



**COMMENTS to the Department of Health and Human Services, Office for Civil Rights,  
Office of the Secretary**

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

Submitted by Community Catalyst

November 9, 2015

Community Catalyst respectfully submits the following comments to the Department of Health and Human Services (HHS), Office of Civil Rights (OCR), in response to proposed rule on Nondiscrimination in Health Programs and Activities, released on September 9th, 2015.

Community Catalyst is a national non-profit advocacy organization dedicated to quality affordable health care for all. Since 1997, Community Catalyst has been working to build the consumer and community leadership required to transform the American health system. With the belief that this transformation will happen when consumers are fully engaged and have an organized voice, Community Catalyst works in partnership with national, state and local consumer organizations, policymakers, and foundations, providing leadership and support to change the health care system so it serves everyone – especially vulnerable members of society.

We greatly appreciate the opportunity to provide comments on the proposed rule on Nondiscrimination in Health Programs and Activities, which is a very important step toward strengthening protections for people who have often been subject to discrimination in our health care system – a core promise of the Affordable Care Act (ACA). As such, we have focused our comments and recommendations on strengthening the application and scope of the proposed rule in terms of language access; disability and sex discrimination; non-discrimination in health insurance and compliance and enforcement through robust data collection.

**§ 92.2 Application**

***Recommendation: Expand the scope of applicability to all health programs and activities that are either federally administered or that receive federal funding.***

The proposed regulations limit the scope of applicability to those health programs and activities that are funded and administered by HHS, or those of entities established under Title I of the ACA. However, this approach leaves out important federal health care programs and activities operated by other federal agencies, such as the Department of Defense, Veterans Administration, and the Office of Personnel Management. As a matter of law and policy, **we believe that HHS should apply these Section 1557 regulations to all federally-administered health programs and activities and to all health programs and activities that receive federal funding.** A broad application of this rule is important to preventing discrimination in all aspects of our health care system. Furthermore, this approach will centralize oversight in the HHS Office of Civil Rights, which specializes in discrimination in health, rather than requiring separate enforcement offices across disparate agencies.

***Recommendation: Fully implement the § 1557 prohibitions on sex discrimination without additional religious exemptions.***

We believe existing federal protections offer sufficient protection for health care refusals based on religious exemptions. Therefore, **we urge HHS not to use this regulation to add any additional religiously-based exemptions to those already in effect through the protections afforded by provider conscience laws,<sup>1</sup> the Religious Freedom Restoration Act,<sup>2</sup> provisions in the ACA related to abortion services,<sup>3</sup> or regulations issued under the ACA related to preventive health services.<sup>4</sup>**

The purpose of Section 1557, and this proposed regulation, is to prohibit health care discrimination, including on the basis of sex, not to enable it through broader exemptions for providers or insurers who want to deny care to patients needing it. The Section 1557 ban against discrimination in health programs includes a single exception – that it applies “[e]xcept as otherwise provided” in Title I of the ACA.<sup>5</sup> Thus, the only exceptions to Section 1557 are those expressly stated in that title. The plain language of the statute bars any interpretation that would suggest any other exceptions apply. In fact, exceptions to general rules like Section 1557’s antidiscrimination provision must be read strictly and narrowly.<sup>6</sup> Nothing in Section 1557, its language or legislative history, allows for any other limitations or exceptions regarding its application. Although Title IX<sup>7</sup> contains limited exceptions to its protection in certain circumstances, these exceptions are not incorporated into Section 1557. First, because those limited exceptions are not explicitly stated in Section 1557, they cannot be read to apply to it. Second, Section 1557 does not import any exceptions from Title IX. Section 1557 references Title IX solely for the ground on which it prohibits discrimination, which is sex.

Women in particular suffer from public policies that allow hospitals, clinics, pharmacies and health insurers to refuse to provide or pay for services to which they have an institutional religious or moral objection. Women can be left with no coverage for or access to basic reproductive health services, such as contraception, sterilization, infertility services or abortion care. In some cases, women suffering miscarriages have been turned away from hospital emergency rooms or sent miles away to other hospitals. Religious exemptions authorize health

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<sup>1</sup> See, e.g., 42 U.S.C. 300a–7; 42 U.S.C. 238n; Consolidated and Continuing Appropriations Act 2015, Pub. L. 113–235, 507(d) (Dec. 16, 2014).

<sup>2</sup> 42 U.S.C. 2000bb–1.

<sup>3</sup> See, e.g., 42 U.S.C. 18023.

<sup>4</sup> See 45 CFR 147.131.

<sup>5</sup> Patient Protection and Affordable Care Act § 1557, codified at 42 U.S.C. § 18116 (2012).

<sup>6</sup> *Nussle v. Willette*, 224 F.3d 95, 99 (2d Cir. 2000) (quoting *Commissioner v. Clark*, 489 U.S. 726, 739 (1989), *overruled on other grounds by Porter v. Nussle*, 534 U.S. 516 (2002)); *Detroit Edison Co. v. SEC*, 119 F.2d 730, 739 (6th Cir. 1941) (holding that “[e]xceptions in statutes must be strictly construed and limited to objects fairly within their terms, since they are intended to restrain or except that which would otherwise be within the scope of the general language.”). See also *McNely v. Ocala Star-Banner Corp.*, 99 F.3d 1068, 1074 (11th Cir. 1996) (limiting language of “except as otherwise provided” precluded the ADA from importing more restrictive language from the Rehabilitation Act); *New York v. Bloomberg*, 524 F.3d 384, 402 (2d Cir. 2008).

<sup>7</sup> 20 U.S.C. 1681(a)(1-9) (2012).

care refusals that have very real and devastating consequences for women, and therefore we urge HHS to implement a final rule without an exemption to the sex discrimination provision.

## § 92.4 Definitions

### Disability

**We strongly recommend that the definition of “Disability” should explicitly include health conditions.** Preventing discrimination on the basis of preexisting conditions was one of the main tenets of the ACA, because individuals with health conditions have historically been the victims of some of the worst forms of discrimination in health care. However, even after the ACA passed, discrimination against those with health conditions has continued. Through a process called “adverse tiering,” some HIV-positive beneficiaries have been forced to pay up to \$3,000 more per year annually for medications than beneficiaries not subject to advertise tiering.<sup>8</sup> Advertise tiering, which has been deemed a form of discrimination by HHS,<sup>9</sup> has also been proven common for health conditions like cancer, schizophrenia, bipolar disorder, depression, rheumatoid arthritis, multiple sclerosis, Hepatitis C, diabetes, and asthma.<sup>10,11</sup>

We support the inclusion of the American with Disabilities Act (ADA) Amendments Act of 2008, which significantly expanded the definition of disability.<sup>12</sup> **For clarity, we believe that § 92.4 should include the non-exhaustive list of health conditions that qualify as disabilities under the ADA Amendments Act of 2008, because these conditions significantly limit major life activities (including major bodily functions).** The list includes: deafness, blindness, intellectual disabilities, missing limbs, autism, cancer, cerebral palsy, diabetes, epilepsy, HIV, multiple sclerosis, muscular dystrophy, major depressive disorder, bipolar disorder, post-traumatic stress disorder, obsessive compulsive disorder, and schizophrenia. **Additionally, we recommend that § 92.4 stress that the list of health conditions are non-exhaustive, and that other health conditions which significantly limit a major life activity (including major bodily functions) will qualify as a disability for the purposes of Section 1557.** This will ensure that covered entities understand that they cannot discriminate against individuals with many health conditions, and can take proactive steps to accommodate individuals with health conditions.

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<sup>8</sup> Jacobs DB, Sommers BD. “Using drugs to discriminate—adverse selection in the insurance marketplace.” *N Engl J Med.* 2015 Jan 29;372(5):399-402.

<sup>9</sup> Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2016; Final Rule. 45 CFR Parts 144, 147, 153, et al. *Federal Registrar.* Available from: <http://www.gpo.gov/fdsys/pkg/FR-2015-02-27/pdf/2015-03751.pdf>.

<sup>10</sup> Avalere Health. “An Analysis of Exchange Plan Benefits for Certain Medicines.” <http://www.phrma.org/media-releases/many-exchange-plans-burden-the-most-vulnerable-patients-with-high-outofpocket-costs-for-vital-medicines>.

<sup>11</sup> Avalere Health. “Exchange Benefit Designs Increasingly Place All Medications for Some Conditions on Specialty Tier.” Available from: <http://avalere.com/expertise/life-sciences/insights/avalere-analysis-exchange-benefit-designs-increasingly-place-all-medication>.

<sup>12</sup> 29 CFR Part 1630 implementing these amendments made any condition a “disability” that substantially limits major bodily functions, such as functions of the immune system, special sense organs, and skin; normal cell growth; and digestive, genitourinary, bowel, bladder, neurological, brain, respiratory, circulatory, cardiovascular, endocrine, hemic, lymphatic, musculoskeletal, and reproductive functions.

**We also recommend that § 92.4 include other health conditions that have been found to be targets of discrimination and likely qualify under the ADA Amendments Act of 2008, including:**

- Asthma, which significantly impairs the respiratory system;
- Hepatitis C, which significantly impairs the liver, an organ in the digestive system; and
- Rheumatoid arthritis, which significantly impairs the musculoskeletal system.

### **Sex Discrimination**

We appreciate the explicit recognition that gender identity and sex stereotypes fall within the definition of sex in Section 1557. To effectively address the full scope of discrimination against LGBT individuals, however, **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 discrimination that has been adopted by other federal agencies and federal courts.

HHS has already used its regulatory authority under the ACA to take steps to address these issues by clarifying that the ACA prohibits insurance carrier practices that discriminate on the basis of sexual orientation.<sup>13</sup> 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. Federal courts and the Equal Employment Opportunity Commission (EEOC) have determined that discrimination based on sexual orientation is a form of sex discrimination prohibited by Title VII. Explicitly incorporating sexual orientation within the definition of sex in Section 1557 in the final rule is both consistent with this current legal doctrine and essential to ensuring that LGB individuals and families have access to the health care they need.

**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.<sup>14</sup> Pregnancy discrimination constitutes sex discrimination under Title IX,<sup>15</sup> other civil rights statutes such as Title VII,<sup>16</sup> and also necessarily constitutes sex discrimination under

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<sup>13</sup> Kellan E. Baker, *Open Doors for All: Sexual Orientation and Gender Identity Protections in Health Care* (Apr. 2015), available at <https://www.americanprogress.org/issues/lgbt/report/2015/04/30/112169/open-doors-for-all/>.

<sup>14</sup> 80 Fed. Reg. at 54177.

<sup>15</sup> 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).

<sup>16</sup> 42 U.S.C. § 2000e(k) (2012).

Section 1557. These laws prohibit discrimination based on pregnancy itself, as well as pregnancy-related conditions.<sup>17</sup>

### **Language Access**

We support codification of the definition of “Individual with limited English proficiency (LEP)” as reflected in the HHS LEP Guidance.

We strongly support the requirements for and definition of a “qualified interpreter,” which requires interpreters to meet both competency and ethical standards such as maintaining client confidentiality. **We recommend that HHS also include the requirement of knowledge of specialized terminology and concepts, as outlined in the LEP guidance, in addition to requiring the ability to “[use] any necessary specialized vocabulary.”**<sup>18</sup>

**We also recommend the inclusion of a definition of “qualified translator” that mirrors the competency requirements for qualified interpreters.** Written translations may be the first or only interaction individuals with LEP have with a covered entity (*e.g.*, outreach materials), or the most permanent record they have of a particular interaction (*e.g.*, explanations of benefits, billing statements, discharge instructions, information about financial assistance programs). Therefore, it is critical that those translating written documents have the requisite skill and knowledge of terminology, critical concepts, and phraseology to ensure the document is effectively and accurately conveying the information it needs to communicate. For similar reasons, **we also suggest that HHS explain that using automated computer-based translation services will not meet the definition of a competent translation.** At this point, these automated systems are not sufficiently accurate to be relied upon for health care purposes.

### **Federal Financial Recipients**

We oppose continuing the exclusion of Medicare Part B providers from coverage under Section 1557.

### **Health Programs and Activities**

As written, the proposed rule relies on the term “health” to define “health program or activity” without providing a definition of “health.” **We recommend HHS add additional language to the definition of “health” 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.”<sup>19</sup> Based on this widely accepted definition of health, a health program or activity includes any

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<sup>17</sup> See, *e.g.*, 42 USC § 2000e(k) (2012); see also 29 C.F.R. pt. 1604 app.; *Newport News Shipbuilding & Dry Dock v. EEOC*, 462 U.S. 669 (1983).

<sup>18</sup> *Guidance to Federal Financial Assistance Recipients Regarding Title VI Prohibition Against National Origin Discrimination Affecting Limited English Proficient Persons*, (hereinafter HHS LEP Guidance), 68 Fed. Reg. at 47316, <http://www.gpo.gov/fdsys/pkg/FR-2003-08-08/pdf/03-20179.pdf>.

<sup>19</sup> Preamble to the Constitution of the World Health Organization as adopted by the International Health Conference, New York, 19-22 June, 1946; signed on 22 July 1946 by representatives of 61 States (Official Records of the World Health Organization, no. 2, p. 100) and entered into force on 8 April 1948.



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 may not be the only state or local government program that is a health program or activity. Additional services or programs operated by state and local governments, such as the Children's Health Insurance Program, 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 additional state or local government programs may be health programs or activities.

## **§ 92.5 Assurances Required**

***Recommendation: Require and support appropriate data collection to assure compliance with Section 1557 and to aid covered entities in assessing and meeting the needs of their constituencies more effectively.***

We strongly support having assurances required for compliance with Section 1557 for covered entities receiving federal funds. We also recommend that HHS require covered entities to collect and maintain data as part of these assurances. We believe that data collection has the added benefit of helping covered entities to more accurately assess the needs of the people in their geographic service areas and adjust how they are responding to those needs, thereby positioning covered entities to adopt a more thoughtful, planned approach towards compliance.

We recommend that covered entities be required to collect data on the groups described in ACA Section 4302, a provision enacted at the same time as Section 1557, which requires that data be collected on race, ethnicity, primary language, sex, and disability status. It also permits the Secretary to extend this requirement to any other demographic data regarding health disparities. Covered entities should be required to collect data on race, ethnicity, language, sex, gender, gender identity, sexual orientation, disability status, and age. Further, covered entities should be required to assess—and update their assessments—of the population(s) they serve and who are eligible to be served so that they can appropriately plan how best to meet the needs of their clients or patients.

However, we strongly discourage the collection of immigration status information as part of any collection of demographic information by any entity covered under Section 1557 unless doing so is required to determine eligibility for program participation, such as for Medicaid, CHIP and the exchanges. The collection of immigration status information, especially when made mandatory, may deter immigrants and persons in mixed-immigration status families from seeking health-related services, raising civil rights concerns rather than assisting an agency in compliance with Section 1557 and civil rights laws.

Finally, we support the recommendations made by the National Health Law Program (NHeLP) in their comments on data collection under § 92.5, including their recommendations that HHS provide covered entities with guidelines on data collection, assessments, existing data sources, and internal policies and procedures to promote best practices in data collection.

## **§ 92.7 Designation of Responsible Employee and Adoption of Grievance Procedures**

As drafted, the proposed regulation requires all covered entities employing 15 or more people to designate an employee to coordinate compliance and establish grievance procedures. We recommend that HHS broaden this requirement so that all covered entities must designate such an employee and establish fair internal grievance procedures.

## **§ 92.8 Notice**

We commend HHS for requiring covered entities to notify the individuals they serve and the public at large of the full scope of applicable nondiscrimination protections available under Section 1557. We offer the following recommendations to further strengthen the value and effectiveness of the notice in reaching protected classes and informing them of the protections available to them under Section 1557.

***Recommendation: Amend §92.8(a) notice requirements to reflect the full list of protected classes described in § 92.4.***

We recommend that § 92.8(a)(1) and the proposed Appendix to Part 92 (“Sample Notice Informing Individuals about Nondiscrimination and Accessibility Requirements”) reflect the full scope of protected classes described in § 92.4. Specifically, we recommend that § 92.8(a) (1) be revised to read as follows (additional categories listed in bold):

The covered entity does not discriminate on the basis of race; color; national origin, ***including primary language and immigration status***; sex, ***including pregnancy, gender identity, sex stereotypes, or sexual orientation***; age; or disability.

Similarly, the Appendix to Part 92 (“Sample Notice Informing Individuals about Nondiscrimination and Accessibility Requirements”) should be revised as follows:

[Name of covered entity] complies with applicable federal civil rights laws and does not discriminate on the basis of race; color; national origin, ***including primary language and immigration status***; age; disability; or sex, including ***pregnancy***, sex stereotypes, ~~and~~ gender identity, ***and sexual orientation***. [Name of covered entity] does not exclude people or treat them worse because of their race, color, national origin, age, disability, or sex.

***Recommendation: Expand upon the language access requirements in the proposed regulations to ensure that individuals with limited English proficiency are able to gain meaningful access to health programs and activities.***

The proposed regulations take important steps towards increasing language access for individuals with limited English proficiency. However, significant gaps remain in terms of making that access “meaningful.” Our comments highlight several areas where HHS can and should go further. In addition, we strongly support the more detailed, comprehensive recommendations made under § 92.8 and to the Appendices, which contain the Sample Notice

and Sample Tagline language, by the National Health Law Program (NHeLP) and the Asian & Pacific Islander American Health Forum (APIAHF). While the recommendations would increase translation requirements for HHS and for covered entities, we believe they are a necessary part of providing meaningful access for people with limited English proficiency.

Specifically, we recommend that HHS do the following:

- **Amend § 92.8(b) to require, rather than merely encourage, covered entities to post notices in languages other than English.** The alternative approach referenced in the Preamble would require, instead of merely encourage, covered entities to post one or more of their notices in the most prevalent non-English languages frequently encountered by covered entities in their geographic region.<sup>20</sup> For example, HHS could require covered entities to post the notice in English and in the top 3 non-English languages spoken in the covered entity's service area.
- **Amend § 92.8(c) so that the sample notice of nondiscrimination, communication assistance, and language access is available in the top 15 languages spoken in each State.** While we commend HHS for assuming the role of translating the sample notices into the top 15 languages spoken nationally, we support a more inclusive approach, wherein HHS adopts its proposed alternative and translates the sample notices and taglines to the top 15 languages spoken in each State.<sup>21</sup> Adopting this standard balances being able to broaden the scope of covered languages included while ensuring a much larger proportion of limited English proficient individuals in a covered entity's service area are reached.
- **Amend § 92.8(d) and (e) so that taglines are available and posted in the top 15 languages spoken in each State in which a covered entity offers health programs or activities.** As with the translated notices, we recommend that HHS make the taglines available in the top 15 languages spoken by limited English proficient persons by State. This would require translation into approximately 10 to 15 additional languages and would ensure consistency with other HHS regulations, such as the 2016 Benefit Payment & Parameters final rule (requiring taglines for the top 15 languages in the state).<sup>22</sup>
- **Amend § 92.8(f) to require taglines to be positioned toward the front of vital and significant documents.** We support the requirement that covered entities post English notices and taglines in “(i) In significant publications and significant communications targeted to beneficiaries, enrollees, applicants, or members of the public; (ii) In conspicuous physical locations where the entity interacts with the public; and (iii) In a conspicuous location accessible from the home page of the covered entity's website.” However, taglines should be positioned toward the front of these communications, where individuals with limited English proficiency are more likely to see them and know that they can get language assistance services.
- **Define “significant publications and significant communications” in § 92.8(f) and clarify the distinction, if any, intended between “significant” publications under the proposed regulations and “vital” documents as defined in previous LEP guidance.** We believe it would be helpful for HHS to clarify and explain any difference between a

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<sup>20</sup> See 80 Fed. Reg. at 54,179.

<sup>21</sup> 80 Fed. Reg. 54,180 (describing statewide versus nationwide determination of top 15 languages).

<sup>22</sup> See 45 C.F.R. § 155.2059(c)(3)(i).



“significant” publication or communication under Section 1557 and a “vital” document, as that term has been used since 2000 in the LEP Guidance. We also recommend including examples of what constitutes vital or significant publications.<sup>23</sup>

Finally, we recognize that language access needs will shift over time. We encourage HHS to work with stakeholders, including covered entities, in gathering examples of translated versions of the sample notice and taglines—along with examples of other significant or vital documents—in languages other than the top 15 identified by State and in making these publicly available.

***Recommendation: Require covered entities to provide additional notice of any exemptions they have received that could impact access to care for protected classes.***

As noted above, religiously-based exemptions are already in effect through the protections afforded by provider conscience laws,<sup>24</sup> the Religious Freedom Restoration Act,<sup>25</sup> provisions in the ACA related to abortion services,<sup>26</sup> or regulations issued under the ACA related to preventive health services.<sup>27</sup> We believe that, as a matter of providing informed consent, it is crucial that patients, enrollees, and members of the public in the covered entity’s geographic service area be placed on notice when a covered entity has received an exemption that could impact their access to health services. Currently, CMS – through its Conditions of Participation – requires hospitals to notify patients upon admission if the hospital will not honor specific aspects of patients’ advance directives for end-of-life care because of religious objections. We recommend that HHS similarly require covered entities to notify beneficiaries, enrollees, applicants, and members of the public of *any exemption* the covered entity has received and any health care services that will not be provided or covered as a result.<sup>28</sup>

## **§ 92.101 Discrimination Prohibited**

***Recommendation: Strengthen civil rights protections for families with members who have mixed-immigration status.***

We recommend that HHS clarify that it has explicit authority to enforce statutory and regulatory provisions based on the principles articulated in the “Tri-Agency Guidance” first issued by the

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<sup>23</sup> The scope of “vital” documents should align with the definition of vital documents originally listed in the HHS LEP Guidance<sup>23</sup> and includes, but is not limited to, the critical publications as defined in 45 C.F.R. §§ 155.205, 156.250 and those that are required of Medicaid managed care plans in 42 C.F.R. § 438.10 as well as any internet pages that reference or contain the documents outlined in those regulations. Because of the growing toll medical debt places on many families, we also recommend that publications and communications about financial obligations and/or financial assistance programs be included as examples. There is some precedent for this with non-profit hospitals, which are currently required to translate “key documents” related to their financial assistance policies—the policy itself, a plain language summary, and the application form—into the primary languages of 5% or 1,000, whichever is less, of the population of individuals likely to be affected or encountered by the hospital under 26 C.F.R. § 1.501(r)-4(b)(6).

<sup>24</sup> See, e.g., 42 U.S.C. 300a-7; 42 U.S.C. 238n; Consolidated and Continuing Appropriations Act 2015, Pub. L. 113-235, 507(d) (Dec. 16, 2014).

<sup>25</sup> 42 U.S.C. 2000bb-1.

<sup>26</sup> See, e.g., 42 U.S.C. 18023.

<sup>27</sup> See 45 C.F.R. § 147.131.

<sup>28</sup> See 42 C.F.R. § 489.102.

HHS and the U.S. Department of Agriculture in 2000.<sup>29</sup> The Guidance, which limits inquiries regarding immigration status and Social Security numbers from family members not applying for assistance, invokes the federal civil rights laws when it notes, “[t]o the extent that states’ application requirements and processes have the effect of deterring eligible applicants and recipients who live in immigrant families from enjoying equal participation in and access to those benefit programs based on their national origin, states inadvertently may be violating Title VI.” In Section 1557, the authority to address disparate, effect-based discrimination resides in the invocation of Title VI and other civil rights statutes.<sup>30</sup> The regulations should provide explicit oversight for protecting confidentiality and limiting the inappropriate collection, use, and disclosure of personally identifiable information from non-applicants, such as Social Security numbers or citizenship or immigration status information, that deter ineligible immigrants from applying on behalf of eligible family members.

***Recommendation: The final rule should prohibit the utilization of criteria or methods of administration that have the effect of subjecting individuals to discrimination on the basis of their sex or substantially impairing program objectives on the basis of sex.***

Section 1557 law 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. Sex discrimination in health care results in women paying more for health care,<sup>31</sup> receiving improper diagnoses more frequently,<sup>32</sup> being provided less effective treatments,<sup>33</sup> and sometimes being denied care altogether.<sup>34</sup> Further, numerous surveys, studies, and reports have documented the widespread discrimination experienced by LGBT individuals and their families in the health system.<sup>35</sup> In response, the ACA included broad protections against sex discrimination in health programs and activities, with Section 1557, which prohibits discrimination in federally funded and operated health programs and activities, as the

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<sup>29</sup> Dept. Health and Human Services and Department of Agriculture, Policy Guidelines Regarding Inquiries into Citizenship, Immigration Status and Social Security Numbers in State Application for Medicaid, State Children’s Insurance Program (SCHIP), Temporary Assistance for Needy Families (TANF), and Food Stamp Benefits.

<sup>30</sup> Dept. 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))).

<sup>31</sup> Danielle Garrett et al., Nat’l Women’s Law Ctr., *Turning to Fairness: Insurance Discrimination Today and the Affordable Care Act 3* (March 2012), [http://www.nwlc.org/sites/default/files/pdfs/nwlc\\_2012\\_turningtofairness\\_report.pdf](http://www.nwlc.org/sites/default/files/pdfs/nwlc_2012_turningtofairness_report.pdf). See also Brigette Courtot & Julia Kaye, Nat’l Women’s Law Ctr., *Still Nowhere to Turn: Insurance Companies Treat Women Like a Pre-Existing Condition* (Oct. 2009), <http://www.nwlc.org/sites/default/files/pdfs/stillnowheretoturn.pdf>.

<sup>32</sup> N. Maserjian et al., *Disparities in Physician’s Interpretations of Heart Disease Symptoms by Patient Gender: Results of a Video Vignette Factorial Experiment*, 18 J. OF Women’s Health 1661 (2009).

<sup>33</sup> Richard J. McMurray et al., *Gender Disparities in Clinical Decision Making*, 266 JAMA 559 (1991).

<sup>34</sup> See National Women’s Law Center, *Health Care Refusals Harm Patients: The Threat to Reproductive Health Care* (Jan. 2013), <http://www.nwlc.org/resource/health-care-refusals-harm-patients-threat-reproductivehealth-care.a>

<sup>35</sup> Liza Baskin, *LGBT patients find little patience in health care*, DAILY RX (July 11, 2012), <http://www.dailyrx.com/lgbt-friendly-health-care-remains-out-reach-most>.

cornerstone of this protection. Strong regulations implementing Section 1557, paired with robust enforcement, are necessary to ensure that all women can access quality, affordable health care.

The proposed Section 1557 regulations set out core sex discrimination prohibitions by incorporating certain implementing regulations for Title IX. However, the cross-referenced Title IX regulations reflect the different educational context for which they were created and accordingly do not reach the full breadth of discriminatory actions that are prohibited by Section 1557. For example, the referenced Title IX regulation 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 sex<sup>36</sup>—a rule that has clear applicability to education programs and activities and limited relevance for health programs and activities. Therefore, in addition to the referenced Title IX provisions, the final regulations should also draw from the incorporated prohibitions for Title VI, Section 504, and Age Act. Such an approach would more fully address discrimination on the basis of sex in health programs and activities.<sup>37</sup>

### **§ 92.201 Meaningful Access for Individuals with Limited English Proficiency**

***Recommendation:*** *Establish clear thresholds and guidance regarding translation of materials into threshold languages for individuals with limited English proficiency.*

We are very disappointed that HHS did not include any thresholds for translating materials in the proposed regulations. The proposed regulation requires covered entities to take “reasonable steps to provide meaningful access to each individual with limited English proficiency that it serves or encounters in its health programs and activities.” We believe that providing standards and guidelines around translation of materials to covered entities that serve or encounter individuals with limited English proficiency is a critical part of what it means to provide “meaningful access.” To that end, we strongly support the rationale and recommendations for translation standards offered by NHeLP and APIAHF in their comments. Those recommendations include:

- **Requiring covered entities to develop a language access plan**, based on the evaluation of the factors weighted for compliance in § 92.201(b). We anticipate that the scope and size of the language access plan will vary based on the scope and size of the covered entity developing the plan. We view this recommendation as consistent with the proposed advanced planning requirement that each covered entity that employs 15 or more persons designate an individual responsible for coordinating and carrying out its efforts to comply with its duties under Section 1557, as outlined in § 92.7.
- **Establishing a standard for mandatory translation of materials into threshold languages.** We recommend that as a mandatory minimum requirement to comply with Section 1557 (as well as Title VI) covered entities should be required to translate vital documents into the threshold languages.<sup>38</sup> Vital documents should be translated for each

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<sup>36</sup> See 45 C.F.R. § 86.31(6) (2015).

<sup>37</sup> See 45 C.F.R. § 80.3(b)(2) (2015); 45 C.F.R. § 84(b)(4) (2015); 45 C.F.R. § 91.11(b) (2015).

<sup>38</sup> Thresholds, as currently used in HHS LEP Guidance, are part of safe harbors which provide “strong evidence of compliance with the recipient’s written-translation obligations” and “a guide for recipients that would like greater certainty of compliance than can be provided by a fact-intensive, four-factor analysis.” HHS LEP Guidance, 68 Fed. Reg. at 47,319.

language group that makes up 5 percent or 1,000 persons, whichever is less, of the population of persons eligible to be served or likely to be affected by the program or recipient in its service area.<sup>39</sup> This percentage and numeric threshold is already employed in other federal agency policy guidance, with some programs and agencies employing even lower thresholds.<sup>40</sup> HHS’s long-standing methodology to determine threshold languages—currently a 5% and 1,000 person standard to determine threshold languages<sup>41</sup>—is something that recipients have worked with for years. We recommend that HHS continue this standard and reinforce this language access by requiring written translations in the threshold languages.

- **Establishing clear guidelines for service areas, for purposes of language access planning.** Service areas relevant for the application of translation thresholds should be program-specific and/or entity-specific, encompassing the geographic area where persons *eligible to be served or likely to be directly or significantly affected* by the recipient’s program are located.
- **Amending the factors listed in § 92.201(b) for evaluating compliance.** In general, we support beginning the fact-dependent inquiry of what type of meaningful access must be provided by starting with and giving substantial weight to the nature and importance of the health program or activity and the communication at issue. We recommend that HHS add two factors. First, we support the inclusion of the current HHS LEP factor of “the frequency with which LEP individuals come into contact with the recipient’s program, activity or service.” This will better serve smaller language populations where speakers of that language may constitute a low prevalence in the service area, but may frequently come into contact with a health program or activity. Second, we support adding a factor that requires analysis of the impact on a consumer if they cannot access language assistance services. The addition of this factor accords with the original HHS LEP Guidance’s vision of “vital documents which considers the “consequence to the LEP person if the information in question is not provided accurately or in a timely manner.”<sup>42</sup>

To the extent that these recommendations impose additional burdens on covered entities, we note that providers and payers have economic incentives to improve their capacity to communicate effectively with limited English proficiency individuals. As the Preamble notes, LEP patients who experience communication barriers with their providers are more likely to have higher readmission rates, longer stays, and poorer health outcomes than their English-speaking peers.

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<sup>39</sup> *See id.*

<sup>40</sup> U.S. Dep’t of Labor, Style and Format of Summary Plan Description, 29 C.F.R. § 2520.102-2(c)(2) (2012) (using the lesser of 500 or 10% standard); Supplemental Nutrition Assistance Program (SNAP), 7 C.F.R. § 272.4(b)(2)(i) (using a 5% standard); U.S. Housing and Urban Development, Final Guidance to Receiving Federal Assistance Recipients Regarding Title VI Prohibition Against National Origin Discrimination Affecting Limited English Proficient Persons, 72 Fed. Reg. 2732, at 2753 (using a shifting 5% or 1000 standard); Internal Revenue Service, 26 C.F.R. § 1.501(r)-4(b)(5) (requiring tax-exempt hospitals to translate key documents on hospital financial assistance programs into the primary language of any LEP population making up 5% of the population or 1,000 individuals, whichever is less).

<sup>41</sup> HHS LEP Guidance, 68 Fed. Reg. at 47,319.

<sup>42</sup> HHS LEP Guidance, 68 Fed. Reg. at 47,318.

And, research indicates that the impact of language barriers on patient experience can also play a role in malpractice claims.<sup>43</sup>

**Recommendation: Clarify what constitutes “timely” for language assistance purposes under § 92.201(c).**

We strongly support the requirement that language assistance services be provided free of charge, be accurate and timely, and protect the privacy and independence of the individual, and we commend HHS for including a timeliness factor in the regulation.

However, we recommend including a specific time limit for written translations, such as: covered entities must translate all newly developed vital documents into threshold languages within 30 days after the English version is finalized. In addition, in evaluating what is “timely,” the covered entity should provide language assistance at a place and time that ensures equal access to persons of all national origins and avoids the delay or denial of the “right, service, or benefit at issue.” Timely services mean that consumers and patients should not wait for more than 30 minutes to receive interpreter services, since at a minimum a telephone interpreter should be available until an in-person interpreter can be located.

**Recommendation: Strengthen the requirements to provide oral interpreter services under § 92.201(d).**

In § 92.201(d), the proposed regulation states that covered entities “shall offer a qualified interpreter for an individual with limited English proficiency when oral interpretation is a reasonable step to provide meaningful access for the individual with limited English proficiency.” We support the requirement to provide interpreter services. However, we recommend that HHS require that oral interpreting services be provided in **all** cases where requested or needed, although the manner of providing these services (in-person, telephonic, video) may differ depending on the entity and frequency of language. Furthermore, in all circumstances when information cannot be translated into multiple languages, taglines should be used to notify limited English proficient individuals that information is available to be interpreted in their primary language.

**Recommendation: Maintain the limits on the use of certain persons as interpreters under § 92.201(e).**

We support the provision that restricts covered entities from: 1) requiring individuals with limited English proficiency to provide their own interpreter; and 2) relying on an adult accompanying an individual with limited English proficiency to interpret except in emergency situations or when the individual specifically requests for that adult to interpret. We also strongly support the provision that prevents minor children from interpreting or facilitating communications except in emergency situations involving imminent danger.

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<sup>43</sup> Kelvin Quan & Jessica Lynch, *The High Costs of Language Barriers in Medical Malpractice* (2010), [http://www.healthlaw.org/images/stories/High\\_Costs\\_of\\_Language\\_Barriers\\_in\\_Malpractice.pdf](http://www.healthlaw.org/images/stories/High_Costs_of_Language_Barriers_in_Malpractice.pdf).



***Recommendation: Prohibit covered entities from pressuring limited English proficient individuals to “opt out” of receiving language assistance under § 92.201(f).***

The proposed regulations stipulate that the individual with limited English proficiency reserves the right to refuse language assistance services. We recommend that HHS incorporate a requirement that explicitly prohibits covered entities from coercing or otherwise pressuring individuals with limited English proficiency into declining language assistance services.

**§ 92.202 Effective Communication for Individuals with Disabilities**

We are pleased to see that HHS proposes to apply the Title II standards to entities covered under this proposed rule. However, we offer the following suggestions to strengthen protections for individuals with disabilities.

***Recommendation: Ensuring that cultural competency standards, such as the CLAS standards, are also applied to those entities serving people with disabilities.***<sup>44</sup>

While disability affects people of all races, ethnicities, genders, languages, sexual orientations, and gender identities, this does not mean that impairment occurs uniformly among racial and ethnic groups. Disability is identified in differing ways among surveys, but national sources indicate that disability prevalence is highest among African Americans who report disability at 20.5 percent compared to 19.7 percent for non-Hispanic whites, 13.1 percent for Hispanics/Latinos and 12.4 percent of Asian Americans.<sup>45</sup>

***Recommendation: Incorporate appropriate communication standards for providers and covered entities, such as implicit bias education for those serving this population.***

HHS should explore ways health professionals could better recognize, address and reduce implicit bias when delivering health care services to diverse communities. There are existing models,<sup>46,47</sup> worth looking at that are instituted at medical schools that aim to help train health care professionals to reduce implicit bias<sup>48</sup> in the delivery of health care services.

An Institute of Medicine report has already observed that there are “clear racial differences in medical service utilization rates of PWD (persons with disabilities) that were not explained by socioeconomic variables,” and “persistent effects of race/ethnicity [in medical service

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<sup>44</sup> The National Standards for Culturally and Linguistically Appropriate Services in Health and Health Care (the National CLAS Standards), available at: <https://www.thinkculturalhealth.hhs.gov/Content/clas.asp>.

<sup>45</sup> Brault, Matthew, *Americans With Disabilities: 2005*, Current Population Reports, P70117, U.S. Census Bureau, Washington, DC, 2008. Many of the differences between the disability rates by race and Hispanic origin can be attributed to differences in the age distributions of their populations. For example, Hispanics are predominantly younger than non-Hispanic whites.

<sup>46</sup> Implicit Association Test is a computerized measurement tool designed to measure the strength of automatic associations people have in their minds. This tool has been used to measure implicit bias in physicians <https://implicit.harvard.edu/implicit/iatdetails.html>.

<sup>47</sup> US National Library of Medicine National Institutes of Health (November 2013). Physician and Implicit Bias: How Doctors May Unwittingly Perpetuate Health Care Disparities <http://www.ncbi.nlm.nih.gov/pubmed/23576243>

<sup>48</sup> [http://khn.org/news/can-health-care-be-cured-of-racial-bias/?utm\\_campaign=KHN%3A+Daily+Health+Policy+Report&utm\\_source=hs\\_email&utm\\_medium](http://khn.org/news/can-health-care-be-cured-of-racial-bias/?utm_campaign=KHN%3A+Daily+Health+Policy+Report&utm_source=hs_email&utm_medium).

utilization] could be the result of culture, class, and/or discrimination.”<sup>49</sup> Therefore, the relationship between race and disability is a complex one that needs to be freshly viewed, as race and disability together may have a previously unaccounted cumulative impact on creating health disparities.

***Recommendation:*** *We urge HHS to ensure that communication technology being used addresses the needs of persons with disabilities, including those from diverse racial/ethnic backgrounds.*

HHS should consider the use of video logs for individuals who are deaf and hard of hearing in their preferred language, qualified interpreters who can translate in preferred language so that an individual does not have to choose between disability accommodations or a spoken language interpreter, and the use of voice over IP technology for placing and transmitting calls over an IP network to facilitate real time communication.

***Recommendation:*** *HHS should apply the standards for persons who can interpret or facilitate communication contained in § 92.201(e) for individuals with limited English proficiency to § 92.202 for individuals with disabilities.*

All of the same rationales for including this section in § 92.201 for individuals with limited English proficiency apply for including it for individuals with disabilities. Making this explicit for individuals with disabilities will remove any confusion regarding the obligations of covered entities with regard to individuals with disabilities.

### **§ 92.203 Accessibility Standards for Buildings and Facilities**

We appreciate the attention OCR is paying to accessibility standards for buildings and facilities. **We believe the following suggestions can strengthen these standards:**

- In addition to physical accessibility, ensure programmatic accessibility as well<sup>50</sup>; such as, appropriate scheduling, communication on medical information, and provider staff training and knowledge.<sup>51</sup>
- Conduct regular assessments of provider competency, physical barriers of provider practice locations, and equipment such as use of appropriate exam tables or diagnostic equipment. This data should be used to make improvements and made publicly available. Beneficiary focus groups should also be held to better understand what is working and where improvements need to be made.
- Conduct provider and staff training on the ADA and the independent living philosophies and practice.

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<sup>49</sup> Institute of Medicine (IOM). 2007. The Future of Disability in America. Washington, DC: The National Academies Press, p. 92.

<sup>50</sup> Disability Competent Care Self-Assessment Tool:  
[https://www.resourcesforintegratedcare.com/sites/default/files/Disability-Competent%20Care%20Self%20Assessment%20Tool\\_508%20Compliant.pdf](https://www.resourcesforintegratedcare.com/sites/default/files/Disability-Competent%20Care%20Self%20Assessment%20Tool_508%20Compliant.pdf).

<sup>51</sup> Disability Rights and Education Defense Fund “Defining Programmatic Access to Healthcare for People with Disabilities” Retrieved: <http://dredf.org/healthcare/Healthcarepgmaccess.pdf>.

## **§ 92.204 Accessibility of Electronic and Information Technology**

We appreciate the attention being paid to ensuring appropriate access to electronic and information technology. Additionally, we are pleased to see the requirements of websites to be compliant with Section 508 of the Rehabilitation Act.

***Recommendation:*** *HHS consider other formats of communications, such as cell phones, tablets and other smart devices, and ensure that users of such technology are able to access information in the format and language of their preference.*

We believe that it would be useful for HHS to publish guidance or FAQs that include examples of the various stages of health care delivery wherein online and electronic and information technology (E&IT) means employed by covered entities need to be accessible. While we support the proposed text of §92.204(a), we believe that a non-exhaustive set of examples would reinforce HHS's intent to ensure applicability of these nondiscrimination requirements to all points at which covered entities use technology both now and in the future.

***Recommendation:*** *HHS should require covered entities to implement privacy safeguards to comply with Section 1557 in their use of electronic and information technology.*

We are concerned, that as proposed, the rule on electronic and information technology would focus on nondiscrimination and accessibility for individuals with disabilities only.<sup>52</sup> Section 1557 is not limited to discrimination on the basis of disability alone; accordingly, the rule on electronic and information technology 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.

While all individuals who engage in the health care system have an interest in the privacy and confidentiality of their health information, these concerns can be particularly salient for women, young adults, individuals affected by domestic violence and those who are lesbian, gay, bisexual or transgender (LGBT). Specific examples that are important for women include health insurance billing and claims processing procedures widely used today—notably the practice of sending “explanation of benefits” forms (EOBs) to a policy holder whenever care is provided under his or her policy. These practices unintentionally but routinely violate confidentiality for anyone enrolled as a dependent on someone else's policy.

Sensitive health information can be used by employers and others to discriminate against women and LGBT people. As a result of these concerns, we urge HHS to require covered entities to implement privacy safeguards to comply with Section 1557 in their use of electronic and information technology and, therefore, we urge HHS to require covered entities to implement privacy safeguards to comply with Section 1557 in their use of electronic and information technology.

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<sup>52</sup> Nondiscrimination in Health Programs and Activities NPRM, proposed § 92.204 (Sept. 8, 2015); Nondiscrimination in Health Programs and Activities NPRM, 80 Fed. Reg. 54172, 54187-88 (Sept. 8, 2015).

## **§ 92.205 Requirements to Make Reasonable Modifications**

We are pleased to see in the proposed rule that a covered entity must make reasonable modifications when necessary to avoid discrimination on basis of disability.

***Recommendation:*** *HHS should specify that modifications to add medically necessary care for individuals with disabilities, or eliminating exclusions of medically necessary services, are not considered fundamental alterations to the nature of the health program.*

In addition, we would also recommend that HHS provide examples of programmatic modifications that may be needed by individuals with disabilities. Such examples should include:

- Coverage of anesthesia for dental services when necessary for an individual with a disability to access dental or other medical care; and
- Modification of wait times, office hours, and other business practices that may not be accessible for individuals with disabilities.<sup>53</sup>

## **§ 92.206 Equal Program Access on the Basis of Sex**

***Recommendation:*** *We strongly support recognition that Section 1557 requires covered entities to treat all individuals regardless of gender, gender identity or gender expression and to provide them with equal access to health programs and activities.*

We support the recognition that health services ordinarily associated with one gender such as cervical cancer screenings or prostate exams may not be denied or limited based on the fact that an individual's sex assigned at birth may differ from current gender identity or current gender expression. We also support recognition of gender affirmative care as a form of medically-necessary surgery on par to reconstructive services resulting from trauma and cancer treatment. Surgical reconstruction to face, breasts and genitals are deemed medically necessary for individuals recovering from trauma and cancer, whereas often gender affirmative care services (including gender reassignment surgery and cross-sex hormone therapy) are routinely considered cosmetic.

***Recommendation:*** *The final rule should state that access to health programs or activities without discrimination on the basis of sex includes equal access without discrimination on the basis of pregnancy.*

We support the requirement that covered entities provide equal access to its health programs or activities without discrimination on the basis of sex and that they treat individuals consistently with their gender identity, but pregnant women have experienced considerable discrimination in

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<sup>53</sup> Further examples of programmatic access are available from the Disability Rights Education and Defense Fund: <http://dredf.org/healthcare/Healthcarepgmaccess.pdf>.

accessing certain health care services such as mental health care and drug treatment services and should be considered by this provision.<sup>54</sup>

***Recommendation:*** *HHS should clarify the narrow circumstances under which sex-specific programs and activities are nondiscriminatory and thus permissible under Section 1557.*

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

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

***Recommendation:*** *We recommend that HHS further clarify the meaning of “impose additional cost sharing or other limitations or restrictions” in the final rule.*

We applaud the inclusion of several discriminatory actions that are prohibited in health insurance and other health-related coverage. As stated previously, insurers have been identified as having discriminated against individuals with HIV (who qualify as disabled, according to the ADA Amendments Act of 2008) by increasing the cost of all HIV medications. Insurers have also been identified as having excluded certain specialties that treat patients with certain health conditions, such as rheumatologists, endocrinologists, and psychiatrists.<sup>55</sup> HHS has the responsibility to counter long-standing and pervasive discriminatory practices by insurers, and we suggest the following strategy:

- **We strongly recommend that HHS adopt a standard way of addressing cost-based discrimination in the final rule.** The omission of a standard way of addressing cost-based discrimination has the potential to undermine the very forms of discrimination that the proposed regulation aims to protect against. Despite the new transgender protections in the rule, plans could still discriminate against transgender people by making hormonal treatments and transition-related care unaffordable. A plan could more broadly still discriminate on the basis of sex by increasing costs for medications predominantly used

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<sup>54</sup> 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% of substance abuse treatment facilities in the U.S. included programs for pregnant or postpartum women. U.S. Department of Health and Human Services, National Survey of Substance Abuse Treatment Services (2011), available at [http://www.dasis.samhsa.gov/webt/state\\_data/US11.pdf](http://www.dasis.samhsa.gov/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), [http://www.guttmacher.org/statecenter/spibs/spib\\_SADP.pdf](http://www.guttmacher.org/statecenter/spibs/spib_SADP.pdf). See also Andrew Solomon, *The Secret Sadness of Pregnancy with Depression*, N.Y. TIMES (May 28, 2015), [http://www.nytimes.com/2015/05/31/magazine/the-secret-sadness-of-pregnancy-with-depression.html?\\_r=0](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).

<sup>55</sup> Paper will be published in JAMA, on October 27<sup>th</sup>, 2015.



by women (like breast cancer treatment), increasing costs for pregnancy care, or severely limiting the number of gynecologists in the plan network.

A cost-based discrimination standard would likely have to define unaffordability. This has a precedent, as the IRS had to already define unaffordability for the purposes of premium assistance.<sup>56</sup> An “unaffordable” medication or service could become discriminatory if there was no lower-cost, but similarly efficacious drug or service available to an individual protected by Section 1557. This would preserve an insurer’s ability to encourage the selection of lower cost drugs and services, while still protecting consumers from discriminatory pricing schemes.

- **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 strongly support HHS’ recognition that Section 1557 prohibits discriminatory benefit designs and marketing practices. However, clarifying what benefit design and marketing practices means is crucial to preventing discrimination in health programs and activities. 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. 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.
- **We also urge HHS to include in the final rule the following examples of insurance practices that are discriminatory:**
  - **Placing all or nearly all medications that treat a certain condition on the highest cost-sharing tiers.** In the preamble of the Notice of Benefit and Payment Parameters for 2016<sup>57</sup> and in the 2016 Letter to Issuers,<sup>58</sup> HHS has gone on record and stated that these practices “may” be discriminatory. In order to protect beneficiaries and to provide clarity to state and federal regulators, now and in the future, HHS must clearly define this practice as discrimination on the basis of disability.
  - **Not covering certain medications that are recommended in treatment guidelines.** Many plans fail to cover commonly prescribed, single pill regimens such as Atripla for HIV positive beneficiaries. Single pill regimens have been shown to improve adherence.

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<sup>56</sup> Internal Revenue Service, Department of the Treasury. 26 CFR Parts 1 and 602. Health Insurance Premium Tax Credit. Available from: <http://www.gpo.gov/fdsys/pkg/FR-2012-05-23/pdf/2012-12421.pdf>.

<sup>57</sup> Patient Protection and Affordable Care Act; HHS Notice of Benefits and Payment Parameters for 2016. Available from: <https://www.federalregister.gov/articles/2015/02/27/2015-03751/patient-protection-and-affordable-care-act-hhs-notice-of-benefit-and-payment-parameters-for-2016>.

<sup>58</sup> Final 2016 Letter to Issuers in the Federally-facilitated Marketplaces. Center for Consumer Information and Insurance Oversight, Centers for Medicare and Medicaid Services (CMS). February 20<sup>th</sup>, 2015. Available from: <https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/2016-Letter-to-Issuers-2-20-2015-R.pdf>.

- **Imposing arbitrary or unreasonable medication management tools such as requiring prior authorizations and/or step therapy for all or nearly all medications that treat a certain condition.** Some insurance plans in Illinois were found to require prior authorization or step-therapy for all or many HIV medications. In response, the Illinois Department of Insurance banned these plans from the exchange, labeling them as discriminatory.<sup>59</sup>
- **Not including all or nearly all of a certain specialist provider type in the plan network.** Plans have been shown to completely exclude certain providers, such as rheumatologists, endocrinologists, and psychiatrists at alarming rates, which necessarily discriminates against those with disabilities requiring access to these providers.
- **Excluding dependent enrollees from maternity coverage, or excluding coverage of maternity care or services related to labor and delivery outside the service area.**<sup>60</sup> For example, a Tennessee insurance issuer explicitly excludes maternity coverage for dependent enrollees, stating that maternity expenses for dependents are excluded from coverage “unless there are life-threatening complications.”<sup>61</sup> As noted in the Preamble, discrimination on the basis of sex includes discrimination on the basis of pregnancy. Therefore, treating maternity coverage differently is unlawful under Section 1557.
- **Placing age limits on certain types of reproductive health services based on the age of the recipient.** One issuer in one state denies coverage of birth control without cost-sharing based on a woman’s age, regardless of her reproductive capacity. An issuer in Colorado limits coverage to women under age 50. But, many women over the age of 50 continue to use birth control to prevent pregnancy.<sup>62</sup>

## § 92.209 Nondiscrimination on the Basis of Association

We applaud the inclusion of the explicit prohibition against nondiscrimination on the basis of association. This language is critical for protecting members of many vulnerable groups from discrimination, such as people with disabilities and lesbian, gay, or bisexual individuals in relationships with a same-sex partner.

## §§ 92.301-92.303 Enforcement Mechanisms

We strongly support Section 1557’s inclusion of both administrative and judicial remedies for discrimination. However, we recommend that the rule better reflect the statutory language by clarifying and strengthening the judicial enforcement opportunities and by directly recognizing that Section 1557 permits judicial claims for disparate impact discrimination and permits private enforcement against any Executive Agency or any entity established under the ACA.

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<sup>59</sup> Illinois governor’s office warns ACA health insurance plans against HIV/AIDS discrimination.

<sup>60</sup> State of Women’s Coverage: Health Plan Violations of the Affordable Care Act at 19 ([http://www.nwlc.org/sites/default/files/pdfs/stateofcoverage2015final\\_0.pdf](http://www.nwlc.org/sites/default/files/pdfs/stateofcoverage2015final_0.pdf)).

<sup>61</sup> Community Health Alliance, offered in Tennessee (2014).

<sup>62</sup> State of Women’s Coverage: Health Plan Violations of the Affordable Care Act at 19 ([http://www.nwlc.org/sites/default/files/pdfs/stateofcoverage2015final\\_0.pdf](http://www.nwlc.org/sites/default/files/pdfs/stateofcoverage2015final_0.pdf)).

Respectfully submitted,

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