specifically references the enforcement mechanisms "provided for" and "available under" Title VI, Title IX, Section 504, and the Age Act. Therefore, the regulations adopted for Section 1557 must reflect the entire range of equitable relief and enforcement mechanisms established and available under the statutes, including agency enforcement as well as the private right of action for monetary damages.¹²⁵ And, although HHS has primary oversight over Section 1557, DOJ also has the responsibility to coordinate implementation and enforcement of the statute pursuant to Executive Order 12250.¹²⁶ In addition, each agency must have implementing regulations for Section 1557.

It is essential that Section 1557 regulations recognize both discriminatory intent and disparate impact claims. Disparate impact claims are allowed under the civil rights

^{124 28} C.F.R. pt. 35, app. B (2015) (interpreting Title I and Title III of the ADA to protect "health care providers, employees of social service agencies, and others who provide professional services to persons with disabilities").

²⁵ Some of these enforcement mechanisms are expressly or implicitly provided for in statutory text. Others are established by the implementing regulations (e.g., administrative complaints, agency compliance reviews and formal investigations). ¹²⁶ Exec. Order No. 12,250, 3 C.F.R. 298 (1980).

statutes referenced by Section 1557.¹²⁷ Section 1557 thus imports this important antidiscrimination principle. The disparate impact standard is crucial for smoking out discrimination in an era in which discrimination takes ever more subtle forms—as documented in the examples described throughout these comments—and is often hidden in the very structures of our society. Section 1557 regulations should protect against disparate impact discrimination in the strongest possible terms.

Section 1557 provides for individual, class, and third party complaints. Title IX, Title VI, Section 504, and the Age Act provide for individual, class, and third party complaints. Because Section 1557 incorporates the enforcement mechanisms in those statutes, it too must be interpreted to provide for complaints brought on behalf of an individual, a class, or by a third party. Each of these vehicles for agency enforcement is crucial and a hallmark of civil rights enforcement under the laws Section 1557 references. The ability to file an administrative complaint can make it easier for victims of discrimination to seek a resolution of their claim than going to court, which can be more costly and more public than administrative complaints.

Class complaints and third party complaints also allow OCR to resolve problems of systemic discrimination. They are particularly important in the health care area because of the consequences of allowing system-wide patterns of discrimination to continue. Individual victims of discrimination may be hesitant to file complaints themselves because, for example, they fear retaliation from individuals or entities on which they rely for health care or insurance coverage. This creates a strong disincentive for some to file complaints and reinforces the importance of class and third party complaints.

Moreover, because Section 1557, like the civil rights statutes to which it refers, prevents federal funds from being used to finance discrimination, all complaint mechanisms are crucial to ensuring that the government neither operates its programs in a discriminatory manner nor fosters discrimination by providing federal funds to discriminatory entities.

It is essential that OCR conducts Section 1557 compliance reviews of covered entities and provides technical assistance regarding compliance with Section 1557. Section 1557 is a powerful proactive tool in OCR's work to combat discrimination in health care. OCR's authority is not limited to responding to complaints under Section 1557. It can—and should—also address discriminatory policies and practices at covered entities through technical assistance, systemic investigations, and compliance reviews of selected entities. OCR already conducts these reviews pursuant to its authority under other civil rights laws,¹²⁸ as do other agencies.¹²⁹

Because Section 1557 is a new law, it is especially important that OCR completes compliance reviews to both identify discrimination and set precedents under this new law. Without knowledge of Section 1557's protection or how to file a complaint, individuals

¹²⁷ Dep't of Justice, *Title VI Legal Manual* (2001), *available at* http://www.justice.gov/crt/about/cor/coord/vimanual.php#B (stating that Title VI regulations "may validly prohibit practices having a disparate impact on protected groups, even if the actions or practices are not intentionally discriminatory" (citing *Guardians Ass'n v. Civil Serv. Comm'n*, 463 U.S. 582, 582 (1983) and *Alexander v. Choate*, 469 U.S. 287, 293 (1985))); Dep't of Justice, *Title IX Legal Manual* (2001), *available at*

http://www.justice.gov/crt/about/cor/coord/ixlegal.php#2 (stating "[i]n furtherance of [Congress'] broad delegation of authority [to implement Title IX's prohibition of sex discrimination], federal agencies have uniformly implemented Title IX in a manner that incorporates and applies the disparate impact theory of discrimination"). ¹²⁸ See, e.g., Dep't of Health & Human Servs., Office for Civ. Rts., Compliance Review Initiative: Advancing Effective Communication in Critical Access Hospitals (Apr. 2013), available at http://www.hhs.gov/ocr/civilrights/activities/agreements/compliancereview initiative.pdf.

¹²⁹ For example, agencies including the Department of Justice, the Office of Federal Contract Compliance Programs (OFCCP), the Department of Housing and Urban Development and the Department of Education, among others, regularly conduct compliance reviews.

remain vulnerable to discrimination in health care settings, and covered entities may continue discriminatory practices.¹³⁰ The results of any compliance reviews should also be made public. The reports from such reviews can serve as guidance for other covered entities as to what it means to comply with Section 1557.

This could include reviewing compliance with protections against discrimination based on sex, sex stereotypes and gender identity and antidiscrimination protections for LGBT people at hospital systems or under the Exchanges.¹³¹ In general, because the Exchanges are newly created entities under the ACA—and will be a critical point for accessing health insurance for many individuals—OCR could select Exchanges in certain states to review for compliance with Section 1557. Specifically, given the large lower-income population that is LEP-more than half of LEP children and children with LEP parents have Medicaid or CHIP coverage and about 95 percent of uninsured individuals with LEP will be eligible for Medicaid or Exchange subsidies¹³²—both the Exchanges and state Medicaid programs are important focuses for OCR compliance reviews regarding language access services. For the same reason, reviewing Medicaid providers and state Medicaid programs for compliance with language access standards is essential.

An individual, complaint-driven system of enforcement is particularly limiting in health care, where many factors increase an individual's reluctance to make complaints: need for an ongoing relationship with health care providers (especially rare specialists); limited financial, internal and support resources due to illness; many people with functional limitations not self-identifying with the disability rights community (especially true of older persons who have acquired disabilities) and internalizing barriers as their own problem rather than a systemic failure to comply with nondiscrimination law.

We strongly support Section 1557's inclusion of both administrative and judicial remedies for discrimination. However, we recommend that the rule clearly reflect the statutory language by recognizing that Section 1557: (1) permits judicial claims for disparate impact discrimination and (2) permits private enforcement against any Executive Agency or any entity established under the ACA.

Failing to include disparate impact discrimination would result in facially neutral but highly discriminatory policies going largely unchecked. In Alexander v. Sandoval, the Supreme Court held that there is no private right of action for disparate impact discrimination under Title VI of the Civil Rights Act of 1964.¹³³ As a result, private individuals could only go to court to challenge a federal fund recipient's intentional discrimination on the basis of race, color, or national origin. To resolve disparate impact discrimination, such individuals could only file an administrative complaint with the overworked and understaffed HHS OCR.

treatment of same-sex couples in rental housing advertised over the internet).

¹³⁰ For instance, staff for the California Health and Human Services Agency, which oversees California's Medicaid program, indicated a lack of complaints to the agency on language access issues in 2011 and 2012. Linda Bennett interview with Amanda Ream, Organizing Director, Interpreting for California (August 2013). The absence of complaints, however, is not an indication that discrimination does not exist; to the contrary, it suggests that individuals may not know their rights or about the complaint process 131 See, e.g., Samantha Friedman et. al. for U.S. Dep't of Housing & Urban Dev., Office of Pol'y Dev. & Res., An Estimate of Housing Discrimination Against Same-Sex Couples (June 2013), available at http://www.huduser.org/portal/publications/fairhsg/discrim_samesex.html (describing study using testers that demonstrates evidence of discriminatory

² See Kaiser Commission on Medicaid & the Uninsured, Overview of Health Coverage for Individuals with Limited English Proficiency (Aug. 2012), available at https://kaiserfamilyfoundation.files.wordpress.com/2013/01/8343.pdf ("About 95% of uninsured individuals with LEP have incomes below 400% of poverty meaning they will be income-eligible for Medicaid or Exchange subsidies in 2014."). ¹³³ 532 U.S. 275, 293 (2001).

The ACA addresses this by referencing four different civil rights statutes: Title VI, which prohibits discrimination based on race, color, or national origin; Title IX, which prohibits discrimination on the basis of sex; Section 504, which prohibits discrimination based on disability; and the Age Discrimination Act, which prohibits discrimination on the basis of age. Section 1557 references these four statutes to list "the grounds" on which discrimination is prohibited in health care settings.¹³⁴ The statute then provides a single enforcement mechanism for challenging discrimination in health care settings:

The enforcement mechanisms provided for and available under ... title VI, title IX, section 504, or ... [the] Age Discrimination Act shall apply for purposes of violations of this subsection.¹³⁵

By using the disjunctive word "or," section 1557's enforcement mechanism gives individuals their choice of any of the review processes authorized by any of the four listed statutes "for purposes of violations of this subsection." Notably, the provision *does not* say that the enforcement mechanisms provided for under the listed statutes "shall apply for purposes of violations of the subsection *depending upon the protected class at issue*." As a matter of statutory construction, this second reading would impermissibly add words to the statute that are not there; and as a practical matter, it would be unmanageable for an elderly, African-American woman who wanted to complain of discrimination under the ACA. As its title states, Section 1557 is meant to ensure "nondiscrimination" in health care settings; it would make no sense to distinguish the judicial relief available for age-based discrimination. Disparate treatment and disparate impact discrimination against any individual – regardless of their protected class – is discrimination under the ACA, and rights and remedies should not vary.

Notably, the preamble to the proposed regulations acknowledges the statute's wording:

[B]ased on the statutory language, a private right of action and damages for violations of Section 1557 are available to the same extent that such enforcement mechanisms are provided for and available under Title VI, Title IX, Section 504, or the Age Act with respect to recipients of Federal financial assistance.¹³⁶

The proposed regulatory language also directly echoes the statute:

The enforcement mechanisms available for and provided under Title VI, Title IX, Section 504, or the Age Act shall apply for purposes of Section 1557 and this part with respect to covered entities.¹³⁷

The statutory provision is not ambiguous. Nevertheless, in a decision pre-dating the proposed rule, a district court in Pennsylvania decided that the relief available under Section 1557 depends on the nature of the alleged discrimination, for example age versus disability discrimination.¹³⁸ To prevent such misreadings, we recommend that the preamble

 $^{^{134}}$ Patient Protection and Affordable Care Act § 1557(b), 42 U.S.C. § 18116(b) (2012). 135 $_{Id}$

¹³⁶ Nondiscrimination in Health Programs and Activities, 80 Fed. Reg. at 54,192.

¹³⁷ Id. at 54,220.

¹³⁸ See Southeastern Penn. Trans. Auth. v. Gilead Sci., No. 14-6978, 2015 WL 1963588 (E.D. Penn. May 4, 2015).

section explicitly state that the enforcement mechanisms available under Section 1557 are not limited by the protected status at issue, and that any remedy available under *one* of the statutes is available for claims arising from *any* of the statutes.

Section 1557 prohibits discrimination and applies to any health program or activity receiving Federal financial assistance, any Executive Agency, and any entity established under the ACA. The enforcement regulations must reflect this. They also must adhere to the holding of the Supreme Court in *King v. Burwell*,¹³⁹ namely that, unless specifically exempted by the ACA, provisions that apply to State-based Exchanges apply whether the Exchange is operated by the State or the federal government.

We specifically recommend the following:

1. Amend § 92.302 as follows:

§ 92.302.Procedures for health programs and activities conducted by *federal fund* recipients and State based Marketplaces American Health Benefit Exchanges

(c) For any discrimination claim under Section 1557 or this part, aAn individual or entity may bring a civil action to challenge a violation of Section 1557 or this part in a United States District Court in which the recipient or State based Marketplace American Health Benefit Exchange is found or transacts business.

2. Amend § 92.303 as follows:

92.303 Procedures for health programs and activities administered by the Department an Executive Agency

(a) This section applies to discrimination on the basis of race, color, national origin, sex, age, or disability in health programs or activities administered by *an Executive Agency* the Department, including the Federally facilitated Marketplaces.

(b) The procedural ... shall apply with respect to enforcement actions against the Department—an Executive Agency concerning discrimination....

(c) Access to sources of information. The Department Executive Agency shall permit access.... Where any information required of the Department Executive Agency is in the exclusion possession.... the Department Executive Agency shall so certify....

(d) Relief. For any discrimination claim under Section 1557 or this part, an individual or entity may bring a civil action in a United States District Court in which the Executive Agency is found or transacts business.

(de) Intimidatory or retaliatory acts prohibited. The Department Executive Agency shall not intimidate...

^{139 135} S. Ct. 2480, 2487, 2496 (2015).

Conclusion

Thank you for this opportunity to submit these comments and recommendations. We look forward to continuing to work with the Department to ensure that consumers have strong protections against discrimination in health care. If you have any questions about our comments and recommendations, please contact Theresa Chalhoub, Health Policy Counsel, at tchalhoub@nationalpartnership.org or (202) 986-2600.

Sincerely,

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